The

RRT Best Practices Manual

Key Components of Effective Rapid Response for Food and Feed Emergencies

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Developed by the FDA Rapid Response Teams (RRTs)

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November, 2017

The "RRT Best Practices Manual – Key Components of Effective Rapid Response for Food and Feed Emergencies" describes best practices identified by the FDA Rapid Response Teams (RRTs) from 2008-2017.

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EXECUTIVE SUMMARY

The U.S. Food and Drug Administration (FDA) Rapid Response Teams (RRTs) Program is an FDA initiative that partners with state programs to build food safety infrastructure and a concept of integrated rapid response for all-hazards human and animal food[1] emergencies.

Since 2008, FDA has worked with nine pilot RRTs through cooperative agreements to explore and establish innovative models of effective response. This involves engaging a range of key concepts such as national food program standards, the establishment of an Integrated Food Safety System (IFSS), the National Response Framework, and the Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines. Nine additional RRTs were added to the program in August, 2012, and their work and experiences are also reflected in this Manual.

The RRT Best Practices Manual (the "RRT Manual") documents the best practices that the RRT states and their partner FDA Human and Animal Food Division and District Offices have identified over the course of the project. Each chapter in this document was developed by a working group comprised of multiple RRTs and was reviewed by a broad range of food safety partners.

Each chapter describes best practices for a key response capability, providing both broad concepts and specific details so that other groups can easily customize the chapter to address unique capability development needs.

This document is expected to change over time to reflect further development of RRT models and other relevant policies and programs in food emergency response.

[1] Note that the term "food," as defined in the Food Drug and Cosmetic Act, includes food or drink for man or other animals (i.e., feed). See Glossary entry for "Food" for exact definition.

I. INTRODUCTION

Purpose of the RRT Best Practices Manual

The Rapid Response Teams (RRT) Best Practices Manual provides a set of concepts, definitions, tools, and examples that organizations can use to incrementally develop core emergency response capabilities.[2]

Examples of uses of this RRT Manual include:

1. Identifying areas of achievement and improvement by comparing Manual-described practices to existing program elements.
2. Utilizing RRT Manual plans and procedures in actual emergency responses or exercises and sharing lessons learned to revise and improve the program and Manual.
3. Integrating these best practices into relevant initiatives and frameworks (e.g., Manufactured Food Regulatory Program Standards (MFRPS)).

Background

In 2008, the FDA initiated a cooperative agreement with nine states across the country to develop pilot food protection Rapid Response Teams (RRTs). These pilots worked to improve food program infrastructure; strengthen collaboration among local, state, and federal partners; and create fully integrated and sustained response capabilities for food emergencies.

Audience of the RRT Manual

The RRT Best Practices Manual is a compilation of best practices, developed by members of the RRT Program for use by State human and animal food regulatory programs wishing to develop integrated, multi-jurisdictional response capabilities.[3] This current volume more heavily reflects the experiences and perspectives of FDA and state food regulatory partners in a food emergency response, as the primary players engaged in the RRT Program.[4] Representatives from a variety of organizations (e.g., national associations) provided input on this manual; in the future, the Manual will further incorporate perspectives of the many different partners in food emergency response.

The concepts in this Manual can also be translated for application in other disciplines and jurisdictions (secondary audiences). Such secondary audiences include local agencies with responsibilities related to all-hazards human and animal food emergency response and/or environmental investigations as part of a response effort, as well as public health agencies involved in epidemiologic and laboratory investigations as part of a food contamination

[2] This is a working document that will be updated over time based on feedback and other external changes (e.g., policy).
[3] This Manual is written with the assumption that readers have a basic understanding of human and animal food safety and defense and emergency response terminology and principles.
[4] Although this focuses on one set of players, other partners such as industry, federal groups (e.g., the Federal Emergency Management Agency), local jurisdictions, etc. are often involved in these responses.

incident. These secondary audiences represent entities that should be part of the RRT, and thus would benefit from an understanding and implementation of the best practices described in this Manual.

Though not the target audience, this Manual offers transparency to industry and consumers on best practices for all-hazards human and animal food emergency response that may be adopted by RRTs. Additionally, industry may find this Manual useful from a situational awareness standpoint as they interact with RRTs or other public health/regulatory agencies when a product they produce is found to be contaminated or linked to a foodborne illness or outbreak.

Membership in a RRT (funded through the FDA RRT Cooperative Agreement or otherwise) does not in any way, shape or form obligate or otherwise indicate that a RRT or any of its member agencies/partners have implemented the entire contents of the RRT Best Practices Manual.

How to Use the RRT Manual

How to Approach Each Chapter

Each chapter in this Manual describes a key component in a food emergency response program, including both summary information (desired outcomes and steps needed) and detailed descriptions and tools. While these chapters can be reviewed as stand-alone topics, the RRT Pilots have demonstrated that these best practices components are interrelated elements of a broader response program.

Each chapter begins with "Achievement Levels" that identify various capacity levels. These are included so that interested parties can work jointly with their food emergency response partners toward a targeted "Achievement Level" that is appropriate for their circumstances.

Which Chapter First?

The first chapter of the Manual, "Working with Other Agencies," should be utilized before any other chapters because it identifies the foundational collaboration needed for effective response capabilities. Effectively working with partner agencies prevents the "silo effect" and duplication of efforts. Establishing strong partnerships early on ensures identification of priority needs, optimizes leveraging of resources, prevents future conflict, and benefits all parties involved.

Following application of the "Working with Other Agencies" chapter, readers can choose to assess their programs in all the chapters to identify a priority area of need. Alternatively, they may also simply select chapters of value for their programs.

What are Some Key Considerations?

Agencies working to enhance their human and animal food emergency response capabilities should do so within the context of all-hazards preparedness and response capability development. Some key national concepts for these are the following:

- The National Response Framework (NRF) presents the nation's guiding principles for all-hazards preparedness and domestic incident response. The online NRF Resource Center provides extensive resources guidance. (https://www.fema.gov/national-response-framework)
- The National Preparedness Guidelines address how agencies nationwide should pursue risk-based capacity development. (https://www.dhs.gov/national-preparedness-guidelines)

This Manual is most effective when used along with other tools for partnership-building (e.g., Food Safety and Defense Taskforces) and food program and process improvement (e.g., the Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines and Toolkit).

What are the "Achievement Levels"?

Chapters of the RRT Manual identify "Achievement Levels," which can be used to informally assess existing capacities and to identify tiered steps for improvement. Initial assessment is important and will help clarify which elements of the chapter are relevant to a program. (For example, "advanced components" of a capability would not be relevant to programs in early stages of their development.) Following the assessment, each program can then identify an improvement plan that focuses on the specific activities needed to achieve the (next) desired capacity level. State resources and food program risks vary significantly across the country, based on different types of commodities (e.g., fresh produce versus shellfish) or geographic factors (e.g., hurricanes, ports). These Achievement Levels can improve the helpfulness of the information in the RRT Manual and inform a program's risk-based capacity development efforts. In the future, the application of these capacity levels may help to characterize associations between response capabilities and public health outcome (e.g., illnesses averted).

Summary of Changes in the 2017 Edition

The RRT Manual was first issued in 2012 and consisted of 7 Chapters (Working with Other Agencies, Food Emergency Response Plans, Communication SOPs, Incident Command System, Training, Tracebacks, and Joint Inspections & Investigations). The 2nd Edition of the RRT Manual was issued in 2013 and added 7 new Chapters (Cooperative Programs, Industry Relations, CIFOR, Environmental Sampling, Recalls, After Action Reviews, and Metrics). This 3rd Edition of the RRT Manual, issued in 2017, adds one new Chapter (Exercises), and features significant revision of the following Chapters to address changes in best practices since the original issuance: Working with Other Agencies, Communication SOPs, ICS, Tracebacks, and Environmental Sampling.

Future Plans for the RRT Manual

The RRT Manual will be updated periodically. The RRT Manual may also expand to better address different levels of government, different sectors, commodities, phases of response, threats/hazards, etc., as deemed necessary and appropriate by the RRT Program.

The "First" Chapter

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Working With Other Agencies (WWOA)

Chapter 1. Working with Other Agencies (WWOA)

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1. PURPOSE

Effectively working with other agencies during a human and animal food emergency response to encourage a unified approach and a speedy recovery is a priority for building an effective RRT. This chapter describes a model on which any other group can base the development of its own procedures when coordinating with its human and animal food response partners.

2. SCOPE

This chapter focuses on three areas in which federal, state, local, tribal and territorial agencies involved in food emergency response often work together and strong interagency relationships are essential:

2.1. Building Relationships: This section describes best practices to build trust, familiarity, and credibility among agencies through joint training, meetings, exercises, and participation in human or animal food safety and defense task forces.

2.2. Defining Roles and Responsibilities in an Investigation/Response: This section identifies roles and responsibilities for key communication exchanges among

agencies comprising the three legs of the "investigative stool": epidemiology, laboratory, and environmental health (Dept. of Health and/or Agriculture).

2.3. Maintaining Infrastructure: This section describes procedures and mechanisms to maintain relationships through a robust infrastructure. Many of these concepts are continuations of the activities designed to build relationships.

The best practices described in this chapter identify key areas and elements for each of these capabilities, but are neither comprehensive nor specific to unique situations. State, local, tribal, territorial and federal agencies seeking to improve multi-agency food emergency responses (e.g., States, FDA field offices) may utilize this chapter to assess and improve their response capabilities. Agencies with varying responsibilities (e.g., regulatory, public health, feed/animal health, law enforcement, and laboratory) and target response capability levels may differ in how they customize and apply these best practices.

3. RESPONSIBILITY

3.1. Agency/Organization Leadership

Leadership of federal, state, and local agencies involved in responses to human and animal food incidents will (jointly) approve any customizations made to this template to ensure that WWOA policies and procedures developed are appropriate for that jurisdiction.

3.2. RRT (or investigatory team, in states without an RRT) Leadership:

3.2.1. Familiarization/training with the adopted policies and procedures: RRT leadership is responsible for ensuring that the personnel assigned to respond to a human or animal food incident have been provided with the ICS and investigation-related training necessary to implement this chapter.

3.2.2. Maintenance of these policies and procedures: This should be the duty of combined leadership of the response team (e.g., State principal investigator, FDA District Emergency Response Coordinator).

3.3. RRT Members:

3.3.1. Procedure Familiarization/awareness: RRT Members must be familiar (through orientation, training, exercises, etc.) with RRT SOPs and their implementation.

3.3.2. Skills maintenance: RRT members are each responsible for actively maintaining both their subject matter expertise and ability to work effectively in multidisciplinary and multi-agency response teams.

4. DEFINITIONS

The following terms are used frequently in this chapter: environmental, epidemiology, laboratory, and Food Safety and Defense Task Force.

See "Glossary of Key Terms" for definitions.

5. BACKGROUND
None

6. SAFETY
N/A

7. EQUIPMENT/MATERIALS
N/A

8. PROCESS DESCRIPTION

8.1. Standard Practices

Before building a new relationship between partnering agencies or when looking to strengthen an existing partnership, the following concepts should be considered:

8.1.1. Know the lead contact person(s) in other agency.

1. Know the current primary and secondary contacts in each appropriate agency for human and animal food incidents.
2. Attempt to contact these individuals *prior* to an event. Attempting to get to know someone during an emergency response can be difficult.

8.1.2. Understand the roles and responsibilities of each agency responsible for human and animal food safety activities.

1. Be aware that agency missions (and definitions of success) differ.
2. Be aware that each agency will have both capabilities that they can offer during a multi-jurisdictional response as well as limitations; it is important to understand both.

8.1.3. Understand the laws governing the release of confidential information (e.g., commercial distribution, medical records).

1. Know how to share the information appropriately. Know who in your agency is commissioned and know which agencies maintain a current 20.88 status[1].
2. Identify, understand, and develop confidentiality agreements between local, state, federal partners (e.g., FDA State/Local Commissioning Program). See Section 12.2.3.

[1] 20.88 Single-Signature Agreements Database:
https://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=singlesignaturefood

8.1.4. Share updates and/or materials prior to meetings or conference calls with partners. (See III.E. "Conference Call Etiquette.")

1. Provide information ahead of time so as not to surprise local, state, or federal partners when going into a meeting or conference call.
2. Distribute summaries of previous calls and meetings to all attendees.
3. Ensure all partners have the materials for the current meeting. Do not forget partners who may be attending the meeting remotely.

8.1.5. Keep feed issues and agency feed partners in mind when investigating food incidents.

8.1.6. Keep in mind that laboratory response partners may need to be notified of planned activities early as to order necessary supplies, prepare media, etc.

8.2. Building Relationships

Interagency coordination during an incident requires clearly defined responsibilities, communication strategies, and interaction prior to an incident. This section identifies documents and activities that help establish effective working relationships for the development of these key elements for multi-agency responses.

8.2.1. Working as a multi-level, multi-agency team

Despite a large degree of variability in how public health programs are structured throughout the nation, one commonality tends to be that multiple agencies and programs are required to work together to effectively address human and animal food-related emergencies. The RRTs are able to serve as conduits to unify and coordinate multi-disciplinary (epidemiology, lab, environmental/regulatory) and multi-jurisdictional (federal, state, local, and tribal agencies) responses to human and animal food-related emergencies within a state. These coordination activities are broad in scope and can be related to joint training, investigations, data sharing, and data analysis to name a few.

Regardless of the coordination topic, all multi-agency activities require some degree of communication and collaboration. The RRTs create a structure that facilitates bringing response partners together both in times of emergency and in times of team building. The latter is a particularly useful time to establish familiar relationships with counterparts in other agencies/programs versus the fast-paced nature of most responses.

Similar to how RRT responses can be "scaled" based on the size and complexity of a human and animal food incident, so too can opportunities for multi-jurisdictional collaboration. RRTs that are just

beginning to build their collaborative foundation can start out with small face-to-face meetings with the partners with whom they most commonly respond. As the foundation continues to be built, the collaborative process can become more complex where additional partners are eventually approached and invited to attend. This flexibility allows for each RRT to address strengths and weaknesses in their jurisdictions so the end result for collaboration is strong and public health can be protected more effectively and efficiently.

RRTs have previously highlighted some specific areas of discussion that may serve as a starting point for other teams when considering how to approach multi-agency coordination in their region. Some of these discussion points may include:

- Does the RRT encompass the regulatory response component or is it inclusive of both the epidemiologic and regulatory response?
- To what human and animal food commodities is the RRT responding? What agencies are involved in responding to incidents involving these commodity areas?
    - Farms (produce and raw agricultural commodities)
    - Manufactured Foods
    - Retail (food service, grocery stores, etc. – jurisdiction may be shared across multiple agencies)
    - Meat
    - Eggs (in-shell, egg products, etc.)
    - Grade A Dairy
    - Raw Molluscan Shellfish
    - Fish/Seafood
    - Animal Food (animal feed, pet food)
    - Other
- Would the role of participating agencies change if it was suspected/confirmed that any of the commodities above were contaminated intentionally?
- Should local health jurisdictions be approached to be formal members of the RRT?
    - Does this change if your local jurisdictions are centralized under a state agency or autonomous?
- Is the RRT inclusive of epidemiology/lab partners or does the RRT just have defined communications with those partners?
- Does the RRT lab component include both the clinical and human and animal food regulatory labs? Are there other labs that should be included in the team?
- How should a multi-agency RRT Steering Committee be structured?

- Who should be on this committee?
- How often should the committee meet?

- Does the RRT only come into play during a high workload or surge capacity need, or are all responses to a potential human and animal food contamination event handled by the RRT?

A common thread when determining how to answer these questions is communication, both within an agency and with appropriate response partners. By discussing the capabilities and limitations of each agency or program early on, each RRT can structure their team based on their specific dynamics/needs/desires. Despite variances in team structure, the common goal of minimizing the time from RRT notification of an incident to the effective Implementation of public health control measures is maintained.

8.2.2. Additional multi-agency coordination efforts

Development of a multidisciplinary, interagency team of highly trained participants to jointly investigate foodborne illness outbreaks and other food and agricultural emergencies is advantageous to all involved. In addition to those conducting investigational activities, the team should have working relationships with and be able to ask for assistance from Public Information Officers (PIOs), emergency management coordinators, and agency legal resources.

It is best to develop working multi-agency policies and procedures before initiating joint field operations.

Teams should create and maintain contact lists for RRT member agencies/partners. Key questions to consider include:

- How will RRT member agency/partner contact information be maintained, updated and accessed?
  - How often will these be updated?
  - How will RRT member agencies/partners be made aware of changes to contact lists? See the Communications SOPs Chapter for more information on contact lists.
  - Where will the most current contact lists be stored so appropriate partners can easily reference them?

In general, agencies should also use ICS concepts and roles in routine situations. This practice establishes the foundation necessary for effective responses using ICS during emergencies (i.e., urgent/unusual situations). See National Incident Management system concepts at: https://www.fema.gov/pdf/emergency/nims/NIMS_core.pdf

Team members should meet regularly to train for responding to an event. This training may include topics such as agency and office procedures, field activities, and sampling techniques.

Teams should also regularly conduct exercises using realistic scenarios to continually refine existing procedures and develop new techniques. For these, team members may be assigned to a variety of response roles including conducting inspections, sampling, record review, laboratory testing, compliance, and enforcement. These concepts are explored further in the Joint Exercises (12.2.6) and Joint Training (12.2.7) portions of this chapter.

8.2.3. Legal Framework

The process of establishing a joint inspection and investigation program begins with a review of each agency's legal framework. This may include drafting memoranda of understanding (described below) to delineate each agency's roles and commitments to coordinate activities. For example, when coordinating with the FDA, key state personnel must receive FDA commissions and/or credentials (or be operating under a valid 20.88 agreement) so that they can receive critical information gathered during investigations. This ensures that agencies can:

- Share information;
- Take the most appropriate regulatory action;
- Share staff resources; and
- Document activities interchangeably.

These websites[2] provide materials and resources on information sharing under FDA confidentiality agreements, such as an information sharing matrix, information sharing ownership and disclosure chart, information sharing pyramid and trade secret flowchart, as well as a searchable database of agencies with current 20.88 long term information sharing agreements.

When the RRT is unable to share information freely among member agencies/partners due to confidentiality restrictions or other information sharing policies and laws, it is important to take time to share and explain these restrictions to avoid misunderstandings, false expectations and negative relationship impacts among RRT member agencies/partners. It is also important to share and discuss any actions that could be taken to

[2] https://www.fda.gov/ForFederalStateandLocalOfficials/ResourcesforRegulatoryPartners/default.htm
https://www.fda.gov/ForFederalStateandLocalOfficials/CommunicationsOutreach/default.htm

mitigate the impacts (e.g., signing a confidentiality agreement, a 20.88 agreement or establishing a MOU).

These discussions could serve as a platform for partners to discuss ways to increase information sharing such as applying for commissions, credentialing, and/or signing a 20.88 agreement.

8.2.4. Memorandum of Understanding (MOU)

An MOU is a document that formally describes the relationship between parties, indicating an intended common line of action during a coordinated incident response.

MOUs should exist between any or all agencies represented under the epidemiology, environmental, and laboratory components of the response system. In addition, MOUs may capture the roles and responsibilities of the partnering organizations and how their combined actions will enhance the coordinated incident response.

The documents should clearly define how communications will flow between the groups before, during, and after an event, and how those communications should be formatted and disseminated. If not specified elsewhere, such as in an RRT operations manual, an MOU can also delineate the specific events required for each of the agencies to consider an incident response successfully completed.

Examples of MOUs between different partnering agencies are included at the end of this chapter (see Attachments A and B).

8.2.5. Joint Management Team

Organizations regularly participating in joint investigations and inspections should consider establishing a Joint Management Team. The Management Team is comprised of appropriate coordinators and supervisors from involved agencies. These coordinators may or may not be in a leadership role within their respective agencies; however, they should have some level of decision-making authority related to the functioning of the RRT. When not engaged in an outbreak or other human and animal food contamination event, these designees are responsible for maintaining a properly planned, organized, equipped, trained, and exercised team by:

- Scheduling and facilitating meetings for team members.
- Establishing thresholds for joint agency response.
- Providing updates to the agencies' senior leadership and other parties.

    - Keeping agency leadership apprised of RRT activities can encourage a "top-down" buy-in for maintaining multi-agency collaboration capacity through the RRT.
- Coordinating with agencies' training and exercising officers to develop programs for field team and support team members.
- Setting standards for approval of reports and other documentation.
- Ensuring that an After Action Review (AAR) takes place after responses are conducted and that lessons learned are integrated into future operations.
- Identifying staff to relieve personnel during extended operations and planning for the transition to normal operations after the incident.
- Establishing a process or method for working through disagreements and disputes, including elevation of the issue to a higher management level for resolution, when warranted.

8.2.6. "Regularly" Scheduled Meetings

Agencies participating in joint human and animal food incidents should consider scheduling regular meetings between the coordinators or designees of the partnering organizations. Routineness is key when ensuring that communication is maintained among response partners and RRTs should adjust their meeting frequency as necessary to maintain this capacity.

Bringing individuals together is important in setting the tone for cooperating agencies and ensuring that the top-down message within each group is one that promotes and supports working together with all partners. As individuals become more familiar with the routine and top-down endorsement is maintained, inter-agency communication has a better chance of becoming institutionalized as part the agency's "culture" or routine operational framework.

The meetings should include designated coordinators, management, or designees from all agencies and may address a range of topic areas including:

- Setting triggers for joint agency investigations and responses.
- Discussing roles and responsibilities for multi-agency response activities (e.g., recalls, audit checks, public notification, etc.)
- Providing updates to the agencies' senior leadership and other parties.
- Coordinating training and exercises programs.

- Setting standards for approval of reports, forms and other documentation.
- Ensuring that an After Action Review takes place and that lessons learned are integrated into future operations.
- Identifying staff to relieve personnel during extended operations and planning for the transition to normal operations after the incident.
- Establishing a process or method for working through disagreements and disputes, including elevation of the issue to a higher management level for resolution, when warranted.

8.2.7. Joint Trainings/Meetings

Having the management and staff of multiple agencies train together is an effective way to build relationships and the trust necessary for a coordinated response.

Inspectional staff included under the environmental group may represent several different agencies, each operating under their own regulations and enforcement procedures. Training these staff together on risk management, food safety, information sharing, intentional contamination procedures, and other areas can ensure a consistent approach across agencies as well as familiarity with their differences in responsibility, oversight and enforcement.

Conducting joint training sessions is also a means to discuss concerns about how a specific process works (e.g., ICS) among agencies prior to developing an official document such as a policy, procedure, or MOU.

8.2.8. Joint Exercises

Conducting exercises with other agencies is an effective way to further define and refine the roles and responsibilities of the agencies involved in the investigation and mitigation of incidents.

Each participating agency should be involved in all steps of the process, from initial planning to post-exercise evaluation and/or After Action Review. These exercises should be designed to challenge existing response systems (including use of ICS) with the goal of identifying gaps in the process. After Action Review of the exercise should be open, accurate, promote actions that went well, and help to improve any actions that hindered the response.

Exercises should be performed in a non-threatening environment to build trust and relationships between the agencies before an actual incident occurs. See the Exercises Chapter within this RRT Best Practices Manual

for more information and best practices on planning/conducting/evaluating RRT Exercises.

8.2.9. Task Forces

Food Protection Task Forces exist to encourage cooperation and communication among all human and animal food safety stakeholders within a state.

The ideal Task Force includes membership from federal, state, local, tribal, territorial regulators, academia, and industry. The Task Force should provide expert input into matters of food safety/defense and is an important prerequisite to the creation of formal agreements such as Memoranda of Understanding between stakeholders. Often, the members of a state's task force may also commonly be partner agencies during RRT responses.

- **Task Force Creation**
  Task Forces are encouraged but not obligated to gain legal recognition as a cooperative, multi-jurisdictional panel of human and animal food safety/defense experts. This may be achieved by agency declaration, executive order (e.g., see North Carolina Executive Order 38; see chapter references (part 8)), or statutory authority (e.g., see 500.033 Florida Statute; see chapter references (part 8)).

  Formal recognition of the Task Force as an entity provides greater credibility to the actions of the organization.

- **Task Force Participation**
  In order for the Food Protection Task Force to be successful, representatives from the following fields and agencies should be invited to participate:

  a) Manufactured food safety/defense
  b) Foodborne disease epidemiology
  c) Retail/foodservice food safety/defense
  d) Animal feed safety/defense
  e) Human and animal food safety laboratories
  f) United States Food and Drug Administration (FDA)
  g) United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS)
  h) Agency media professionals
  i) State Emergency Management
  j) Local Health Departments
  k) Tribes

l) Territories
m) United States Department of Homeland Security/State Fusion Centers
n) Other laboratory partners
o) State Law Enforcement Agencies
p) Local Law Enforcement Agencies
q) Federal Bureau of Investigation
r) Food Industry Representatives
s) State or Local Restaurant Trade Associations
t) State or Local Agricultural Trade Associations
u) State or Local Retail or Grocers Associations
v) State or Local Public Health Associations
w) State Universities and/or Community Colleges
x) State Cooperative Extension
y) Other participants, as deemed appropriate.

- **Task Force Funding Mechanisms**
  Task Forces may benefit from grant funding available through the FDA Office of Partnerships (OP)[3]. These funds are designated to support task force activities with the goal of strengthening state-level human and animal food safety infrastructure.

- **Hold Regular Meetings**
  Task Forces are encouraged to meet on a regular basis (best practice to define "regular" ahead of time) to:

  a) Develop relationships among human and animal food safety stakeholders.
  b) Discuss new and emerging issues in human and animal food safety.
  c) Identify opportunities for joint work-planning.
  d) Explore means by which greater cooperation can be achieved among those responsible for protection of the food supply.
  e) Discuss outreach activities and training opportunities.
  f) Discuss policy development strategies.

- **Conduct Outreach Activities**
  The Task Force should conduct outreach and educational activities to promote human and animal food safety within the state. Activities may include development of consumer educational

[3] https://www.fda.gov/ForFederalStateandLocalOfficials/ProgramsInitiatives/ucm475029.htm

campaigns, industry outreach for the development of recall plans, providing training opportunity notices on the task force website or through the RRT Coordinators, or sponsorship of forums or meetings to discuss pertinent food safety issues.

- **Conduct Policy Development and Analysis**
  The non-partisan Task Force should develop and evaluate human and animal food safety policy within the state. The Task Force should monitor legislative actions relating to human and animal food safety and advise state legislatures and rulemaking bodies on these matters.

8.3. Defining Roles and Responsibilities in an Investigation/Response

Below are examples of information shared among agencies as they fulfill their roles and responsibilities as the "three legs of the investigative stool" during a human and animal food incident. Each team should modify these components to meet the needs and structure of the regulatory framework of the state. They are described here to provide context for the kind of communication that should be completed when working with other agencies during an incident.

Note that the roles described below can be shared across multiple agencies (e.g., State Dept. of Health laboratory that supports the epidemiology program and a State Dept. of Agriculture laboratory that supports the environmental program; similarly, a food service environmental program may be in the State Dept. of Health while a manufactured foods environmental program may be in the State Dept. of Agriculture). A flow chart representing the types of communications that should occur during an event is included in section 13 of this chapter (Attachment C - Flowchart - Communications between Agencies).

Note: It is important to consult applicable Federal, State and Local policies when releasing information to partnering agencies (See Section 12.2.3 for more details).

Please refer to the Communication SOPs chapter for additional details on appropriate policies and procedures to facilitate communication.

8.3.1. Epidemiology to Laboratory

1. Current epidemiology investigation updates of any outbreak that may engage the laboratory (e.g., reported from local health department, multistate, in-state).
2. Early notification of incoming outbreak-associated samples.
3. Provide historical illness data associated with a commodity being sampled.

8.3.2. Epidemiology to Environmental

1. Clusters of notable epidemiological interest indicating human or animal food vehicle.
2. Pulsed-field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS), or other subtyping results and updates of isolates for active investigations (e.g., isolates from clinical samples, may also include isolates from human or animal food samples if submitted to the lab by the epidemiology program). Routing of sample results may differ between RRTs and may depend on where the lab running the samples is housed (i.e., which agency).
3. Laboratory results of products tested at the laboratory that supports the epidemiology program (may be human or animal food).
4. Outbreaks identified by local communicable disease partners that are of interest for environmental health.
5. Specifics of the human or animal food vehicle: product information, purchase dates, consumption date, purchase locations, sell-by/best if used by dates.

8.3.3. Laboratory to Epidemiology

1. Detected serotype, subtype, PFGE, or WGS clusters.
2. Cases or clusters in-state matching cases in other states or multi-state clusters.
3. PFGE, WGS, or other subtyping results and updates of isolates for active investigations (e.g., isolates from clinical samples, isolates from human and animal food samples if submitted to the lab by the epidemiology program). Routing of sample results may differ between RRTs and may depend on where the lab running the samples is housed (i.e., which agency).
4. Laboratory results of outbreak-related testing (e.g., clinical samples, may also include human and animal food samples if submitted to the lab by the epidemiology program).
5. Interpretation of results (e.g., tissue residues, contaminants, microbiological).

8.3.4. Laboratory to Environmental

1. Recommendations for sampling protocols (e.g., quantities, types, locations, shipping, preservatives).
2. Laboratory point of contact (POC) for technical questions, shipment notifications, etc.
3. PFGE, WGS, or other subtyping results and updates of isolates for active investigations (e.g., isolates from human and animal food samples submitted by the environmental program). Routing of sample results may differ between RRTs.
4. Communicate clearly about when analytical results are expected to be available/released to avoid false expectations.

5. Results of presumptive positive or confirmed positive samples for human or animal food testing related to active investigations (e.g., outbreaks, chemical contamination, etc.).
6. Interpretation of results (e.g., tissue residues, chemical or microbiological contaminants).

8.3.5. Environmental to Epidemiology

1. Significant findings of environmental investigations, including any root cause findings or environmental antecedents.
2. Results of presumptive positive or confirmed positive human or animal food samples collected by the environmental program and tested at local, state, or federal laboratories (or private laboratories, if confidentiality agreements allow). Routing of presumptive or positive sample results may vary between RRTs depending on which agency the servicing laboratory is housed.
3. Recall of any products due to bacterial, chemical or physical contamination with distribution in state.
4. Notable progress on traceback investigations.
5. Outbreaks identified by local environmental health agencies that are of interest for epidemiology partners.

8.3.6. Environmental to Laboratory

1. Incoming samples that are incident or outbreak-associated, routine, or special-project related.
2. Notable investigations in which the environmental program is currently involved.
3. Notify laboratory response partners of when samples related to an active investigation are or will be collected, as well as how many. This way laboratory staff will know to prioritize the samples accordingly.
4. Understand the agency's capabilities and capacity prior to the event.
5. Consider sharing agency Continuity of Operations Plans (COOP), when applicable.

8.3.7. State (Environmental, Epidemiology, Laboratory) to Federal Agency (FDA[4], USDA, CDC, EPA, FBI, and Laboratories)

State programs (including environmental, epidemiology, laboratory) should clearly and methodically communicate the results of investigations and report emerging outbreaks, recalls, complaints, and

[4] Primary FDA contacts to the States are the Office of Regulatory Affairs (ORA) District/Program Division Offices. States with an RRT must have jointly established communication procedures between the state and their respective FDA District/Program Division Offices. (See the "Communication SOPs" chapter for additional details.)

positive pathogen findings to the appropriate Federal Agency (e.g., FDA, FSIS, CDC, EPA) in situations like the following:

1. An adulterant (including pathogens and chemicals [including pesticides]), is suspected in an outbreak or detected in a product (may or may not be under the jurisdiction of the Federal Agency).
2. A pathogen or chemical (including pesticides) is found in a food that may be distributed in interstate commerce or otherwise under the jurisdiction of one or more federal agencies.
3. An outbreak occurs on an international or interstate airplane, bus, train, or vessel.
4. The State program requires support with laboratory testing (e.g., bacterial enumeration or WGS).
5. Intentional product contamination is suspected or confirmed.
6. The suspected food item is:
    a. Imported
    b. Previously implicated in multistate outbreaks
    c. Prepackaged
    d. Transported across state lines
    e. Regulated by appropriate Federal Agency as listed above

8.3.8. Federal (FDA, USDA, CDC, EPA, FBI and Laboratories) to State (Environmental, Epidemiology, Laboratory)

Federal public health and regulatory agencies (e.g., FDA, USDA CDC, EPA) should communicate the results of investigations and report emerging outbreaks, recalls, complaints, and positive pathogen findings to the appropriate state program(s) (environmental, epidemiology, and/or laboratory) for the situations like the following:

1. A multi-state or multi-jurisdictional cluster of illnesses involving the state is identified and being investigated by the federal agency.
2. A pathogen or chemical (including pesticides) is suspected in an outbreak or detected in a product manufactured or distributed in the state.
3. A pathogen or chemical (including pesticides) that renders a product adulterated is found in a food that may be distributed in the state.
4. An outbreak occurs on an international or interstate airplane, bus, train, or vessel that could impact the state.
5. Intentional product contamination is suspected or confirmed in the state or in commodities that may enter the state via commerce.

8.4. Maintaining Relationships

A formally established RRT must develop procedures and mechanisms to maintain its continued viability. Many of the components discussed in section 12.2 of this chapter are essential to building relationships for continual development and maintenance of existing partnerships. These components must be a continual part of team activities to ensure that the relationships built among cooperating

agencies are not diminished over time or in the absence of actual, real-world response activities.

Examples of these multi-purpose components essential to team building and maintenance include:

- Joint Management Team (See Section 12.2.5)
- Regularly Scheduled Meetings (See Section 12.2.6)
  - Meeting response partners *before* an incident to increase familiarity and build personal relationships.
- Joint Training (See Section 12.2.7)
- Joint Exercises (See Section 12.2.8)
- Participation in Human or animal food Safety and Defense Task Forces (See Section 12.2.9)

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

Level	Description
1	"Working with Other Agencies" (WWOA) best practices (as described in this chapter) are not incorporated into the RRT's Standard Operating Procedures (SOPs) or other documents. NOTE: Best practices can be included in a single or coordinated series of documents.
2	WWOA best practices are incorporated into applicable RRT SOPs/documents and properly identify all relevant partners. NOTE: WWOA best practices may be addressed within a single SOP, but are more likely to be addressed within a coordinated series of SOPs or other documents maintained by the RRT (e.g., Communications SOPs, RRT or Foodborne Illness Manual, Joint Investigations SOP, Training SOP, ICS procedures, etc.).
3	All parties included in the RRT SOPs/documents that encompass WWOA best practices know that procedure(s) exist, know where the procedures are located, and clearly understand their respective roles and responsibilities.
4	The RRT SOPs/documents that encompass WWOA best practices are followed during incident response and/or planned exercises.
5	The RRT SOPs/documents that encompass WWOA best practices include a formal review and update process.

9.2. Process Overview

9.2.1. Level 1: WWOA best practices are not incorporated into the RRT's SOPs/procedures

1. Identify status of current SOPs
   a. Do informal/incomplete written or verbal agreements for WWOA exist?
   b. Do other existing documents (Memoranda of Understanding (MOUs), etc.) contain information or sections that could be utilized to address "working with other agencies" best practices?

c. Do formal communications or joint investigations SOPs exist?

9.2.2. Level 2: WWOA best practices (as described in this chapter) are incorporated into applicable RRT SOPs/documents and properly identify all relevant partners

NOTE: WWOA best practices may be addressed within a single SOP, but are more likely to be addressed within a coordinated series of SOPs or other documents maintained by the RRT (e.g., Communications SOPs, RRT or Foodborne Illness Manual, Joint Investigations SOP, Training SOP, ICS procedures, etc.).

1. All partnering agencies have been identified and included in the developed procedure(s). References include:
   a. Food Safety Taskforce membership lists
   b. Existing MOUs or other agreements
2. Lead person(s) and backup for each partnering agency have been identified and contact information is current.
   a. RRT identifies a frequency in which contact information is checked/updated.
3. Procedure(s) addresses the relationships and communication among RRT member agencies/partners, including: epidemiology, laboratory, and environmental health (Dept. of Health and/or Agriculture, human and animal food commodity programs, Federal/State/Local levels, as applicable).
   a. Identification of all relevant partners
   b. Reference RRT Manual "Communication SOPs" Chapter
4. Procedure(s) appropriately includes other groups with which the RRT may need to communicate, interface or partner. Examples:
   a. Emergency Operations Center (EOC)
   b. Fusion Center
   c. Industry
   d. Academia
   e. Law enforcement
   f. Professional associations
5. Procedure(s) adequately describes the relationship between state programs and federal partners. Federal partners may include:
   a. Health and Human Services (HHS) (Food and Drug Administration [FDA], Centers for Disease Control and Prevention [CDC])
   b. United States Department of Agriculture (USDA)
   c. Environmental Protection Agency (EPA)
   d. Department of Homeland Security (DHS)
   e. Federal Bureau of Investigation (FBI), FDA/OCI Office Criminal Investigation

9.2.3. Level 3: All parties included in the RRT SOPs/documents that encompass WWOA best practices know the procedure(s) exists, know where the procedure(s) are located, and clearly understand their respective roles and responsibilities

1. The procedure(s) adequately describes the roles and responsibilities of partners, including jurisdiction/regulatory authority, and properly references other documents for this purpose. Examples:
   a. MOUs
   b. Other SOPs
2. Individuals and/or agencies listed on the procedure(s) receive role-appropriate training in the relevant procedure(s), such as:
   a. Communications/Information Sharing SOP
   b. Joint Investigations SOP
   c. Training SOP
   d. Incident Command System (ICS) procedures
3. Training sessions are developed and scheduled to include all partners listed in the procedure(s).
4. A lead agency, which is *most likely* the RRT grantee agency, is identified as responsible for maintaining and sharing the RRT's procedure(s) that encompass WWOA best practices (electronically, physically, etc.).

9.2.4. Level 4: The RRT SOPs/documents that encompass WWOA best practices are followed during incident response and/or planned exercises

1. Triggers for implementing the procedure(s) in response to an incident/emergency are identified and understood.
2. Individuals and agencies listed in the procedure(s) will exercise response plans on a routine basis.

9.2.5. Level 5: The RRT SOPs/documents that encompass WWOA best practices include a formal review and update process

1. A timeframe is established for review of the procedure(s).
2. A procedure exists for incorporating after action review/reporting and other comments/suggestions into the procedure(s).
3. A process to ensure the accuracy of contact information included in the procedure(s) is implemented.
4. If not addressed in the review of the procedure(s) themselves, the procedure(s) review considers implementation of updates needed for other documents which impact WWOA, such as the following:
   a. Communications/Information Sharing SOP
   b. Joint Investigations SOP
   c. Training SOP
   d. ICS procedures

10. RELATED DOCUMENTS

Examples of a Memorandum of Understanding (MOU) between different partnering agencies are included in section 12 (Attachments A & B) of this chapter.

11. REFERENCES AND OTHER RESOURCES

(Full citations are in the References Section, "List of Reference Documents," listed by author.)

11.1. Council to Improve Foodborne Outbreak Response (CIFOR). *Guidelines for Foodborne Disease Outbreak Response.* (http://www.cifor.us/documents/CIFOR%20Industry%20Guidelines/CIFOR-Industry-Guideline.pdf)

11.2. National Food Safety System Project. "Multistate Foodborne Outbreak Investigations Guidelines for Improving Coordination and Communication." (http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/UCM143338.pdf)

11.3. North Carolina Executive Order of the Governor 38 (12/23/2009): Reestablishing the Food Safety and Defense Task Force. (http://digital.ncdcr.gov/cdm/ref/collection/p16062coll5/id/11989)

11.4. Florida Food Safety and Food Defense Advisory Council. §500.033 Florida Statutes. (http://leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0500-0599/0500/Sections/0500.033.html)

11.5. Treadwell, Randy J.; 2014 International Food Protection Training Institute (IFPTI) Fellowship in Food Protection: Factors Influencing Multi-Jurisdictional Collaboration within State Food Emergency Rapid Response Teams (RRTs). https://3fxgnc3uy9ywv72fc3hj7rdd-wpengine.netdna-ssl.com/wp-content/uploads/2016/11/JTreadwell-Article.pdf

12. ATTACHMENTS

12.1. Attachment A – Epidemiological MOU between Agencies

12.2. Attachment B – Laboratory MOU between Agencies

12.3. Attachment C – Flowchart – Communications between Agencies

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	9/26/2011	RRT Working with other Agencies WG (VA**, Baltimore District**, MI, NC, Florida District, CFSAN, MA)
1.1	R	2/1/2012	ORA/OP
1.2	R	1/24/2013	ORA/OP
2.0	R	5/26/2017	RRT Working with other Agencies WG (WA**, MD, NC, ORA OPRM)

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)

**Workgroup Lead

Change History

1.1 – Editorial revisions made by ORA for document clearance.
1.2 – Minor editorial revisions to achievement level for clarification purposes.
2.0 – Revised for the 2017 Edition of the RRT Manual.

Attachment A – Epidemiological MOU between State Agencies

Example from North Carolina

MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN THE NORTH CAROLINA (NC) DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES (NCDA&CS) AND THE NC DEPARTMENT OF HEALTH AND HUMAN SERVICES (NCDHHS) CONCERNING THE INVESTIGATION OF FOODBORNE ILLNESSES ASSOCIATED WITH FOOD SERVICE ESTABLISHMENTS AND FOOD PLANTS

I. GENERAL

This Memorandum of Understanding (MOU) is between the North Carolina Department of Health and Human Services Division of Public Health (NCDHHS DPH) and the North Carolina Department of Agriculture and Consumer Services (NCDA&CS), Food and Drug Protection Division.

The purpose of this MOU is to clarify the respective responsibilities of NCDA&CS and NCDHHS DPH in the investigation of foodborne illnesses associated with food service establishments, food facilities or other relevant food operations, and in furtherance of such purpose, to broaden cooperative efforts between the two agencies.

Responsible Agencies

NCDA&CS and NCDHHS DPH are the responsible agencies for the implementation of this MOU. The authority of the Secretary of Health and Human Services to investigate outbreaks of communicable disease is established under NCGS § 130A-5 (Duties and Powers of the Secretary of Health and Human Services). The authority of the Secretary of Health and Human Services to regulate food and lodging establishments is established under NCGS § 130A-248 and § 130A-227 (Food and Lodging Establishments). The authority for the Commissioner of Agriculture to regulate the branding or misbranding and adulteration of any food, drug, device, cosmetic or consumer commodity is established under NCGS § 106-120 et. seq (Food, Drugs, and Cosmetics). Pursuant to the power granted to the Secretary of Health and Human Services, execution of this instrument binds all authorized agents when conducting activities on behalf of each respective agency. For purposes of this agreement, NCDHHS DPH and NCDA&CS will be responsible for its implementation.

Jurisdiction

This MOU applies throughout the State of North Carolina.

Effective Date

This agreement will be effective upon approval by all agencies and will remain in effect indefinitely until superseded, rescinded, or modified by written, mutual agreement of both parties.

Amendment, Modification and Termination

This MOU may be amended or modified only by written, mutual agreement of the parties. Either party may terminate this MOU by providing written notice to the other party. The termination shall be effective upon the sixtieth calendar day following notice, unless a later date is set.

Agreement Administrators

The administrator of this MOU for NC DA&CS is the Director, NCDA&CS Food and Drug Protection Division, 4000 Reedy Creek Rd., Raleigh, NC 27607-6465, (919) 733-7366 and the administrator for NCDHHS DPH is the Foodborne Disease Epidemiologist, Medical Consultation Unit, Communicable Disease Branch, 225 N. McDowell St., Raleigh, NC 27603, (919) 715-1162.

Legal Authority

NCGS § 130A-481 (Food Defense) provides requisite authority for NCDA&CS and NCDHHS DPH to enter into this MOU. The authority of the Secretary of Health and Human Services to enter into this agreement is also established under NCGS § 130A-6 (DHHS Delegation of Authority). NCGS § 106-141 (Food and Drug Examinations and Investigations) also authorizes this MOU. For the purposes of this agreement only, "contaminated" and "adulterated" are equivalent terms.

II. RESPONSIBILITIES AND IMPLEMENTATION

Determination of Responsibility

When a reported case or outbreak of food-related illness is determined to be caused by a manufactured food product regulated by NCDA&CS, then NCDHHS DPH will collaborate with NCDA&CS on the investigation. NCDHHS will be responsible for conducting the epidemiologic investigation. NCDA&CS will be responsible for conducting an investigation at the food facility or other relevant food operations. NCDA&CS will send a copy of these reports to NCDHHS DPH. Shared information may be designated as confidential, privileged or otherwise protected and all agencies will handle such information in a manner that will continue to protect such information. Any reports containing proprietary business information will continue to be exempt from the Public Records Law when shared outside of NCDA&CS. NCDA&CS will notify NCDHHS DPH when sharing records that may contain privileged information and such documents will be conspicuously marked as such. NCDHHS DPH will notify NCDA&CS when sharing records that may contain privileged information and such documents will be conspicuously marked as such. NCDA&CS and NCDHHS DPH will also coordinate any resulting actions to remove the contaminated food from distribution. Laboratory support for investigations will be coordinated by each agency under separate existing agreements.

NCDHHS DPH will coordinate the operations of local authorized agents in the investigation of food service establishments and the control of contaminated food leading to foodborne illnesses. NCDHHS DPH will send a copy of the final outbreak report to NCDA&CS. NCDA&CS will assist in the investigation of food service establishments if the contaminated food is determined to be a manufactured food or agricultural commodity.

Implementation

NCDA&CS will inform its field representatives of their areas of responsibility. NCDHHS will define areas of responsibility among local health department officials. NCDHHS and NCDA&CS will provide or sponsor joint training sessions in the interpretation and application of principles, regulations, standards, and techniques of common concern or interest.

III. MECHANISMS FOR INFORMATION EXCHANGE

NCDHHS DPH and NCDA&CS shall maintain rosters of regional and local health officials and NCDA&CS food program supervisors and make such rosters available to each other on at least an annual basis. Whenever one agency becomes aware of actual or suspected cases of food borne illness, it shall report such cases by telephone-without delay to the other agency. NCDHHS DPH will report such cases to the local health department having jurisdiction for that locality as appropriate. Any reports relative to the incident will be exchanged with the relevant agencies. Whenever one agency learns of an FDA Class I or similar recall of food or food products distributed in North Carolina, it shall notify a designee at the other agency of such recall. If a food recall resulted from a food borne illness each agency shall notify a designee at the other agency of such illness. Throughout the recall process, agencies at all levels will make an effort to keep the other agency informed and cooperate in every way possible to expedite the removal of hazardous food from the marketplace.

IV. MECHANISMS FOR EMBARGO OF FOOD SOURCES IMPLICATED IN INVESTIGATION

Epidemiological Investigation

NCDHHS DPH will investigate food borne disease outbreaks. These investigations are initiated following receipt of reports of food borne illness, injury or suspected outbreak report via routine communicable disease surveillance, consumer complaint or notification by external partners to NCDHHS DPH or following receipt of food borne illness, injury or suspected outbreak report via consumer complaint or notification by external partners to NCDA&CS. These investigations are conducted and documented by county health departments, following procedures outlined in existing protocols. NCDHHS DPH will notify NCDA&CS of all on-going investigations where a contaminated food source is the suspected cause of a disease outbreak as appropriate. NCDA&CS will provide assistance in the investigation and may play the lead role in performing trace back of contaminated foods to their source by visiting retailers, wholesalers, and producers to review and obtain records that document the chain of distribution for the products and performing trace forward as appropriate to consignees. NCDHHS DPH will conduct investigations at retail foodservice establishments as guided and

needed by its investigation of reported case(s), and will coordinate the activities of local environmental health offices. NCDHHS DPH will analyze the findings of the epidemiologic and source investigations and make a determination as to the likelihood of an association between the illness outbreak and its cause being one or more sources. When warranted, based on the evaluation of the investigation data and analysis, the Secretary of Health and Human Services or a designee will inform the Commissioner of Agriculture that food from the source(s) constitute(s) a danger to the health of the people of the State and that such source(s) is/are unapproved source(s) for food service establishments in the State. Investigational findings will be documented and maintained following existing protocols and retention schedules.

Embargo, Recall, and Public Notification

After receiving a notification from the Secretary of Health and Human Services, the Commissioner of Agriculture shall direct and oversee the embargo, and disposition of the food in question in accordance with the provisions of the North Carolina Food, Drug, and Cosmetic Act. When deemed appropriate, NCDA&CS shall request the firm's responsible party to implement a recall of such adulterated food and to notify the public of such recall. NCDA&CS and NCDHHS DPH shall assist in cases involving embargo and recall by monitoring the disposition of contaminated food from food service establishments, food facilities, or other relevant food operations and by making available witnesses for any administrative proceedings and/or litigation associated with such actions. Nothing herein contained shall be construed to restrict the power of the Secretary of Health and Human Services and/or the Commissioner of Agriculture to take Summary Action under their respective authorities to require the discontinuance of conditions or activities constituting a danger to public health when such action is deemed appropriate under the circumstances.

Acceptance of Agreement

For the Department of Agriculture and Consumer Services

Signature

Name:
Title: Director, Food and Drug Protection Division
Date

For the North Carolina Department of Health and Human Services Division of Public Health

Signature

Name:
Title: Director, Division of Public Health
Date:

Attachment B – Laboratory MOU between State Agencies

North Carolina Example

MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN THE NORTH CAROLINA (NC) DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES (NCDA&CS), THE NC DEPARTMENT OF HEALTH AND HUMAN SERVICES (NCDHHS), DIVISION OF PUBLIC HEALTH FOR ITS STATE LABORATORY OF PUBLIC HEALTH.

I. GENERAL

This Memorandum of Understanding (MOU) is between the North Carolina Department of Health and Human Services, Division of Public Health (NCDHHS DPH) and the North Carolina Department of Agriculture and Consumer Services (NCDA&CS). The purpose of this MOU is to clarify the respective laboratory testing responsibilities of NCDA&CS and NCDHHS DPH in the investigation of food borne illness outbreaks associated with food service establishments and food plants, and in furtherance of such purpose, to broaden cooperative efforts between the two agencies.

Responsible Agencies

NCDA&CS and NCDHHS DPH are the responsible agencies for the implementation of this MOU. The authority of the Secretary of Health and Human Services to investigate outbreaks of communicable disease is established under NCGS § 130A-5 (Duties and Powers of the Secretary of Health and Human Services), and to regulate food and lodging establishments is established under NCGS § 130A-248 and § 130A-227 (Food and Lodging Establishments). The authority for the Commissioner of Agriculture to regulate the misbranding and adulteration of any food, drug, device, cosmetic or consumer commodity is established under NCGS § 106-120 et. seq. Food, Drugs, and Cosmetics).

Jurisdiction

This MOU applies throughout the State of North Carolina.

Effective Date

This agreement will be effective upon approval of both agencies and will remain in effect indefinitely until superseded, rescinded, or modified by written, mutual agreement of both parties.

Amendment, Modification and Termination

This MOU may be amended or modified only by written, mutual agreement of the parties. Either party may terminate this MOU by providing written notice to the other party. The termination shall be effective upon the sixtieth calendar day following notice, unless a later date is set forth.

Agreement Administrators
The administrator of this MOU for NCDA&CS is the Director of NCDA&CS Food and Drug Protection Division, 4000 Reedy Creek Rd., Raleigh, NC 27607-6465, (919)-733-7366 and the administrator for NCDHHS DPH is the Director of the North Carolina State Laboratory of Public Health, 4312 District Drive, Raleigh, NC 27607, (919)-807-8960.

Legal Authority

NCGS § 130A-481 (Food Defense) provides requisite authority for NCDA&CS and NCDHHS DPH to enter into this MOU. The authority of the Secretary of Health and Human Services and its delegates to enter into this agreement is also established under NCGS § 130A-6 (DHHS Delegation of Authority). NCGS § 106-141 (Food and Drug Examinations and Investigations) also authorizes this MOU.

II. RESPONSIBILITIES AND IMPLEMENTATION

Determination of Responsibility

When a reported case of foodborne illness is determined to be caused by a food product regulated by NCDA&CS, NCDHHS DPH will collaborate with NCDA&CS on the investigation. NCDHHS DPH will be responsible for the laboratory analysis of human clinical samples collected during the investigation. NCDA&CS will be responsible for the laboratory analysis of food and/or environmental samples collected during the investigation. NCDHHS DPH will perform serotyping and molecular subtyping on both clinical isolates and food/environmental isolates collected during the course of an investigation, as approved by the Director of the North Carolina State Laboratory of Public Health or designee. Both agencies will submit a copy of laboratory results to the partner agency.

Shared information may be designated as confidential, privileged or otherwise protected and all agencies will handle such information in a manner that will continue to protect such information. Any reports containing proprietary business information will continue to be exempt from the Public Records Law when shared outside of NCDA&CS. NCDA&CS will provide notification when sharing records that may contain privileged information and such documents will be conspicuously marked as such.

III. MECHANISMS FOR INFORMATION EXCHANGE

Reports detailing laboratory analysis related to food borne illness outbreak investigations or cases will be shared between the agencies through the most efficient means such as telephone, email, or fax.

IV. LABORATORY FINDINGS

NCDA&CS will test food and/or environmental samples collected during investigations. NCDHHS DPH will perform serotyping and molecular subtyping on both clinical isolates and food/environmental isolates collected during the course of an investigation, as approved by the Director of the North Carolina State Laboratory of Public Health or designee. If a laboratory analyses requires Biosafety Level 3 (BSL-3), the specimen will be transferred to the State Laboratory of Public Health. Director of the North Carolina State Laboratory of Public Health or designee and/or NCDA&CS Food & Drug Protection Division Director or designee will notify the other agency of all on-going laboratory investigations where a contaminated food source is the suspected cause of a food borne illness outbreak.

For the Department of Agriculture and Consumer Services

Signature

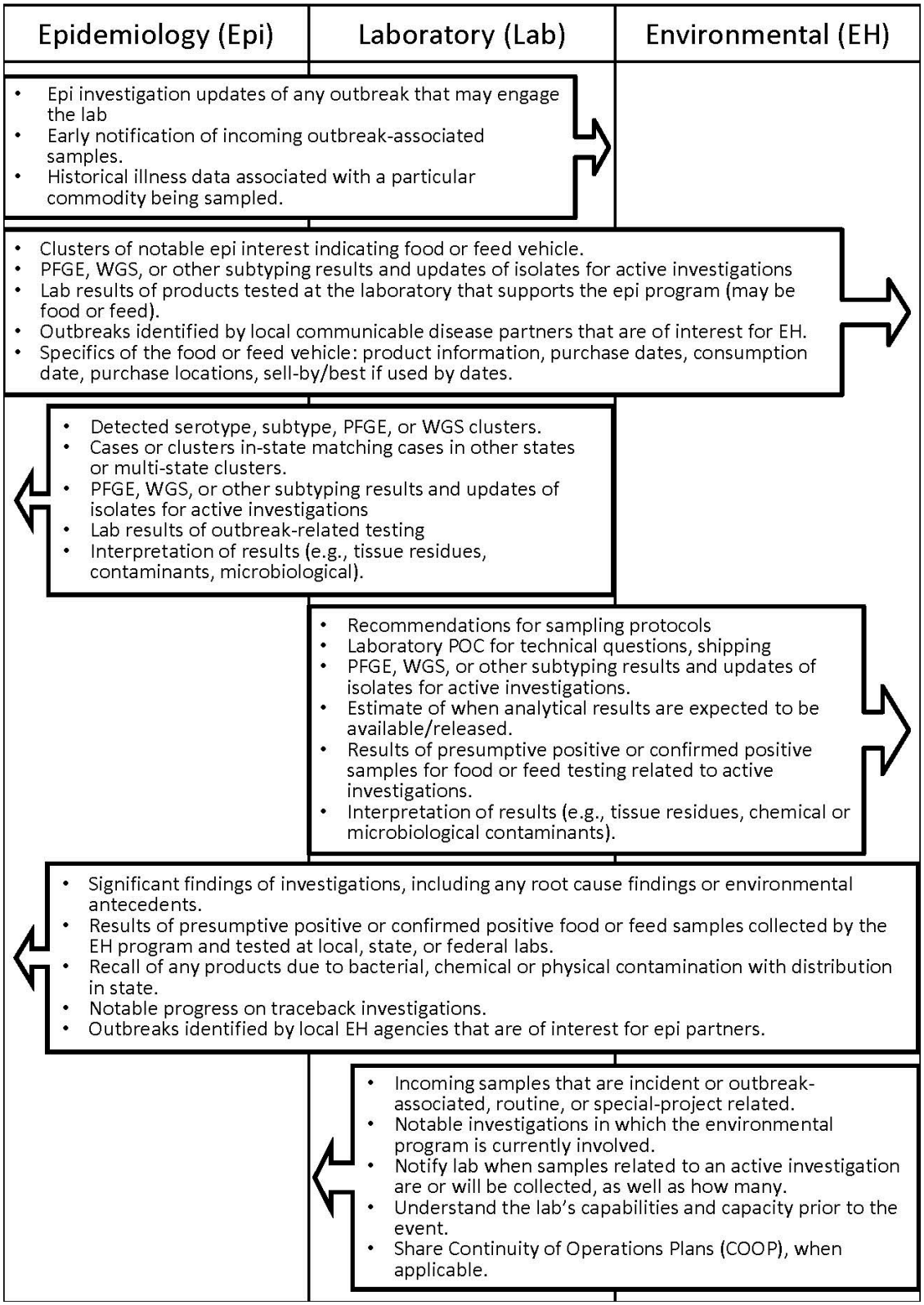
Name:
Title: Director, Food and Drug Protection Division
Date:

For the Department of Health and Human Services

Signature

Name:
Title: Director, Division of Public Health
Date:

Attachment C – Flowchart – Communications between Agencies



Relationship Building

Chapter 2. Federal-State Cooperative Programs

TABLE OF CONTENTS

1. PURPOSE

This document is designed to introduce readers to the four (4) areas of the Federal-State Cooperative Programs (the Interstate Milk Shippers Program, the National Shellfish Sanitation Program, the Retail Food Protection Program, and the Radiological Health Program). These programs represent a significant part of state food safety/security programs and should be included in any response teams, taskforces, or other organizations of that nature. This document is not intended as a guide to the actual incorporation of Cooperative Programs personnel and activities into an integrated food safety system such as a Rapid Response Team. The development, structure, and function of response teams, taskforces, and other related organizations are topics that must be addressed on an individual basis considering the needs, resources, and limitations of the parties involved. Other chapters of the RRT Best Practices Manual (Working with Other Agencies, Communications, Joint Investigations) provide more specific instructions and examples on the development of these types of organizations (i.e., Rapid Response Teams). The goal of this chapter is to introduce and detail the roles and responsibilities of the four areas of the Federal-State Cooperative Programs so that, when appropriate, they can be included in the development of an integrated food safety response system.

2. SCOPE

This document focuses on defining the key activities and responsibilities within each of the Federal-State Cooperative Program areas. This information can be used to determine those areas in which federal, state, and local agencies involved in food emergency response may incorporate Cooperative Programs into their various food safety systems and organizations.

3. RESPONSIBILITY

These four programs are monitored by FDA, but regulatory and administrative actions are implemented by the states.

3.1. Agency/Organization Leadership

Representatives from federal, state, local, and all levels of cooperative program areas will (jointly) approve any customizations made to this template to ensure that procedures developed are appropriate for state-specific jurisdiction.

3.2. RRT (or investigatory team, in states without an RRT) Leadership

3.2.1. Procedure familiarization/training: RRT leadership is responsible for ensuring that the personnel assigned to respond to a human or animal food incident, involving cooperative programs have been provided with the ICS and investigation-related training necessary to implement the best practices described in this chapter.

3.2.2. Procedure maintenance: Ongoing updates and maintenance of procedures would ideally be the duty of combined leadership of the RRT (or in jurisdictions without a RRT, the responsibility of the manager of the appropriate department). In an RRT, this would include representatives such as the FDA District Emergency Response Coordinator, the state RRT program director or principle investigator, and both state and FDA representation in each of the four cooperative programs**.**

3.3. RRT Members

3.3.1. Procedure Familiarization/awareness: RRT Members must be familiar (through orientation, training, exercises, etc.) with RRT and Cooperative Program SOPs and their implementation.

3.3.2. Skills maintenance: RRT members are each responsible for actively maintaining both their subject matter expertise and ability to work effectively in multi-disciplinary and multi-agency response teams

4. DEFINITIONS

The following terms are used frequently in this Chapter: Environmental, Epidemiology, Laboratory, and Food Safety Defense Task Force. See Manual "Glossary of Key Terms" for definitions.

5. BACKGROUND

Overview of Federal-State Cooperative Programs

The Federal-State Cooperative Programs are composed of four (4) separate food safety programs, the Interstate Milk Shippers Program, the National Shellfish Sanitation Program, the Retail Food Protection Program, and the Radiological Health Program. The authority for these programs is provided in the Public Health Services Act (42 USC 243). Section 311(a) of the Act states in part, "The Secretary shall…assist states and their political subdivision in the prevention and suppression of communicable diseases with respect to public health matters, shall cooperate with and aid states and local authorities in enforcement…health regulations and shall advise the several states on matters relating to preservation and improvement of the public health." Responsibility for carrying out the provisions of the Act related to food protection was delegated within Public Health Service (PHS) to the Commissioner of Food and Drugs in 1968 (21 CFR 5.1 (a)(2)&(4)). These programs are often cited as a force multiplier and are examples of how a small expenditure of Federal resources may be leveraged to guide a much larger resource investment by state and local governments. The Milk, Shellfish and Retail Food programs each have a governing conference: The National Conference on Interstate Milk Shipments, the Interstate Shellfish Sanitation Conference, and the Conference for Food Protection. The goal of these conferences is to develop and adopt national rules and model regulations that can be implemented by the participating states thereby promoting program uniformity throughout the nation.

5.1. Grade "A" Milk Program

The FDA State Cooperative Milk Safety Program was established under an MOU, signed in 1977, between the Commissioner of the FDA and the National Conference on Interstate Milk Shipments (NCIMS). The NCIMS is the mechanism through which the *Grade "A" Pasteurized Milk Ordinance* (PMO) is revised. The PMO is a model regulation for states to adopt which regulates the production of Grade "A "raw milk on the farm; its pickup and transfer from the farm to the dairy plant; and the processing, packaging and handling of Grade "A" milk and milk products in the United States.

5.2. Shellfish Sanitation Program

The National Shellfish Sanitation Program (NSSP) was formed in 1925 when the U.S. Public Health Service responded to requests for assistance from Local and State public health officials in controlling disease (primarily typhoid fever) associated with the consumption of raw oysters. Several workshops involving the States and the Federal government were subsequently held to develop program guidelines and address emerging problems pertaining to shellfish (oysters, clams,

mussels, and now, whole scallops and scallop adductor muscle meat with attached roe) such as marine biotoxins, heavy metals, pesticides, etc.

The First National Shellfish Sanitation Workshop was held in 1954, and subsequent workshops were held in following years. In 1982, a delegation of State shellfish officials from 22 states met in Annapolis, MD and formed the Interstate Shellfish Sanitation Conference (ISSC) using the successful National Conference of Interstate Milk Shippers (NCIMS) as a model. Food and Drug Administration has a formal Memorandum of Understanding (MOU) with the Interstate Shellfish Sanitation Conference (ISSC) which outlines the responsibilities of each in the sanitary control of shellfish (oysters, clams, and mussels).

5.3. Retail Food Program

FDA's Retail Food Protection Program provides assistance to the more than 3,000 state and local government agencies that regulate the retail food industry. In 1993, FDA signed an MOU with the Conference for Food Protection, which is an organization that brings together representatives from the food industry, government, academia, and consumer organizations to identify and address emerging problems of food safety and formulate recommendations to be incorporated into public policy and industry practice. The stated purpose of this MOU is to establish a working relationship between the Conference for Food Protection and FDA to:

- place greater emphasis on food safety at the point of sale, and
- be more successful in promoting food safety, mutual respect and uniformity

5.4. Radiological Health Program

Regional Radiological Health Representatives (RRHR) are FDA's liaisons to the states for areas of radiological health and radiological emergencies. Radiological emergencies can include malfunctions at nuclear power plants as well as hostile actions to comprise the integrity of a nuclear reactor, or other terrorist activities involving bombs containing nuclear or radioactive materials. Any of these events could compromise the nation's food supply and allow radioactive materials to enter the ingestion pathway. Additionally, the RRHR is responsible for general oversight of all radiological health program areas and training, and considered the Subject Matter Expert for radiological health.

6. SAFETY

N/A

7. EQUIPMENT/MATERIALS

N/A

8. PROCESS DESCRIPTION

The four (4) cooperative program areas (the Interstate Milk Shippers Program, the National Shellfish Sanitation Program, the Retail Food Protection Program, and the Radiological Health Program) can play an important part in food safety response. These partners should be considered as participants on Food Safety Defense Task Forces, Rapid Response Teams and other Food Safety Response entities. Best practices for the integration of cooperative program representation at the state, local, and FDA regional levels can be found in many of the other chapters of the RRT Best Practices Manual including "Working with Other Agencies", "Communications", and "Joint Investigations".

The four programs are described below to familiarize readers with the structure and responsibilities of each.

8.1. Grade "A" Milk Program

The *Grade "A" Pasteurized Milk Ordinance* (PMO) creates a three tier system consisting of (i) state enforcement, (ii) state rating, and (iii) FDA check rating. State enforcement consists of permitting, inspection, and sampling and enforcement activities. State ratings consist of conducting reviews of state enforcement activity to ensure milk supplies and plants are in substantial compliance with the requirements of the PMO before they are listed in the *Interstate Milk Shippers List* (IMS List). Firms on the IMS List are authorized for interstate shipment of Grade "A" product. FDA check rating activity consist of reviewing IMS listed milk supplies and plants in each state to ensure the listed state ratings are valid.

FDA is responsible for the following activities:

- Promoting the adoption, implementation and enforcement of regulatory standards as provided in the model *Grade A Pasteurized Milk Ordinance* (PMO);
- Standardization of FDA and state personnel performing ratings, listings and laboratory certifications;
- Maintaining and publishing the IMS List of milk supplies, dairy plants, and approved laboratories quarterly;
- Providing training to state personnel;
- Conducting check ratings (consisting of a monitoring inspection of a plant and/or farm group and the review of processing, laboratory and regulatory records to evaluate how the State is carrying out their program) and single-service audits for sanitation compliance of listed shippers;
- Issuing interpretations of the PMO; and
- Evaluating and approving milk testing laboratories and evaluation of state milk enforcement and rating programs.

States are responsible for the following:

- Adopting regulations equivalent to the PMO;
- Issuing permits to Grade "A" dairy farms and Grade "A" plants; inspecting each at required frequencies; collecting milk, milk product and water samples at required frequencies;
- Ensuring all milk is screened for Beta lactam drug residues prior to processing;
- Issuing permits and conducting evaluations of bulk milk haulers and samplers;
- Issuing permits and conducting inspections of milk tank trucks;
- Maintaining FDA certification of state personnel conducting ratings, laboratory certification and sample surveillance; and conducting laboratory certifications at required frequencies;
- Maintaining permit, inspection and sample records for all permit holders;

8.2. Shellfish Sanitation Program

The Interstate Shellfish Sanitation Conference (ISSC) membership is comprised of representatives from Federal agencies (FDA, Centers for Communicable Disease Control, US Department of Commerce, National Marine Fisheries Service, and Environmental Protection Agency); State authorities associated with shellfish management and regulation, shellfish industry, academia, and consumer advocacy groups. The Conference meets biannually to discuss program proposals to address shellfish safety, and to make necessary changes to shellfish program guidelines. The FDA has a MOU with the ISSC that outlines the responsibilities of the States and FDA in the sanitary control of shellfish

The National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, Model Ordinance (MO) section contains the minimum requirements that States must implement and enforce if they wish to ship shellfish in interstate commerce. Firms meeting these requirements are listed on the Interstate Certified Shellfish Shippers list and therefore are authorized to ship molluscan shellfish interstate commerce. These requirements are debated and developed by the ISSC members. State shellfish authority delegates vote on proposed or revised requirements (only states vote for final requirements). Following FDA concurrence (proposals may not conflict with existing federal regulation or policy), the new or amended requirements are published in the next revision of the NSSP Guide for the Control of Molluscan Shellfish.

As with all food products, rapid response is needed in dealing with illness outbreaks. Since shellfish are harvested from coastal waters and often consumed raw, incidents that affect the sanitary quality of coastal waters can have significant public health impacts and require rapid response by public health officials. Such events would include major storm events, major spills (sewage, oil, toxic chemical,

radiological) and major blooms of toxic algae. Planning for timely coordination and communication at all levels of public health agencies is critical in these events.

FDA is responsible for the following activities:

- Evaluation of State Shellfish Programs using the guidelines found in NSSP MO and the FDA Molluscan Shellfish Compliance Program (7318.004).
- Providing the ISSC Executive Board with information on any State Shellfish Program not in substantial compliance with NSSP MO guidelines, procedures, and criteria.
- Standardization of State Shellfish Standardization Officers and standardization training for State inspectors.
- Maintaining and publishing (on-line) a dynamic monthly current listing of all shellfish dealers and shippers certified under the NSSP by the States (Interstate Certified Shellfish Shippers List - ICSSL).
- Participation to the fullest extent possible in ISSC Task Forces, Committee/Subcommittee/Workgroup meetings, and any other deliberative groups that support the ISSC and the NSSP in the safe production and shipment of molluscan shellfish.
- Coordination with State Shellfish Program Managers, State Health Departments, State Epidemiologists, FDA District/Division/Program personnel, FDA CORE and Industry in the investigation, recalls, national reporting, and sampling in response to all illnesses/deaths/outbreaks associated with the consumption of raw or undercooked molluscan shellfish.
- Supporting and/or providing shellfish sanitation training, seminars, technical assistance, and scientific research as resources permit. FDA is committed to maintaining a current scientific basis for the shellfish sanitation guidelines and standards.
- Participation in Incident Response; technical assistance, research and training are critical for response to incidents such as illness outbreaks, large sewage spills, oil spills, toxic chemical spills, radiological events, and major storm events. Often, these events have impacts that cross State lines. Therefore, these events require advance planning, communication and coordination among multiple agencies from the Local, State and Federal levels.
- Promoting and maintaining MOUs or other agreements with participating foreign countries regarding shellfish sanitation programs. There are currently four (4) foreign countries that have MOUs or other State Department agreements with FDA allowing them to participate in the NSSP; FDA evaluates these programs just as they do the State programs.
- Coordinating Federal interagency affairs on matters concerning shellfish sanitation, including the classification of shellfish growing waters under Federal jurisdiction.
- Maintaining the National Shellfish Consumption-Associated Vibrio Illness Database; all reported Vibrio illnesses are included in this database.

The States are responsible for the following activities:

- Adoption of adequate laws and regulations to provide a legal basis for sanitary control of all phases of State shellfish programs.
- Conducting Sanitary Surveys and implementing proper classification of all shellfish growing waters in the state in accordance with the requirements outlined in the NSSP MO.
- Development of comprehensive Sanitary Survey reports (including shoreline surveys) that identify and evaluate all actual and potential pollution sources, analyze and evaluate bacteriological seawater sample results, and determine proper classification of shellfish growing areas.
- Inspection and certification of each shellfish processor that meets NSSP MO requirements, and submission of the names of certified facilities to FDA for inclusion in the Interstate Certified Shellfish Shippers List (ICSSL).
- Enforcement of classification boundaries, prevention of illegal harvesting, and enforcement of other harvester requirements in all productive shellfish growing areas.
- Supervision of the relaying of shellfish from closed areas to approved areas and subsequent cleansing (depuration) of shellfish.
- Adequate training of State shellfish program personnel to allow proper implementation of the State's shellfish program.
- Utilization of laboratories that reliably perform seawater, shellfish, and biotoxin sample analyses in accordance with the latest approved editions of the APHA, AOAC, or other methods approved by the ISSC.
- Participation in Incident Response, e.g., illness outbreaks associated with consumption of shellfish, large sewage spills, oil spills, toxic chemical spills, radiological events, and major storm events.
- Communicating and coordinating recall information with firms and ensuring recalled product is off the market

8.3. Retail Food Program

The primary objective of the Retail Food Program is to minimize the incidence of foodborne illness at retail, by directing activities related to the promotion of effective state and local retail food regulatory programs.

These agencies regulate more than 1,000,000 retail food establishments nationally (restaurants, grocery stores, health facilities and nursing homes, schools, correctional facilities, temporary event food service, food vending facilities, etc.). This is highly significant because, it is estimated, that the American public now consumes more than 50% of their meals outside the home. Agencies regulating this multi-billion dollar industry look to the Regional Retail Food Specialists for training, technical assistance, program evaluation, and to serve as a liaison between FDA, the states, and industry as needed.

FDA is responsible for the following activities:

- Promoting adoption of the *FDA Food Code* and application of science based food safety principles and methods at the state, local, and tribal level.
- Providing technical assistance on *FDA Food Code* requirements and retail food safety issues.
- Providing uniform training on food safety principles and regulations.
- Standardizing state regulatory Retail Food Inspection Officers.
- Promoting national uniformity among retail food regulatory programs by encouraging state, local, and tribal participation in the Voluntary National Retail Food Regulatory Program Standards.
- Conducting Risk Factor Studies.
- Promoting and participating on state and local food safety and defense task forces.
- Providing risk based inspection and food defense and surveillance activities/assistance, in conjunction with state and local regulatory authorities, during special security and emergency/disaster response events.
- Conducting Foodborne Illness Risk Factor studies to track the occurrence of behaviors and practices that commonly lead to foodborne illness in various types of retail and foodservice establishments.

8.4. Radiological Health Program

Regional Radiological Health Representatives (RRHR) are FDA's liaisons to the states for areas of radiological health and radiological emergencies. Radiological emergencies can include malfunctions at nuclear power plants, hostile actions to comprise the integrity of a nuclear reactor, or other terrorist activities involving bombs or Radiation Dispersal Devices (RDDs) containing nuclear or radioactive materials. Any of these events could compromise the nation's food supply and allow radioactive materials to enter the ingestion pathway. The RRHRs act as the FDA's representatives for The Advisory Team for Environment, Food and Health (Advisory Team), which is a radiological emergency response group tasked with providing protective action recommendations to state and local governments, including Indian Governmental Agencies, on behalf of its member agencies. The permanent membership includes representatives from the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA). The permanent members may invite other agencies to participate in Advisory Team activities.

The Advisory Team was incorporated into the Nuclear/Radiological Incident Annex of the National Response Plan (NRP) in December 2005. The NRP has been replaced by the National Response Framework. Program activities performed by RRHRs relative to Emergency Planning and Response Activities are covered under CPGM 7386.009.

Additionally, the RRHR is responsible for general program oversight for the following program areas: The Mammography Quality Standards Act: Inspections of Federal Facilities which provide mammography services, which include VHA facilities as regulated under the VHAMQSA (through an MOU for inspections), Indian Health Services, Department of Defense, and the Federal Bureau of Prisons. Also, RRHRs oversight of the current contracts with state radiological health agencies for annual inspections of mammography facilities, and tracking of audits of all inspectors, FDA and state, to meet the annual joint audit requirement. These activities are covered under CPGM 7385.014.

- Electronic Product Radiation Control (includes suntan beds/booths, bulbs, cabinet x-ray systems, microwaves, therapeutic ultrasound devices, x-ray equipment, lasers, and medical devices utilizing electronically-produced radiation) as outlined under CPGM 7386.001.
- Inspection of Domestic and Foreign Manufacturers of Diagnostic X Ray Equipment as outlined under CPGM 7386.003a.
- X-Ray Field Testing as outlined under CPGM 7386.003.
- Compliance assistance as requested by the Centers or Division/Program Offices.

The RRHR is considered the regional Subject Matter Expert for all Radiological Issues as regulated by FDA.

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

Level	Description
1	Program has little to no knowledge of the roles and responsibilities of the four Federal-State Cooperative Programs[1], how they operate within their jurisdiction (local, state, regional), and how they would be incorporated as part of an integrated food safety system.
2	Program is aware of the roles and responsibilities of the four Federal-State Cooperative Programs and has a basic understanding of how they operate within their jurisdiction (local, state, regional), and how they would be incorporated as part of an integrated food safety system.
3	Program has a strong understanding of the roles and responsibilities of the four Federal-State Cooperative Programs and fully understands how they operate within their jurisdiction (local, state, regional), and how they would be incorporated as part of an integrated food safety system.

[1] There are four Federal-State Cooperative Programs (grade A milk, shellfish, retail, radiological).

Level	Description
4	Program has developed a Standard Operating Procedure (SOP), MOU or other agreement and/or documentation[2] that describe incorporation of the four Federal-State Cooperative Programs within the RRT and associated capabilities or functional areas.
5	Any SOPs or MOUs include a formal review and update process including how and when they will be exercised.

9.2. Process Overview

9.2.1. Level 1: Little to no knowledge about Federal-State Cooperative Programs operating within jurisdiction (local, state, regional)

1. Identify Cooperative Programs operating within the jurisdiction
   a. Contact state or local health and agriculture programs to identify what Cooperative Program areas are operating within the jurisdiction
   b. Contact appropriate FDA Program office (District FDA office may provide this information) and speak with Director of Cooperative Programs

9.2.2. Level 2: Basic knowledge of Federal-State Cooperative Programs operating within jurisdiction (local, state, regional)

1. Obtain contact information for and individuals or organizations responsible for the Cooperative Program areas operating within the jurisdiction
   a. Taskforce membership lists
   b. Trade organizations
   c. Conference Contacts
   d. Workgroups
   e. Professional Associations
   f. State or local regulatory agencies
   g. Federal management and Federal subject matter experts-Specialists
2. Identify roles, responsibilities, and authorities covered under the specific Cooperative Program area
   a. Face-to-face meeting
   b. Conference calls
   c. Sharing of operational documentation and legal authorities
3. Ensure that Cooperative Program personnel have completed required training to be a part of the jurisdiction's integrated food safety response system (i.e., Rapid Response Team)

[2] Stand-alone documentation not required; the documentation can be part of a larger MOU, SOP or other agreement/documentation.

   a. Provide Cooperative Program directors in FDA and State Agency management with a list of required training (i.e., List of courses required to serve as a member of the response team)
   b. Identify means of completing required training
   c. Catalog documentation showing completion of required training
4. Establish role of Cooperative Program personnel as part of the jurisdiction's integrated food safety response system (i.e., Rapid Response Team)
   a. Participation in RRT exercises and other team building events
   b. Sharing of resources
      i. Purchase of equipment required to fulfill role as part of the response team
      ii. Equipment and training necessary for communication during response team activation

9.2.3. Level 3: Complete knowledge of Federal-State Cooperative Programs operating within jurisdiction (local, state, regional)

1. Document activation, operation, and communication procedures for Cooperative Program personnel involved as member of the jurisdictions integrated food safety response system
   a. MOUs – Note FDA MOU with Conferences
   b. SOPs

9.2.4. Level 4: SOPs for Cooperative Program integration into the response system have been developed

1. A timeframe is established for review of the SOP
   a. Is the timeframe between reviews appropriate for the document?
2. A procedure has been developed to check the accuracy of contact information included in the SOP
3. A schedule has been developed for exercising the SOP
4. A procedure exists for incorporating after action reporting and other comments/suggestions into the SOP
5. The SOP review includes a process for incorporating and implementing changes to other documents which would impact the Federal-State Cooperative Program areas
   a. Communications SOPs
   b. Joint Investigations SOPs
   c. Training SOPs

9.2.5. Level 5: The SOP includes a formal review and update process including provisions for exercising the procedure.

1. Establish personnel responsible for insuring that review and revision of the SOP is accomplished within the required timeframe

10. RELATED DOCUMENTS

RRT Manual Chapter 1: Working with Other Agencies

11. REFERENCES AND OTHER RESOURCES

11.1. National Shellfish Sanitation Program (model ordinance)

11.2. Interstate Certified Shellfish Shippers List - ICSSL (Updated monthly on FDA website)

11.3. Grade "A" Pasteurized Milk Ordinance (PMO)

11.4. Interstate Milk Shippers List – IMSL (Updated monthly on FDA website)

12. ATTACHMENTS

N/A

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	7/16/2012	RRT Cooperative Programs WG (VA**, FDA CER, FDA SER, FL)
1.1	R	1/24/2013	ORA/OP
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**Workgroup Lead

Change History

1.1 – Minor editorial revisions to achievement level for clarification purposes.

1.2 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.

Chapter 3. Industry Relations

TABLE OF CONTENTS

1. PURPOSE

The purpose of this document is to assist state human and animal food regulatory agencies in identifying various types of industry-regulatory interactions and in improving their relations with human and animal food industries, firms, and trade associations. This document introduces the topic of industry relations to be used by agencies to assess the level and extent of engagement they desire, understand the different types of interactions, and recognize aspects that help and hinder industry-regulatory interactions. "Industry" in this document includes individual human or animal food firms (growers, manufacturers, wholesalers, retailers that are impacted by the emergency) as well as trade associations. While the primary audience of this document is regulatory agencies, this should not preclude other governmental and private entities from using this as a resource.

2. SCOPE

This document serves as a high-level orientation to industry-regulatory interactions. It is meant to guide regulatory agencies in assessing their current level of relations with industry and to identify steps for improvement. This is not a comprehensive manual of the subject nor is it an obligatory process; every agency differs in resources, responsibilities, and priorities. Leadership of regulatory agencies involved in responses to human or animal food incidents are encouraged to apply the best practices described in this chapter to any processes and procedures regarding industry relations that are appropriate for and in use by their jurisdictions.

3. RESPONSIBILITY

3.1. Agency/Organization Leadership

Leadership of federal, state, and local agencies involved in responses to human or animal food incidents will jointly work to apply the best practices described in this chapter to any processes and procedures regarding industry relations that are appropriate for and in use by their jurisdictions.

3.2. RRT (or investigatory team, in states without an RRT) Leadership

RRT leadership is responsible for ensuring that the personnel assigned to respond to human or animal food incident have been provided with the Incident Command System (ICS) and investigation-related training necessary for them to successfully complete the tasks they are assigned.

3.3. RRT Members (or investigatory team, in states without an RRT)

RRT members are each responsible for playing an active role in maintaining both their subject matter expertise and ability to work effectively in multi-disciplinary and multi-agency response teams.

4. DEFINITIONS

N/A

5. BACKGROUND

Building and maintaining good relationships between regulatory agencies and industry are important for several reasons. Firstly, there is a shared public health vision between industry and regulatory that is important to foster and capitalize upon. While there exists an inherent tension between the regulatory agencies and the regulated industry, public health and the economy both benefit when the relationship is constructive rather than antagonistic. Industry often knows more than regulatory agencies about itself and in many cases will have much deeper knowledge of their products, how they are made, how they move through commerce, and how those things have changed over time. Industry associations and individual companies can often be assets to regulatory agencies, containing a wealth and depth of subject matter expertise on areas including sourcing, standards, audits, processing, marketing, logistics, and consumer preferences. They can help regulatory agencies better understand risks in the marketplace, and can also help to reach consumers on overarching efforts like hand-washing campaigns, and aid in specific responses like product recalls.

Industry can also benefit from engaging in partnerships with regulatory agencies. In many cases, regulatory agencies were created because of significant health and safety issues within the food and agriculture sector. These agencies represent the public and are charged with licensing, testing, and enforcement of businesses and products. As issues emerge in the public and in the media, including new threats and awareness of vulnerabilities of the food supply, there will be calls to address those issues through

changes in legislation and regulation. By actively engaging with regulatory agencies through trade associations and other groups, industry can help provide a perspective on proposed language that can lead to more workable final products and less contention during the legislative process. Through interaction with regulatory agencies, industry can also better learn about how these agencies work, what their legal and program constraints are, and other important issues that may aid in understanding why and when regulatory actions are taken.

6. SAFETY

N/A

7. EQUIPMENT/MATERIALS

N/A

8. PROCESS DESCRIPTION

8.1. Types of Industry-Regulatory Interactions

There are multiple examples of interactions between industry and the regulatory communities that can lead to positive results for both.

8.1.1. Temporary or ad-hoc working groups

These are working groups comprised of regulatory agency and industry representatives that are formed on a temporary basis to make a specific decision or complete a specific task. Examples include: updating a state food code, or creating guidelines for reducing the risk of *Salmonella* contamination on a commodity.

8.1.2. On-going working groups

These are working groups, comprised of regulatory agency and industry representatives, that are formed for continued collaboration around a subject. Examples include: Food Safety Task Forces or Food Defense/Agro-Terrorism Working Groups.

8.1.3. Foodborne illness outbreak investigation or crisis event response

These are interactions during a foodborne illness outbreak investigation or response to a human or animal food emergency. Particularly in a natural or man-made disaster, the regulatory agencies and industry may need to work closely together in both the response and recovery phases, including coordination in a Joint Information Center (for more information, see “Incident Command System – Best Practices” in the RRT Best Practices Manual, September, 2011).

8.1.4. Training, education, and other outreach

These are opportunities to share best practices and knowledge with industry representatives. These include in-person events, such as classroom training or workshops, or informational materials delivered on fact sheets or web sites. They can be co-hosted/co-authored by the working groups mentioned above, or can be stand-alone offerings based on need. These can also occur as "cross-training", or joint training, in which industry and regulatory representatives train together (for example, ICS or food defense joint trainings).

8.2. Issues to Consider with Working Groups

There are several considerations that need to be factored into creating and maintaining working groups. The points below describe important areas that should be discussed internally by both industry and regulatory, and then between the two.

8.2.1. Creating a working group

Ideally, a working group should be working **before** an issue or problem arises. When possible, be pro-active versus reactive when addressing emerging issues.

8.2.2. Defining the working group mission

Defining the mission of a working group is fundamental to its success. The mission should state whether the working group is designed to be temporary or on-going. Also, if there is a specific product, deliverable, or outcome that needs to be developed by this group, this should be clearly stated along with a deadline for the product.

8.2.3. Identifying who to include

The working group mission, goals, and deliverables should help to identify potential group members. Consider identifying and recruiting members from different sized entities within an industry or industry sector, since they will have different needs, resources, and viewpoints. The RRT Best Practices Manual may be useful in laying out the scope of work, especially if multiple agencies at the state and local levels are responsible for the subject area (see "Working with Other Agencies", "Communication Standard Operating Procedures (SOPs)", and "Joint Inspections & Investigations" sections of the RRT Best Practices Manual, September, 2011).

8.2.4. Procedural and logistical considerations

When building a working group, there are several procedural and logistical considerations to be made. It is strongly suggested that regulatory-industry groups delineate the procedures by which the group will operate. These include:

1. **Formation of the group:** How will members be invited and chosen? Will this be the Governor, Commissioner/Secretary/Director? Will there be a general announcement and call for interest, allowing everyone who wants to take part to do so? Or will it be a select invitation?
2. **Governance of the group:** How formal will the structure be? Is there a need for a charter or bylaws? Will there be voting that binds the group to a decision? If so, will minority viewpoints be included in any reports or documents? Will there be meeting minutes taken or annual reports written? If so, what is the distribution of these documents – group members only or available to the public?
3. **Membership length of service:** What will be the term of service of the members? How will vacancies be filled?
4. **Logistical support:** Who will provide administrative staff resources to support the working groups? Will members receive reimbursement for their travel and related expenses?

8.2.5. Open meetings and public records laws

Several states have laws governing open meetings and public records. These vary by state and agencies should check with legal counsel about applicability. This also includes minutes and notes taken at these meetings, as well as membership lists and contact information.

8.2.6. Securing confidential information

It is important to identify types of confidential information that could be sought or shared by the working group, know the legal bounds for sharing and securing this information, and set working group guidelines based on the laws and policies that govern its members. For instance, it may be helpful for the agencies to understand how industry manages some part of the process or for the work group to tour a facility to better understand how something works. However, that may be proprietary or confidential business information. State laws vary on disclosure, so agencies should consult with legal counsel to determine the access and availability of information collected through participation in this group.

Securing information also includes development of processes within the regulatory agency to ensure that protected information remains protected and a process to ensure that other working group members representing private businesses do not receive an advantage by having access to this kind of information. For these situations, seeking information from industry associations or trade groups may be more appropriate than from individual businesses as these groups will have an understanding about proprietary sensitivities and can provide information at a generic level. Documents such as confidentiality

agreements, if applicable, should be in place before the start of a working group.

The following are additional special considerations for securing information:

1. **Protected Critical Infrastructure Information (PCII)**: Some information provided by the private sector to federal, state, or local agencies may be considered PCII, meaning that it was gathered as part of the national effort to protect critical infrastructure, including the food and agriculture sector. This information is voluntarily provided by industry to government and helps provide a better understanding of threats, risks, and vulnerabilities. However, under federal law it cannot be disclosed to the public and it also cannot be used for any regulatory or enforcement actions.
2. **Information supplied by federal agencies (CDC, FDA, USDA)**: Some information may be provided to state or local agencies through agreements with the FDA or USDA that with limits on further disclosure. Federal law prohibits working group review of these kinds of materials if the working group contains any members who do not have explicit authorization to review such documents.
3. **Protecting regulatory information distributed to working group members**: Regulatory agencies may have internal policies and procedures (for example, how inspections are planned and carried out). Depending on state open meetings and public records laws, disclosure of any documents—including those considered internal or sensitive—may result in them being considered public. They may also become public through loss or intentional distribution by working group members; measures to safeguard against such distribution should be taken.
4. **Competing interests between industry and regulatory entities and among different types/sizes of industry**: There are some potential conflicts that both sides should be aware of in working groups. These include ensuring that working groups:
    a. Have a balance of viewpoints.
    b. Have a balance of industry participants so that individual companies cannot use the process to negatively impact their competition, or that a group of firms of a similar size do not steer the process toward an outcome that is unworkable for those of any other size or configuration.
    c. Identify and recruit members from different-sized entities within an industry or industry sector. Large- and medium-sized entities may have staff that can more easily participate in working groups or be represented by industry trade associations. In some cases, smaller entities including cottage industries may be affected by

the outcomes of the working group but not have been aware of or invited to participate in the working group. Also, smaller entities may not be as likely to belong to trade associations. Including individuals representing entities of a smaller size may help to ensure that the concerns of smaller entities are brought forth and included in the discussion.

d. Create a mechanism or process to let all members, and potentially the public, submit and openly discuss all proposals.

8.2.7. Keeping working group members engaged

This is an issue for on-going working groups. Both industry and the regulatory agencies have limited staff time, and both must make decisions about how much time to commit to efforts like these groups. The regulators, due to their public service mission, may have more flexibility to spend time and energy on these kinds of projects. Industry representatives may have to evaluate how serving on a working group, especially a long-term one, will benefit both the individual company and the industry. If the working group is coordinated out of a regulatory agency, the agency should regularly ask industry if the working group is meeting their needs, so as to keep the private sector at the table and engaged.

8.2.8. Building and maintaining trust among all members

There may be certain topics addressed in working groups that are contentious or require a level of trust to resolve. For contentious issues, it may be advisable to use third-party facilitators without a stake in the outcome to help a working group understand all perspectives and reach consensus. This may be very useful for temporary/ad- hoc groups working on issues like creating a new type of licensed activity or setting fees, and for long-term working groups where there has been a history of poor communication or distrust.

8.3. Issues to Consider During Outbreak Investigations and Crisis Responses

The language below covers two types of crises: The first, where the firm/industry is at the center of an outbreak investigation and potential recall; and the second when the firm/industry is involved in a response to a natural disaster or criminal action.

8.3.1. Outbreak investigations and recalls

The following are considerations for industry-regulatory relations when the crisis is related to an outbreak investigation and recall.

1. **Sharing information during the investigation:** The firm and/or industry is generally very interested in all actions being taken by the regulators and will want to know what steps are being taken and

being planned. In some cases, the firm/industry can be a very useful partner and can act quickly to address the situation, thereby protecting the public health and reducing exposure and their liability.

2. **Balancing multiple interests:** There are often multiple aims and interests among those involved in an outbreak investigation. The regulatory agency may be concerned about taking sufficient time to conduct a thorough investigation. The firm may be concerned about recovering as quickly and inexpensively as possible. Also, in some cases the regulatory agency may be considering penalties against the firm during an investigation and this can lead to a lack of information sharing by both the agency and the firm. Both parties should be aware of the pros and cons when an agency or firm withholds information. For example, a firm may destroy product when they believe their involvement is over, but the regulatory agency may still have need of that product. Or a regulatory agency may have product under seizure or embargo at a firm. The firm may take legal action like suing the agency to try to get the seizure lifted so they could recondition and sell the product. The balance here is between the firm's desire to get rid of implicated product to stop paying storage costs and to try to regain customer trust versus the regulatory agency's desire of having more with which to perform laboratory analyses to best ensure public health.
3. **Describing the process and what to expect:** There can be a lot of confusion during an outbreak or food contamination investigation at a food facility. These investigations can last a long time--several days or even weeks--and require collection of many different types of information. While there are situations when the regulatory personnel cannot predict next steps, often the general framework of the investigatory process is known. Communicating to industry the process and what to expect, when possible, will often improve how well the firm and the regulatory agency work together during an outbreak or crisis. Tools that assist this communication can be developed in working groups, tested in exercises and real-world responses, and then taken back to working groups for additional discussion.

8.3.2. Examples of the kinds of information and tools that can be used:

1. **Guidance documents:** Several federal, academic, and trade organizations have written food safety, HACCP, environmental sampling, and sanitation guidance documents for specific foods and processes.
2. **On-site investigation daily timelines:** Lists of what parts of the investigations are going on that day and how the firm can facilitate these actions. For example, by compiling the records that regulators

will need, or making available the employees a regulator will need to interview that day.

3. **Laboratory analysis timelines:** Turn-around times and information that describe how long different types of laboratory tests take.
4. **Regulatory authority:** Materials that explain the legal basis for actions and the thresholds for action. This helps ensure that regulatory actions are predictable and implemented uniformly.
5. **Discussion of potential outcomes:** What are the possible outcomes and what would be expected actions in each of those outcomes? For example, if food contact surface or finished product samples test positive for a pathogen (outcome), the regulatory authority may expect to issue a Consumer Advisory and recommend that product be recalled.
6. **Describing the process for "appeal":** What if the firm doesn't like what a regulatory agency is doing and vice versa?

8.3.3. All-hazards crisis response

When a firm, industry, or food sector is involved in a crisis response such as a natural disaster or terrorist event, the relationship may be very different because of differences in how enforcement and litigation are considered. However, other contributions are still very relevant, including information sharing, public and risk communication, and coordinated response.

8.4. Issues to Consider for Training and Educational Events or Materials

There is a need for establishing a common understanding of food safety among regulatory agencies and industry and for a common format for providing training and education. There is also a need to develop a consistent means to educate and communicate information to industry and the public.

8.4.1. Seek input from industry and academia

When creating training and educational events or materials, whether for a regulatory audience, an industry audience, or a mixed audience, consider seeking input from industry and academia. These sources may help define training needs and offer expert information. For in-person trainings or workshops, consider having trainers or speakers from a variety of backgrounds. Industry and academic partners can also help advertise the events or circulate published materials.

8.4.2. When joint training is a good idea

Just as the working relationship between two agencies can be improved by having staff members participate in training together, so can the relationship between the private sector and regulatory agencies. While some of the same concerns as noted in the working group issues above

can also exist in a training situation, the dissemination of good information as widely as possible benefits all players within the sector. Further, both sides can benefit from learning the same information through the course material. For state, local, and tribal entities, it can be helpful to host a course developed by a third party, particularly a federal agency or university.

8.4.3. Considerations when posting information to an agency website

As noted above, each jurisdiction has its own requirements under open records and disclosure laws, which can impact what an agency may have on its website. In some jurisdictions, there are prohibitions on content or links to private sector information or entities to avoid any suggestion of bias. Other jurisdictions routinely share content developed by the private sector on their websites and through social media as a means of disseminating information, particularly on recalls initiated by the private sector itself. Check with your public information officer and counsel for additional information about online posting of information.

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

Level	Description
1	Little or no engagement with the industry
2	Medium engagement with the industry
3	High degree of engagement with the industry

9.2. Process Overview

Use the descriptions of the levels below to help assess an agency's level of engagement. The heads of organizations have a strong influence on the tone and expectations for industry-regulatory partnerships. Therefore, it is important to re-assess the engagement level as leadership at the state and local levels change through elections and other departures and agency perspectives on engagement may vary. For additional resources, refer to Working with Other Agencies chapter of the RRT Best Practices Manual.

9.2.1. Level 1: Little or no engagement with the industry

The regulatory agency does not attend industry conferences or trade shows; the agency gets bills sponsored in the legislative body that have not been shared with the industry; there is a food protection task force but it does not contain representatives from the private sector; there are no or very few working groups with public and private sector representation.

9.2.2. Level 2: Medium engagement with the industry

The regulatory agency's staff occasionally attends industry conferences or trade shows; the agency tells the industry when they get bills sponsored in the legislative body; the food protection task force includes some representatives from the private sector but not many attend; there are some working groups with public and private sector representation.

9.2.3. **Level 3**: **High degree of engagement with the industry**
The regulatory agency's staff attends industry conferences or trade shows and is asked to present or speak; the agency forms working groups that include industry to work on proposed legislation before approaching the legislative body; there is a food protection task force that includes many members from the private sector and many attend; there are many working groups with public and private sector representation.

10. RELATED DOCUMENTS

Related RRT Best Practices Manual Chapters, Topics, and References:

10.1. Working with Other Agencies
10.2. Communication Standard Operation Procedures (SOPs)
10.3. Recalls
10.4. Tracebacks
10.5. Environmental Sampling
10.6. Training
10.7. Joint Inspections & Investigations

11. REFERENCES AND OTHER RESOURCES

N/A

12. ATTACHMENTS

N/A

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	7/16/2012	RRT Industry Relations WG (MN**, MI, VA)
1.1	R	1/24/2013	ORA/OP
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**Workgroup Lead

Change History

1.1 – Minor editorial revisions to achievement level for clarification purposes.
1.2 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.

Planning and Preparedness (Response-Wide Capabilities)

Chapter 4. Exercises: Planning, Implementation and Evaluation

TABLE OF CONTENTS

1. PURPOSE

Even the simplest exercise takes significant time and research, especially when you are not familiar with planning and developing exercises. This process can be even more arduous when trying to develop an exercise focusing on a non-traditional aspect of human and animal food safety or defense, and often human and animal food regulatory programs do not have access to the same array of resources, experience and expertise as other emergency sectors that are more familiar with exercises (e.g., fire, police, hazmat, forestry services, etc.). It can be quite challenging even if you obtain the help of a planner/facilitator.

Well designed and executed exercises are the most effective means of:

- Assessing and validating Rapid Response Team (RRT) policies, plans, procedures, training, equipment, and interagency agreements;

- Clarifying roles and responsibilities;
- Improving interagency coordination and communications;
- Identifying gaps in resources; and
- Measuring performance and identifying opportunities for improvement.

This chapter provides best practices for exercise planning, the process for scenario development, and implementation of exercises focused on RRT plans, processes and procedures. While other aspects of exercises may be covered, the **main focus will be on the planning, design, implementation, and evaluation of RRT exercises**. The best practices included in this chapter are largely based on the Homeland Security Exercise and Evaluation Program (HSEEP), as well as the collective experience and knowledge of RRTs. As such, the content is geared towards a fully mature RRT (in Phase 3 of the RRT Capacity Building Process). We encourage you no matter your level to take the references and examples found within the document to help you develop exercises for your RRT.

Below are key elements included in this chapter:

1. Resources and best practices for scenario development and exercise planning:
   a. Pre-packaged exercise options; best practices for modifying pre-packaged exercises
   b. Identifying clear objectives and end goals; what aspect do you specifically want to test by this exercise (e.g., communication; gathering of Subject Matter Experts (SMEs); Incident Command System (ICS) roles/responsibilities, etc.)
   c. Considering incorporation of other elements into your exercise
      i. Use of Emergency Operations Center or Department Operating Center
      ii. Use of the tracking/assignment systems
2. Establishing exercise logistics
3. List of acronyms commonly encountered in exercises
4. Training and exercise Plan

2. SCOPE

This chapter focuses on exercise planning, design, implementation, and evaluation. These concepts are building blocks that may incorporate a training and exercise plan and will facilitate exercise design, implementation and evaluation:

- **Defining Roles and Responsibilities for Exercise Implementation:** Identifies exercise roles and responsibilities for planners, facilitators, controllers, evaluators, actors and players.
- **Building Your Exercise Planning Team:** Describes best practices to build an exercise planning team.
- **Exercise Implementation**: Describes best practices and tools to conduct and/or implement a discussion based or functional exercise.
- **Exercise Evaluation:** Describes roles and responsibilities, procedures and mechanisms to perform exercise evaluations. To be most effective this should be incorporated into the planning process and a Lead Evaluator should be identified to ensure that the evaluation components are captured during the exercise design.

The best practices described in this chapter identify key areas and elements for each of these concepts (exercise planning, design, implementation, and evaluation), but are neither comprehensive nor specific to unique situations. State, local, and federal agencies seeking to improve multi-agency food emergency responses (e.g., States, FDA field offices) may utilize this chapter to assess and improve their exercise planning, conduct and design, and evaluation capabilities. Agencies with varying responsibilities (e.g., human and animal food regulatory, public health, animal health, law enforcement, and laboratory) and achievement levels may differ in how they customize and apply these best practices.

The Exercise Best Practice Working Group supports existing exercise planning guidance documentation: HSEEP 2013 guidance can be found by using the link below.
http://www.fema.gov/media-library-data/20130726-1914-25045-8890/hseep_apr13_.pdf

FREE-B exercise documentation can be found by using the link below.
https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295902.htm

3. RESPONSIBILITY

3.1. Exercise Planner

Exercise planner responsibilities include defining the Planning team members/workgroup and exercise participants (all individuals involved in the exercise).

Training should be provided to all exercise participants prior to the start of the exercise. For exercise players, the exact training required will depend on the exercise scenario and objectives. For example, if the exercise focuses on RRT Activation procedures, then all players should have completed appropriate ICS training for the role(s) they will play in the exercise and be familiar with RRT Activation protocols or other applicable procedures. This also includes letting exercise players know what response procedures they may need to reference during the exercise. We strongly encourage exercise implementation members (facilitators, observers, actors, controllers, evaluators, etc.) to participate in role-specific training or instructions, and review SOP or Guidance documentation in advance of the exercise, in order to best familiarize themselves with the plans, policies, and procedures of the players who will be performing these duties during the exercise.

3.2. Facilitators

Persons responsible for leading or coordinating the work of a group. Responsible for leading discussions, mediating topic points and keeping the exercise moving forward.

3.3. Observers

Non-participants responsible for testing exercise criteria; views exercise implementation and can provide valuable input during the hotwash sessions.

3.4. Actors
Participants in an action or process. Portrays a role in the scenario to simulate realism.

3.5. Players
Persons who will be participating in the exercise to assess and validate policies, plans, procedures, training, equipment, and interagency agreements

3.6. Controllers
Persons who administer injects from the Master Scenario Event List (MSEL) and ensure the exercise time scheduled is followed. The scope of the exercise will determine the number of controllers needed.

3.7. Evaluators
Persons who evaluate the actions of the players, decision making touchpoints, review if the players are following their plans, policies and procedures through observation or direct questioning of exercise players. They also participate in planning for exercise evaluation criteria.

4. DEFINITIONS

4.1. Exercise Types – The following terms are used in this chapter. Full definitions/descriptions of these terms can be found in the April 2013 Homeland Security Exercise and Evaluation Program (HSEEP), See Section 2, Exercise Program Management, Discussion-Based Exercises and Operations-Based Exercises (https://www.fema.gov/media-library-data/20130726-1914-25045-8890/hseep_apr13_.pdf).

4.1.1. Discussion-Based Exercises
Discussion-based exercises can be used to familiarize players with, or develop new, plans, policies, agreements, and procedures. Discussion-based exercises focus on strategic, policy-oriented issues.

- Seminar
- Workshop
- Tabletop Exercise (TTX)
- Games

4.1.2. Operational-Based Exercises – Operations-based exercises are characterized by actual reaction to an exercise scenario, such as initiating communications or mobilizing personnel and resources.

- Drills
- Functional Exercises (FEs)

- Full Scale Exercises (FSEs)

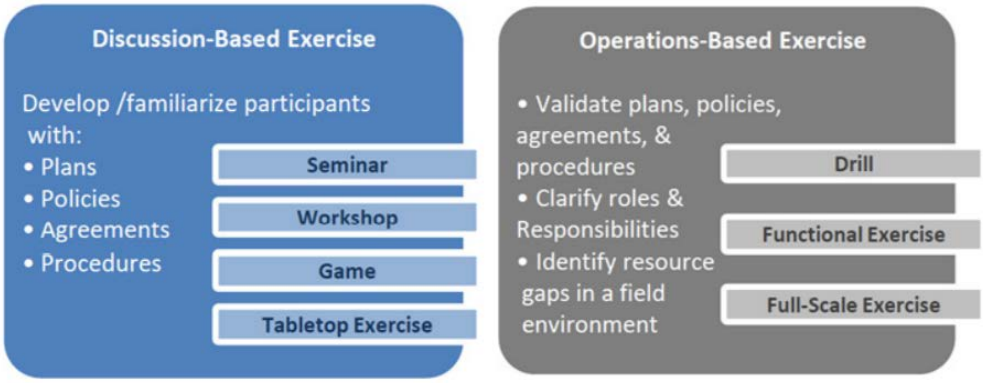

Diagram taken from the EPA "How to Develop a Multi-Year Training and Exercise Plan"

5. BACKGROUND

Conducting exercises is a critical part of preparedness and response planning. Exercises may be conducted to evaluate operational plans/procedures, clarify roles, improve coordination, and find gaps or identify opportunities for improvement. They may also be used to improve teamwork or individual performance prior to responding to an incident or to prepare for non-routine incident response. Ideally, exercises should be conducted using a building block approach that increases in complexity (e.g., starting with conducting a drill or tabletop exercise and building up to a functional or full scale exercise to fully test plans/procedures and overall response capacity).

The way exercises are conducted can vary widely based on the needs of an RRT. The Exercises chapter will focus on using the best practice or Homeland Security Exercise and Evaluation Program (HSEEP) approach. Although this is the best practice for conducting an exercise it also takes the most time to plan and conduct, which may be challenging to some RRTs based on available time and resources. Exercises should be planned to meet the needs of the RRT and test plans, procedures and staff. No matter what type or scale of exercise is conducted, an improvement plan should be developed and improvements tracked as part of the RRT's continuous improvement process. Some smaller scale exercise examples are provided in the chapter attachments (G-I) to go along with the HSEEP recommendations described in this chapter.

6. SAFETY

Exercise Director, Planners, and Controllers are responsible for ensuring safety of all exercise participants (all roles) throughout the planning, design, implementation and evaluation phases. Depending on the nature of the exercise, exercise planners may need to specifically designate someone as responsible for addressing safety issues or concerns during exercise implementation. Some items to include when addressing safety include:

- Develop the ground rules and safety provisions of the exercise
- Review safety items during the briefings (discuss with planning team to ensure it is covered)
- Rally Point (make sure you have a sign-in sheet at your exercise; this is important for when you need to account for participants at the rally point — you may not always know your exercise participants in advance, or be able to rely solely on pre-registration data)
- Water (ensure proper hydration during exercises and drills)
- Food (ensure food purchases follow agency per diem purchasing requirements)

7. EQUIPMENT/MATERIALS

7.1. Exercise Documentation

7.1.1. Exercise Plan (ExPlan):

ExPlans are general information documents that help operations-based exercises run smoothly by providing participants with a synopsis of the exercise. They are published and distributed to the participating organizations following development of most of the critical elements of the exercise. In addition to addressing exercise objectives and scope, ExPlans assign activities and responsibilities for exercise planning, conduct, and evaluation. The ExPlan is intended to be seen by the exercise players and observers; therefore, it does not contain detailed scenario information that may reduce the realism of the exercise. Players and observers should review all elements of the ExPlan prior to exercise participation.

An ExPlan typically contains the following sections:

1. Exercise scope, objectives, and core capabilities
2. Participant roles and responsibilities
3. Rules of conduct
4. Safety issues, notably real emergency codes and phrases, safety
5. controller responsibilities, prohibited activities, and weapons policies
6. Logistics
7. Security of and access to the exercise site
8. Communications (e.g., radio frequencies or channels)
9. Duration, date, and time of exercise and schedule of events
    a. Maps and directions

7.1.2. Controller and Evaluator (C/E) Handbook

The C/E Handbook describes the roles and responsibilities of exercise controllers and evaluators and the procedures they should follow.

Because the C/E Handbook contains information about the scenario AND about exercise administration, **it is distributed to only those individuals designated as controllers or evaluators.**

The C/E Handbook may supplement the ExPlan or be a standalone document. When used as a supplement, it points readers to the ExPlan for more general exercise information, such as participant lists, activity schedules, required briefings, and the roles and responsibilities of specific participants. Used as a standalone document, it should include the basic information contained in the ExPlan, and detailed scenario information.

A **C/E Handbook** usually contains the following sections:

1. Assignments, roles, and responsibilities of group or individual controllers and evaluators
2. Detailed scenario information
3. Exercise safety plan
4. Controller communications plan (e.g., a phone list, a call-down tree etc.)
5. Evaluation instructions

7.1.3. Master Scenario Events List (MSEL)

1. A MSEL is typically used during operations-based or complex discussion-based exercises and contains a chronological listing of the events that drive exercise play.

   Each **MSEL** entry should contain the following at a minimum:

   a. Designated scenario time
   b. Event synopsis
   c. Controller responsible for delivering the inject, with controller or evaluator special instructions (if applicable)
   d. Intended player (i.e., agency or individual player for whom the MSEL event is intended)
   e. Expected participant response (i.e., player response expected upon inject delivery)
   f. Objective, core capability, capability target, and/or critical task to be addressed (if applicable)
   g. Notes section (for controllers and evaluators to track actual events against those listed in the MSEL, with special instructions for individual controllers and evaluators)

   Scenario timelines listed in a MSEL should be as realistic as possible and based on input from SMEs. If the activity occurs sooner than the MSEL writers anticipated, then controllers and evaluators should note the time it occurred, but **play should not be interrupted.**

Controllers delivering MSEL injects will either be co-located with players in the venue of play, or they will reside in a **SimCell[1].**

Prior to Start of Exercise (StartEx), the mechanisms for introducing injects into exercise play should be tested to ensure that controllers are aware of the procedures for delivering MSEL injects and that any systems that will be used to deliver them are functioning properly.

2. The **three types of descriptive MSEL events** that support exercise play include:
   a. **Contextual injects** introduced to a player by a controller help build the exercise operating environment and/or keep the exercise play moving. For example, if the exercise is designed to test information-sharing capabilities, a MSEL inject can be developed to direct an actor to portray a suspect by behaving suspiciously in front of a law enforcement player.
   b. **Expected action events** reserve a place in the MSEL timeline and notify controllers when a response action would typically take place. For example, during an FSE involving a chemical agent, establishing decontamination is an expected action that the players will take without the prompting of an inject.
   c. **Contingency injects** are provided by a controller or simulator to players to ensure play moves forward to adequately evaluate performance of activities. For example, if a simulated secondary device is placed at an incident scene during a terrorism response exercise, but is not discovered, a controller may want to prompt an actor to approach a player and state that he or she witnessed suspicious activity close to the device location. This should prompt the responder to discover the device, resulting in subsequent execution of the desired notification procedures.

7.1.4. Exercise Evaluation Guides (EEGs)

EEGs are intended to help evaluators collect relevant exercise observations. These documents are aligned to objectives, and document the related core capability, capability target(s), and critical tasks. Each EEG provides evaluators with information on what they should expect to see demonstrated or hear discussed.

7.1.5. Participant Feedback Form

[1] A location from which controllers deliver messages representing actions, activities, and conversations of an individual, agency, or organization that is not participating in the exercise but would likely be actively involved during a real incident.

At the end of an exercise, participants may receive a Participant Feedback Form that asks for input regarding observed strengths and areas for improvement that players identified during the exercise. Providing Participant Feedback Forms to players during the exercise wrap up activities allows them to provide their insights into decisions made and actions taken. A Participant Feedback Form also provides players the opportunity to provide constructive criticism about the design, control, or logistics of the exercise to help enhance the planning of future exercises.

At a minimum, the questions on the Participant Feedback Form solicit the following: **Strengths and areas for improvement** pertaining to the implementation of participating agencies and organizations' policies, plans, and SOPs; and **Impressions** about exercise conduct and logistics.

Information collected from feedback forms contributes to the issues, observations, recommendations, and corrective actions in the AAR/IP. Feedback forms can be supplemented by conducting a hotwash immediately following the exercise, during which facilitators, controllers, and evaluators capture participant perspectives on the key strengths and areas for improvement identified during the exercise.

7.2. Exercise Materials

Exercise materials needed on EXERCISE DAY are an integral part of exercise implementation. See Attachment A for a checklist of items for consideration.

8. PROCESS DESCRIPTION

8.1. Building Your Exercise Team

Establishing your planning team is one of the most critical roles in building a successful exercise. You need to select people with the subject matter expertise to aid in crafting an exercise scenario and an understanding of participating agency's plans, policies and procedures, to include players' functional roles and responsibilities. Identify and select team members based on these criteria. It is also helpful to select individuals from each of the participating agencies to provide this subject matter expertise. The more agencies (how many agencies/multi-state endeavor) you have participating in the exercise, the more people you may need to consider consulting with for subject matter expertise that will contribute to exercise planning and implementation. Trying to find a healthy balance of planning team members is important. It is recommended to limit the number of persons on the planning team for efficiency and effective decision-making.

It is highly recommended that you have the Lead Evaluator identified and involved at planning meetings and exercise documentation development as it helps to identify and craft evaluation criteria that will be performed by the Evaluators at the exercise.

It is preferable that the people selected to participate on the planning team are not going to participate as players. You cannot effectively respond to the exercise scenario when you know the concept of play (exercise conditions); in other words, you are not responding as you would in real life as you have "prepared" your responses. Therefore, it is highly recommended that someone else be identified to perform in a PLAYER role.

Determining the exercise type, level of play and exercise objectives helps to determine the number of exercise planners and support persons. Establishing a Lead Evaluator as part of the Planning team is recommended.

Table of Planning Team Member Roles

Role	Exercise Skills	Exercise Tools
Exercise Director	Primary point of contact (POC) and has full responsibility and authority to ensure exercise objectives are met, align with agency priorities, and exercise implementation is completed. This may include budgetary accountability (financial responsibility), signatory for contractual agreements with contractors (exercise design and/or evaluation), project timeline development, and final approval (can be verbal) on work documents for exercise play. This individual needs to be a team builder with good communication and project management skills.	
Lead Facilitator	Identify how many facilitators that you need: Lead Facilitator for primary sessions; and/or teleconference communications Facilitator identified for each room Are there multiple break out rooms? If so, establish one for each location. Facilitator identified per table: Important to have a realistic player count to ensure you have enough facilitators for each table with the subject matter expertise to provide the feedback/answer any questions to help the table reach the required objectives/work assignment goals). Facilitator skill set(s) include: Subject matter expertise related to exercise scope and objectives Excellent communication skills Mediation skills Able to break the ice and provide fillers if a speaker shows up late/technology breaks down Non-judgmental and unbiased; optimistic Ability to develop and elicit responses from players Mediation skills: **Identify WHO will handle heated debates.** It is important to handle this in advance: The exercise area is supposed to be	Handouts/Reference Materials White Boards, Flip Charts, Notecards Audio-Visual Aides/Equipment: important to test these in advance of exercise start time to ensure that they are functioning correctly. PowerPoint Projector/Screen Conference Call Line/Dial in number is correct and functions Speakers/microphones Video conferencing capabilities functioning Equipment technician available to assist with malfunctions.

Role	Exercise Skills	Exercise Tools
	safe zone where all input is welcome and considered; however sometimes discussion/debates can get out of hand. You need someone identified (can be Lead Facilitator and/or Exercise Director) who can help diffuse the situation and address it in a professional non-combative manner. This concept of "safe zone" is to be brought up at the beginning of the actual exercise.	
Lead Controller/ Evaluator	Identify how many controllers and evaluators that you need: Controller identified for each room Are there multiple break out rooms? If so, establish one for each location. Review Controller Expectations with participants It is important to develop exercise evaluation requirements early in the design process, as they will guide development of the exercise scenario, discussion questions, and/or MSEL. Evaluation requirements clearly articulate what will be evaluated during the exercise and how exercise play will be assessed. This information is documented in the Exercise Evaluation Guides (EEGs).	Handouts/Reference Materials: C/E Handbook, MSEL, Inject Notecards for distribution Evaluation tools include exercise evaluation forms, like Exercise Evaluation Guides (EEGs), Checklists, Agency SOPs, Guidance documents, etc., that will be utilized by the evaluators to evaluate the exercise. Good ratio of personnel to operate SimCell to ensure all injects are delivered and tracked according to MSEL Clipboard for taking notes **Inject Tracking Device (whiteboard, electronic, etc.)**

8.2. Establish Expectations Regarding Time Commitment

It is important to relay understanding to all parties that developing an exercise is an intensive time commitment on the behalf of the planning committee members. Serious consideration should be given to accepting this role and responsibility. There is an expectation that all parties will devote the necessary time and provide subject matter expertise in the agreed upon exercise planning, conduct and evaluation roles. Keep in mind that timeframes depend on the type of exercise being conducted (e.g., a TTX requires much less time than a full scale exercise).

There are several meetings held to effectively develop an exercise, it is important to designate someone to take notes/minutes during the meetings:

8.2.1. Initial Planning Meeting (IPM) (see Attachment E for example).

The Lead Planner for the exercise coordinates the IPM. The purpose of the IPM is to (1) determine exercise scope by establishing the intent and direction from RRT partner agencies, and gathering input from the exercise planning team; and (2) identify exercise design requirements and conditions (e.g., assumptions and artificialities), exercise objectives, participant extent of play, and scenario variables (e.g., time, location, hazard selection). The IPM is also used to develop exercise documentation by obtaining the planning team's input on exercise location, schedule, duration, and other relevant details.

During the IPM, exercise planning team members are assigned responsibility for activities associated with designing and developing exercise documents, such as the Exercise Plan (ExPlan) and the Situation Manual (SitMan), and coordinating exercise logistics.

Items to be discussed by the Planning Team at the IPM include:

- Agreement regarding exercise concept (scope, type, mission area(s), exercise program priorities to be addressed), exercise objectives, and aligned core capabilities
- Consensus on the target exercise timeframe: When selecting the exercise duration, the planning team should determine how long it will take to address the exercise objectives effectively. Discussion-based exercises and some drills are generally shorter, ranging from a couple of hours to a full day. Functional Exercises (FEs) and Full Scale Exercises (FSEs) may take longer.
- Anticipated extent of participation
- Identification of exercise planning team members
- Exercise planning timeline with milestones, including the date of the next planning meeting
- Identification of the intended players/participants for this exercise and their associated role(s)
- Exercise setting: virtual, face-to-face, or a combination of both
- Specific requirements for the exercise venue
- Potential need to develop a back-up plan in the event of bad weather or other unforeseen emergency/circumstances. This could include identification of an alternate/back-up venue, methods for notifying/communicating with participants, and dates for postponing or rescheduling the exercise, if needed.
- Possible trainings that may be offered in conjunction with the exercise (as part of exercise objectives) or need to be offered prior to the exercise (training on specific procedures or tasks that are being evaluated as part of the exercise).

Key concepts that should be a point of discussion at the Initial Planning Meeting (IPM) to ensure you have all the necessary subject matter experts to help craft your exercise are:

- Clearly defined exercise objectives and aligned core capabilities
- Evaluation requirements, including Exercise Evaluation Guide(s) (EEG) capability targets and critical tasks
- Relevant plans, policies, and procedures to be tested in the exercise
- Exercise scenario and modules
- Modeling and simulation planning

- Materials list for facilitators, observers, participants, evaluators, etc. (may grow as planning continues). See Attachment A for an example list.
- Extent of play for each participating organization
- Optimum duration of the exercise
- Exercise planners' roles and responsibilities
- Local issues, concerns, or sensitivities
- Responsibilities assigned to workgroup members such as responsibility to create the Situation Manual or the PowerPoint presentations, etc.
- Hotwash and After Action Report (AAR) with Improvement Plan (IP) – Decide on format and parameters that will be used. May add specific questions based on your exercise. Decide who is responsible for the completion of these documents.
- Consensus regarding the date, time, and location for the next meeting
- Contractors – Discussion should take place if you want the services of a contractor to perform planning and exercise conduct duties.
- Contractors' duties and responsibilities should be spelled out in a Statement of Work or Scope of Work (SOW). This will largely depend on what the sponsoring agency decides to do themselves versus what they would like the contractor to do (documented in SOW). This may include the following information or expectations:
  - Project cycle begin and end dates
  - Identification of venue for conducting the exercise, including deadlines for securing the venue
  - Schedule planning calls
  - Develop meeting minutes and track action items from planning calls
  - Expectations for printing of exercise materials
  - Specify that all products should be provided to the exercise lead upon completion of project in electronic format
  - Documents the contractor is responsible for may include:
    i. Exercise plan/Situation manual
    ii. Controller and Evaluator handbook
    iii. Master scenario and Events List
    iv. Exercise evaluation forms
    v. Participant feedback forms
    vi. After Action Report
    vii. Hotwash minutes/notes
    viii. Summary of findings
    ix. Improvement plan
- When defining a SOW, spell out contents of work performance and associated deliverables. Have costs itemized for deliverables,

meetings, etc. with total contracted costs. Consult with other RRT exercise designers on additional items to consider.

- Participant travel costs should be written into the SOW if the contract is expected to cover the cost.

8.2.2. Mid-Term Planning Meeting(s) (MPM) provide an additional opportunity to settle logistical and organizational issues that may arise during exercise planning and track progress to date. MPM tools include, but are not limited to: An agenda, IPM minutes, draft scenario timeline, draft documentation (e.g., ExPlan, C/E Handbook), and other selected documentation needed to illustrate exercise concepts and provide planning guidance. Discuss who will be acquiring and assembling all supplies needed for the exercise.

Providing hard copies of exercise documents and materials is the responsibility of the Exercise Director, Lead Planner and the Lead Evaluator. Discussion regarding these items should be addressed during MPMs. Discussion should include printing and distribution to ensure the materials arrive at the exercise venue in a timely manner. If a contractor will be printing all the exercise materials the deadline and expense should be written into their SOW.

It is important to note that several mid-term level planning meetings may occur during the exercise design phase. Sub-Committee meetings (ancillary meetings) with subject matter experts can/should occur to arrive at fine tuning documents, performing required research, procedural clarifications, etc., to help achieve desired outcomes. The results of such meetings will be brought out at the next scheduled mid-term planning meeting.

The following outcomes are expected from the MPM:

- Fully reviewed SitMan or ExPlan
- Draft Facilitator Guide or C/E Handbook, including EEGs
- A fully reviewed exercise scenario timeline, which is typically the Master Scenario Event List (MSEL) (if an additional MSEL Meeting will not be held)
- Well-developed scenario injects (imperative if an additional MSEL Planning Meeting is not scheduled)
- Confirm the exercise site and modes of communication with other sites/locations if needed
- Finalization of date, time, and location of the MSEL Planning Meeting and/or Final Planning Meeting (FPM)
- Exercise documentation (work products), may include evaluation criteria

8.2.3. Final Planning Meeting (FPM): A FPM should be conducted for all exercises to ensure that all elements of the exercise are ready for implementation. Prior to the FPM, the exercise planning team receives final drafts of all exercise materials. **No major changes to the exercise's design, scope, or supporting documentation should take place at or following the FPM**. The FPM ensures that all logistical requirements have been met, outstanding issues have been identified and resolved, and exercise products are ready for printing.

The following items are addressed during the FPM:

- Conduct a comprehensive, final review and approve all remaining draft exercise documents (e.g., SitMan, MSEL, C/E Handbook, EEGs) and presentation materials.
- Resolve any open exercise planning issues and identify last-minute concerns.
- Review all exercise logistical activities (e.g., schedule, registration, attire, special needs).

Once planning members and Exercise Director have given final approval to all exercise documentation at the FPM, **there will be no additional changes to any work products on exercise day**. **Ensure that someone is responsible for any outstanding tasks that still need to be completed and a deadline is associated with each task.**

8.2.4. Documentation: Anticipate and plan for the time needed to finalize all the exercise documentation, including who will be responsible for creating this documentation (e.g., contractor, exercise planner). For complex, HSEEP-compliant exercises, this may take 5-15 days, but could take more or less time depending on the scale of the exercise.

8.2.5. Venue Selection (paid vs. unpaid)

Recommend booking the venue (paid or unpaid) at least 3-6 months in advance of the exercise dates. Some venues may need to be booked a year or more in advance.

Unpaid-minimal time involved (just securing location reservation). Notify site location coordinator in timely fashion for unpaid venues so that you can book the site, free venues tend to get booked quickly.

Paid venues: expect at least 30 days and possibly longer depending on the procurement process used by the funding agency/organization, to solidify agreement (includes contract negotiations and signatures per established agency guidelines). Expect that a contractor will be able to

execute this more quickly than a government agency. If tasked to a contractor, it is recommended that a deadline for securing a venue be included in the SOW.

It is necessary for a facility walkthrough at all venue sites before committing to ensure it has all the logistical requirements to perform exercise/training, such as adequate seating arrangements, audio/visual equipment, phone conference line if needed, break out rooms are available if needed, etc.

Important to clean-up site after exercise at all venues (increases likelihood of being able to use the venue again). Leave it better than you found it!

8.2.6. Hotwash and After Action Report (AAR) with Improvement Plan

The hotwash should occur immediately following the exercise/event. Hotwash and debriefings should occur at every site location and with each exercise participant providing feedback. Ask for general feedback and specific questions based on your exercise goals and objectives.

Plan on taking approximately 30 days to complete the AAR documentation, and realize it can take longer when drafting and finalizing the AAR involves multiple agencies. Decide on format and parameters that will be used. Decide who is responsible for the completion of these documents.

8.3. The 8 Steps of the Exercise Planning Cycle (Exercise Design and Development)

This section describes the Exercise Planning Cycle, exercise design, and development. The exercise planning team members decide the type and number of planning activities needed to successfully plan a given exercise, based on its scope and complexity. When arranging meeting and exercise site locations, the planning team should take into consideration those individuals who require assistance or accommodations during attendance.

The exercise planning meetings serve as the principal mechanism for executing the major steps of exercise design. The eight core components of design include creating a needs assessment, establishing the scope of the exercise, creating the purpose of the exercise, setting exercise objectives, creating an exercise scenario/narrative, developing major/minor events, developing expected actions, and creating messages. Association items that accompany this process include exercise documentation and evaluation criteria.

The culmination of the 8 Steps of Exercise Design helps to develop the exercise goals, objectives, and setting the stage of exercise play by providing a formalized

structure and methodology for implementation. This information is then translated into the development of exercise documentation for players and exercise conduct members.

8.3.1. Needs Assessment (Creating Exercise Purpose)

An exercise is an instrument to train for, assess, practice, and improve performance in prevention, protection, mitigation, response, and recovery capabilities in a risk-free environment. Exercises can be used for testing and validating policies, plans, procedures, training, equipment, and interagency agreements; clarifying and training personnel in roles and responsibilities; improving interagency coordination and communications; improving individual performance; identifying gaps in resources; and identifying opportunities for improvement. Determining your needs and creating your exercise purpose is the first step.

8.3.2. Defining Exercise Scope

Scope is an indicator of extent of the exercise. The key elements in defining exercise scope include exercise type, participation level, exercise duration, exercise location, and exercise parameters. Determining exercise scope enables planners to "right-size" an exercise to meet the objectives while staying within the resource and personnel constraints of the exercising organizations. Defining the number of functions to be exercise and/or the depth to which the functions are examined (e.g., Prevention and control and/or containment) are additional items to consider.

Some of these elements are determined, or initially discussed, through program management activities or grant requirements. However, the exercise planning team finalizes the scope based on the exercise objectives. Alterations to the scope are reviewed with the exercise objectives in mind; planners must consider whether a change in the scope will improve or impede the ability of players to meet the objectives.

To this end, it is recommended that planners consider the unique benefits of holding the exercise in either a virtual or face-to-face setting. A virtually based exercise may promote everyday realism with participants located at their normal duty stations, but may lack casual networking and communication opportunities among the participants.

8.3.3. Creating Clear Objectives/End Goals

Based on direction from applicable agency officials, program management, and grant requirements the exercise planning team selects one or more exercise program priorities on which to focus an individual

exercise. These priorities drive the development of exercise objectives, which are distinct outcomes that an organization wishes to achieve during an exercise. Exercise objectives should incorporate applicable agency officials, program management, and grant requirements intent and guidance, and exercise participants' plans and procedures, operating environment, and desired outcomes. Generally, planners should select a reasonable number of specific, measurable, achievable, relevant, and time-bound (SMART) exercise objectives to facilitate effective scenario design, exercise conduct, and evaluation.

Objectives are the distinct outcomes an organization wishes to achieve during an individual exercise. Objectives should reflect the specific needs, environment, plans, and procedures of the sponsoring agency/program, while providing a framework for scenario development and a basis for evaluation. Planners should create objectives that are SMART and should limit the number of exercise objectives to enable timely exercise conduct, facilitate reasonable scenario design, and support successful evaluation.

The table below depicts guidelines for developing SMART objectives.

SMART Guidelines for Exercise Objectives	
Specific	Objectives should address the five Ws- who, what, when, where, and why. The objective specifies what needs to be done with a timeline for completion.
Measurable	Objectives should include numeric or descriptive measures that define quantity, quality, cost, etc. Their focus should be on observable actions and outcomes.
Achievable	Objectives should be within the control, influence, and resources of exercise play and participant actions.
Relevant	Objectives should be instrumental to the mission of the organization and link to its goals or strategic intent.
Time-bound	A specified and reasonable timeframe should be incorporated into all objectives.

The Target Capabilities List (TCL) defines and provides the basis for assessing preparedness. It also establishes national guidance for preparing the Nation for major all-hazards events, such as those defined by the National Planning Scenarios. The TCLs serve as a framework to guide operational readiness planning, priority-setting, and program implementation at all levels of government.

The target capabilities list can be found here[2].

8.3.4. Training and Exercise Planning Workshop (TEPW)

[2] http://www.fema.gov/pdf/government/training/tcl.pdf

A TEPW should be a coordinated effort attended by RRT member agencies and should be conducted on an annual or recurring basis to address training needs and requirements.

An exercise program should be based on a set of strategic, high-level priorities selected by applicable agency officials, program management, and grant requirements These priorities guide the development of exercise objectives, ensuring that individual exercises build and sustain preparedness in a progressive and coordinated fashion. Exercise program priorities are developed at the Training and Exercise Planning Workshop.

The purpose of the TEPW is to use the guidance provided by applicable agency officials, program management, and grant requirements to identify and set exercise program priorities and develop a multi-year schedule of exercise events and supporting training activities to meet those priorities.

The following table outlines items for consideration at the TEPW (FEMA TEPW Presentation 2017 found on the www.preptoolkit.org).

A training and exercise plan is developed at the TEPW. A progressive, multi-year exercise program enables organizations to participate in a series of increasingly complex exercises, with each successive exercise building upon the previous one until mastery is achieved. Regardless of exercise type, each exercise within the progressive series is linked to a set of common RRT program priorities and designed to test associated capabilities. A link to the FEMA TEPW User's Handbooks is: https://training.fema.gov/programs/emischool/el361toolkit/assets/tepw

_users_handbook.pdf. The Homeland Security TEPW User Guide is: https://www.hsdl.org/?view&did=778041

8.3.5. Narrative

Developing your exercise narrative helps to set the stage for exercise play; it also helps to prompt player's action implementation and response. When developing the narrative, planners should try to bring as much realism into the scenario as possible to encourage and help facilitate player response.

8.3.6. Major/Minor Events

When building the scenario, it is also important to develop major and minor events to help set the stage and continue the development of exercise play. These events should prompt triggers for player actions, responses, or expected results. (e.g., finding *Listeria monocytogenes* in a frozen food product is the major event to set off exercise play; minor events would then be the investigation, laboratory results, recall, etc.).

8.3.7. Expected Actions

Expected actions are used in functional based exercises to define what the C/E should be expecting from the players based upon the injects provided. Expected actions spell out the response item that is covered in the policies, procedures, and or guidance material being exercised (e.g., NIMS, Environmental Sampling, Communications, etc.). Examples of expected actions include: "RRT PIO will ensure accurate and timely messaging to the community and the media;" or "RRT will coordinate with lab manager and/or request resources to meet needs of sampling response."

8.3.8. Messages

Messages are crafted by the planners and can come in the form of handwritten notes, press releases or other written communications that are utilized in plans, policies, and procedures. They can also be presented in the form of a press briefing by the PIO and/or a pre-recorded or live television presentation.

8.4. Exercise Evaluation

Exercise evaluation helps capture and describe what went well and what problems occurred during an exercise. Examining and recording what went well validates plans, systems and training. By gathering information about responses to an exercise, evaluation also helps participants learn what, how and where responses could improve.

Exercise evaluation begins early in the exercise design process. Exercise designers should always be thinking about how an exercise will test response plans and capabilities and how that can be measured. If possible, a lead evaluator should be appointed to assure that evaluation is considered throughout the exercise design process. A lead evaluator can work to develop tools and materials to assist and guide the evaluation team, such as an evaluation plan and exercise evaluation guides (EEGs).

8.4.1. Exercise Evaluation Tools and Options

- **Exercise Evaluation Guides (EEGs)** include evaluator notes and observations.
- **Hotwash:** An opportunity for all participants to voice their opinions on the exercise and lessons learned. It is helpful to list objectives and or remind participants of exercise objectives when soliciting input. A hotwash is typically held immediately following an exercise. An after action review is largely the same as a hotwash, only it may be conducted later. An after action review is more commonly held after a real-life incident, since it is unlikely that all responders are co-located and able to do a hotwash immediately upon the conclusion of the incident response.
- **Participant Feedback Form:** Provided at the end of an exercise, this form asks for input regarding observed strengths and areas for improvement that players identified during the exercise. It also provides players the opportunity to provide constructive criticism about the design, control, or logistics of the exercise to help enhance the planning of future exercises.
- **Personal Learning Inventory/action items sheet:** A document for exercise participant to notate action items or areas for improvement that they can take back to their agency or organization for implementation**.**
- **Debriefing**: A more formal forum for planners, facilitators, controllers, and evaluators to review and provide feedback on the exercise. It may be held immediately after or within a few days following the exercise.
- **After Action Report (AAR):** A document that is a compilation of the lessons learned, areas that went well, and areas for improvement. The AAR provides recommendations for corrective actions and improvement planning with associated points of contact. **The tools provided above all help to develop a robust and data driven after action report.**

8.4.2. Choosing Evaluators

Choose a lead evaluator, and depending on the number of exercise participants, additional evaluators may be warranted. Smaller discussion-

based exercises conducted at a single site may only need a single evaluator. Larger full-scale exercises may have multiple sites requiring their own evaluator at each site. A lead evaluator and members of the evaluation team should have experience and subject matter expertise in the areas they are assigned to examine. It is also beneficial for evaluators to have knowledge regarding policies, procedures and plans being tested.

8.4.3. Exercise Evaluation Guidance (EEGs) Documents

EEGs provide a consistent guide that tells evaluators key elements exercise designers want responders to accomplish during an exercise. During the exercise design process, planners will develop objectives based on core capabilities and determine critical tasks that show responders have the ability to accomplish objectives. Critical tasks may be obtained from Standard Operating Procedures (SOPs), organizational operating plans or discipline specific standards.

The Homeland Security Exercise Evaluation Program (HSEEP) provides EEG templates. An HSEEP EEG sample can be found by searching the Homeland Security Digital Library for "Exercise Evaluation Guide".[3] These templates are customizable so the guides can meet specific needs.

[3] https://www.hsdl.org/?search=&searchfield=&all=exercise+evaluation+guide&collection=public&tabsection=Templates&fct=&submitted=Search

Federal Emergency Management Agency HSEEP Blank EEG Template
Exercise Evaluation Guide Form

Exercise Name: *Exercise Date:*	*Organization/Jurisdiction:*	*Venue:*
Exercise Objective:		
Core Capability:		
Organizational Capability Target 1: *Critical Task:* *Critical Task:* **Source(s):**		
Organizational Capability Target 2: *Critical Task:* *Critical Task:* **Source(s):**		
Organizational Capability Target 3: *Critical Task:* *Critical Task:* **Source(s):**		

Organizational Capability Target	Associated Critical Tasks	Observation Notes and Explanation of Rating	Target Rating
		Final Core Capability Rating	

Ratings Key
P – Performed without Challenges
S – Performed with Some Challenges
M – Performed with Major Challenges
U – Unable to be Performed

The HSEEP EEG Format is designed to present the following evaluation requirements to evaluators:

- **Core Capabilities**: The distinct critical elements necessary to achieve a specific mission area (Prevention, Protection, Mitigation, Response, and/or Recovery).
- **Capability Target(s)**: The performance thresholds for each core capability; they state the exact amount of capability that exercise participants aim to achieve. Capability targets are typically written as quantitative or qualitative statements.
- **Critical Tasks**: The distinct elements required to perform a core capability; they describe how the capability target will be met. Critical tasks generally include the activities, resources and responsibilities required to fulfill capability targets. Capability targets and critical tasks are based on operational plans, policies and procedures to be tested during the exercise.
- **Performance Ratings**: The summary description of performance against target levels. Performance ratings include both Target Ratings, describing how exercise participants performed relative to each capability target, and Core Capability Ratings, describing overall performance relative to the entire Core Capability. Performance Ratings are described as P-performed without challenges; S-performed with some challenges: M-performed with major challenges; and U-unable to be performed).

When briefing evaluators about using EEGs, be sure to tell them not to use the EEG simply as a checklist. In other words, you do not want them to mark a check when something is completed and left blank when it is not accomplished. It is vital that evaluators take notes and describe as much as possible. Problems encountered during an exercise lead to improvements that are based on the quality of information gathered about what happened. The more quality information gathered, the better solutions will be developed. Evaluators should not only be able to describe what happened, but why it happened.

As evaluators work to document information during an exercise through their notes and EEGs, there are some key factors that evaluators should be aware of describing as they observe:

- **If** and **how** quantitative and qualitative targets or objectives were met.
- **Actual time** required for exercise participants to complete critical tasks.
- **How** a target was met or not met.
- **Decisions** made and information gathered to make a decision.
- **Requests** made and how requests were handled.

- **Resources** utilized.
- **Plans, policies, procedures or statutory authority used** or implemented
- **Challenges** that arose during the exercise and how they were addressed
- **Any other factors** that contributed to outcomes.

EEGs may be included in the Facilitator Guide used for discussion-based exercises. EEGs may also be included in a stand-alone Evaluation Plan or an Evaluation Plan included in the Controller/Evaluator Handbook.
In the case of the Facilitator Guide and the Evaluation Plan and the Controller/Evaluator Handbook, evaluators will need instructions about:

- Where they report to and to whom.
- Contact information for the Lead Evaluator and other evaluators
- Instructions, locations and times regarding pre-exercise briefing and training, as well as post-exercise debriefing (hotwash) locations, times and expectations
- EEGs
- In the case of larger exercises, a copy of the MSEL that shows inject times, inject sources and expected actions.
- How to report their completed notes and EEGs.

It is advisable to provide evaluators with guidance documents ahead of an exercise so they have at least several days to read the documents before the exercise and any pre-exercise briefings. In a large, full-scale exercise, the documentation can present a considerable amount of reading that includes the Controller/Evaluator Handbook, the MSEL and the EEGs.

It is important to have a briefing with evaluators prior to an exercise to assure that they know what is expected of them, discuss exercise documents and answer remaining questions.

The Exercise Plan, which is distributed to exercise participants, should emphasize how important feedback is from exercise participants. Any other opportunity to stress the importance of feedback from exercise participants should be made before and after an exercise. Feedback is especially important for the exercise debriefing or hotwash at the end of an exercise.

It is vital to conduct a hotwash/debriefing of the exercise participants. The debriefing should occur as soon after the exercise as possible so events are fresh in peoples' minds. Ideally, the hotwash should happen immediately after an exercise. In fact, exercise planners should block out

a time at the end of an exercise to allow for a hotwash. In a large exercise, it might be necessary to conduct the hotwash the very next day, but time and costs can be a factor if the debriefing is held the next day. Someone will be needed to facilitate the hotwash and someone else (such as the Lead Evaluator/Scribes) should be available to take notes. If possible, it is desirable to have more than one note taker to capture as much information as possible. Evaluators should attend the hotwash, so if there are questions or explanations that need clarification, evaluators can still ask questions of the participants.

A simple way of structuring a hotwash debriefing is to ask participants what went well first. Once participants have described strengths from the simulated response, the facilitator would then ask participants to describe problems encountered that should be considered areas for improvement. The facilitator may have someone record a list of strengths and areas for improvement on a dry erase board so everyone can track key issues during the debriefing.

The Lead Evaluator should take time to talk with the evaluation team about what they documented were important strengths and areas for improvement. The Lead Evaluator should assure that all the EEGs and evaluator notes are collected. If the Lead Evaluator is tasked with writing the AAR, he or she will want to be sure to gather as much information as possible from the evaluation team members. There may also be supplemental information that can be collected after an exercise including records produced by automated systems, logs and message forms.

8.4.4. Writing Recommendations: The "Whos", "Whats" and "Whens"

TIPS FOR WRITING RECOMMENDATIONS

1. (Who) should prepare/revise _____ plan to (correct what) by (when)?
2. (Who) should prepare/revise _____ policy or procedure to (correct what) by (when)?
3. (Who) will conduct training for (group) in (what) so that _____ by (when)?
4. (Who) will obtain _____ equipment/facilities so that _____ by (when)?
5. (Who) will conduct _____ study/analysis to (action required) so that _____?
6. (Who) will convene a working group of (people/agencies) to (action required) so as to (what)?

8.4.5. After Action Reports/Improvement Plans

The Homeland Security Exercise Evaluation Program AAR format uses the description "Organization Point of Contact" (POC) to name the person responsible for completing improvements in the table located on the following page to describe and track improvements.

HSEEP Improvement Plan Template

APPENDIX A: IMPROVEMENT PLAN

This IP has been developed specifically for [Organization or Jurisdiction] as a result of [Exercise Name] conducted on [date of exercise].

Core Capability	Issue/Area for Improvement	Corrective Action	Capability Element[1]	Primary Responsible Organization	Organization POC	Start Date	Completion Date
Core Capability 1: [Capability Name]	1. [Area for Improvement]	[Corrective Action 1]					
		[Corrective Action 2]					
		[Corrective Action 3]					
	2. [Area for Improvement]	[Corrective Action 1]					
		[Corrective Action 2]					

1 Capability Elements are: Planning, Organization, Equipment, Training, or Exercise

Considerations when writing or planning to write an AAR:

- AARs show concrete preparedness benefits generated by exercise activity and provide accountability for improvement planning implementation.
- AARs are used to provide feedback to the participating entities on their performance during the exercise.
- AARs summarize exercise events and analyze performance of the tasks identified as important during the planning process.
- AARs evaluate achievement of the selected exercise objectives using the EEGs
- AARs analyze data collected from the hotwash, debriefing, Participant Feedback Forms, and other sources.
- AAR Meeting: assignment of improvement actions/items to be performed by whom and by when. It specifically details the actions that the participating agency will take to address each recommendation presented in the AAR/IP, who or what agency will be responsible for taking the action, creating benchmarks and deadlines for completion, and the timeline for completion for the listed improvements.
- When working with a contracted evaluation team it is important to have a contract or Statement of Work that covers the duties, responsibilities and outcomes expected of the Contracted Evaluation Team.

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

Level	Description
1	No formal written Training and Exercise Plan (TEP).
2	Formal written TEP which properly identifies all relevant partners.
3	All parties included in the TEP know the plan exists, have identified a key POC that knows the exercise specifics, its location, and clearly understand their respective roles as they are explained in the plan.
4	The exercise planning process is incorporated into exercises and exercise conduct has a building approach.
5	The exercise plan includes a formal review and update process. AARs are utilized after exercises and "lessons learned" are incorporated into improvement plans, RRT SOP updates and/or exercise design.

9.2. Process Overview

9.2.1. Level 1: No formal written "Training and Exercise Plan"

1. Identify Training and Exercise planning schedule.
    a. Has your RRT developed a training and exercise schedule?
    b. Has your RRT conducted a Training and Exercise Plan Workshop (TEPW) or participated in a TEPW with other agencies?

9.2.2. Level 2: Formal written "Training and Exercise Plan" has been developed which properly identifies all relevant partners

1. All partnering agencies have been identified and included in the TEP. References include:
    a. RRT membership.
    b. Human and animal food partner/support agencies.
2. Lead person(s) for training and exercises for each partner agency have been identified and contact information is current.
3. Training and Exercise Plan has been shared with home agency contacts to help facilitate exercise implementation.

9.2.3. Level 3: All parties included in the SOP know the Training and Exercise Plan exists, know how to access the plan, and clearly understand their respective roles as they are explained in the plan

1. The SOP adequately describes the roles and responsibilities of partners and properly references other documents for this purpose. Examples:
    a. Exercise Lead
    b. Exercise Controller
    c. Exercise Facilitator(s)
    d. Exercise Evaluator
    e. Players
    f. Scribes and Runners

g. A/V Tech
h. Exercise Timelines (discussion vs. operational)
i. Other exercise guidance documents

2. Members of the RRT have been trained on the exercise facilitation roles.
   a. Facilitator
   b. Controller
   c. Evaluator
   d. Observer
3. Training sessions are developed and scheduled to include training partners in the exercise roles.
4. Lead planner is identified for each agency to help participate in exercise design.

9.2.4. Level 4: The exercise planning process is incorporated into exercises and exercise conduct has a building approach

1. The exercise planning process is understood by pre-identified RRT members and utilized in exercise design process.
2. The RRT has identified individuals or POCs to perform exercise roles (e.g., Facilitator, Controller, Evaluator, Observer).
3. The exercise has a "Crawl, Walk, Run" approach: exercises build from discussion based exercises to functional (operational) exercises that test RRT SOPs identified by the Rapid Response Teams and/or in the RRT Best Practice manual.

9.2.5. Level 5: The Training and Exercise plan includes a formal review and update process. AARs are developed post exercise and can be referenced/utilized in the exercise design process

1. A timeframe is established for review of the Training and Exercise plan.
2. A procedure exists for incorporating after action reporting into the exercise implementation.
3. A process to ensure the AARs are referenced and/or utilized in the exercise design process is incorporated.

10. RELATED DOCUMENTS

10.1. RRT Best Practices Manual, US Food and Drug Administration, 2011
10.2. Council to Improve Foodborne Outbreak Response (CIFOR). Guidelines for Foodborne Disease Outbreak Response. Atlanta: Council of State and Territorial Epidemiologists, 2009
10.3. Voluntary National Food Retail Food Regulatory Program Standards
10.4. Manufactured Food Regulatory Program Standards (MFRPS)
10.5. Food Related Emergency Exercise Bundle (FREE-B)

11. REFERENCES AND OTHER RESOURCES

11.1. Manufactured Food Regulatory Program Standards (MFRPS) https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf

11.2. Voluntary National Retail Food Regulatory Program Standards https://www.fda.gov/food/guidanceregulation/retailfoodprotection/programstandards/ucm245409.htm

11.3. National Association of State Departments of Agriculture Food Emergency Response Plan Guidance http://www.nasda.org/Policy/6460/9885/6138/11681.aspx

11.4. Council to Improve Foodborne Outbreak Response *Guidelines for Foodborne Disease Outbreak Response* and related resources

- **11.4.1.** Guidelines http://www.cifor.us/
- **11.4.2.** Toolkit http://www.cifor.us/toolkit.cfm
- ***11.4.3.*** Clearinghouse http://www.cifor.us/clearinghouse/keywordsearch.cfm
- **11.4.4.** Crosswalk http://www.cifor.us/clearinghouse/uploads/Document%20H_Crosswalks%20between%20National%20Initiatives%20and%20CIFOR%20Toolkit.pdf?CFID=42475325&CFTOKEN=78980292&jsessionid=A2FA380C84B33F21162553C983863F0D.cfusion

11.5. FoodSHIELD https://www.foodshield.org/

12. ATTACHMENTS

12.1. Attachment A – Exercise Materials Checklist
12.2. Attachment B – Exercise Logistics Checklist
12.3. Attachment C – Final Exercise Task Considerations
12.4. Attachment D – Exercise Scenario Development
12.5. Attachment E – Initial Planning Meeting (IPM) Worksheet—RRT Exercise Program
12.6. Attachment F – Glossary & Acronyms
12.7. Attachment G – Resources for Planning and Executing Large Scale Exercises, MI RRT
12.8. Attachment H – Example Exercise & Materials (Small), WA RRT, "The Crisis of Spices"
12.9. Attachment I – Example Exercise & Materials (Complex/HSEEP), IN RRT, "Insider Addition at the Campus Café"

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	5/26/2017	RRT Exercises WG (FL**, GA**, MO, TX, FDA FDECS, FDA OCM/EPEES)

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)
**Workgroup Lead

Change History

Special thanks to the inaugural Exercise Chapter Workgroup participants who helped to make this document a success! For additional questions, you can reach out to committee members to tap into their expertise in exercise conduct and design.

Exercise Workgroup Members

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Attachment A – Exercise Materials Checklist

- ❑ Exercise Documentations (SitMan, ExPlan, MSEL, Controller/Evaluator/Facilitator documentation, maps, etc.)
- ❑ Q&A for SitMan if you don't want to hand out all at one time
    - o Strongly Recommend that you color code the distribution of documentation so that they don't get distributed in the incorrect order
- ❑ Participant List (master copy with Exercise Director or Lead Planner)
- ❑ Sign-In Sheet(s); need to have sign-in sheet for each exercise location
- ❑ Notepads for player participants to take notes
- ❑ Pens or pencils for note taking
- ❑ Notecards (for questions/comments)
- ❑ Flip Charts; Markers (Dry-Erase/White Board)
- ❑ Easels
- ❑ Evaluation Materials: (notecards, player evaluations, Exercise Evaluation Guides (EEGs); Hotwash material/presentation
- ❑ Audio-Visual Requirements
    - o Does the facility provide or do you need to bring your own (power point projector, speakers)?
    - o What is the cost for A/V charges?
- ❑ Share host code with at least 2 conduct individuals to have redundancy measures in place; test dial in capabilities in advance of StartEx
    - o Host Code: _____
    - o Guest Code: _____
- ❑ Actor Supplies and/or Equipment
- ❑ Vests to designate participant roles
- ❑ Name Badges (order lanyards/table tents in advance to ensure time for printing; have printer on site if possible, presentation is everything)
- ❑ Signage to get to exercise location (if using a large facility, or multiple floors within a building(s); Plan on utilizing signage to guide participants to exercise location(s) (yard signs, signs to post on doors, placard signs, etc.)
- ❑ Maps of exercise site(s) that indicate entry and exit points; add main identifying roads, if available
- ❑ Thumb Drive with all exercise material
- ❑ Caterer Contact Information and establish delivery point(s)
- ❑ Beverage Location (water at a minimum is recommended, especially in extreme heat conditions); need to have ice/coolers for beverages
- ❑ Restrooms identified (do you have enough facilities for number of participants? Should you order portable units due to remote facility location?)
- ❑ Food: Fed participants are happy participants; consider dining locations as they impact exercise schedule and timing of meal(s)

Attachment B – Exercise Logistics Checklist

Exercise Venue/Facility

- ❑ Document Exercise Venue(s) _____
  - o Meetings, briefings, and exercises should be conducted in facilities that are appropriate for the exercise scope and attendance
- ❑ Determine Exercise Participant Number and verify the facility can accommodate number of participants safely and for logistical set-up
  - o How many people are participating? _____
- ❑ Verify there are enough tables and chairs for each participant
- ❑ Determine table arrangement (e.g., U-shaped layout for exercises requiring facilitation and participant interaction)
  - o Consider assigned seating for participants (e.g., seating at each table or group composed of persons form different agencies and experiences) to facilitate cross-agency or cross-program discussion and learning.
- ❑ Access/select a facility with room acoustics that facilitate ease of discussion
- ❑ Select a facility with accessibility of parking and restrooms for all participants
- ❑ Provide map of the exercise sites(s). Include this material in the briefings

Exercise Duration & Lodging

- ❑ Determine how many days the exercise will take place? _____
- ❑ Obtain lodging for multi-day events

Exercise AV & Communication Needs

- ❑ Document how are you communicating with the controllers, evaluators & facilitators?
- ❑ Perform Communications Check
- ❑ Have you tested the A/V hook-ups? Determine your Plan B if they fail?
- ❑ Web conferencing test/check (Important to get to the site early to ensure that your telecommunications are working properly)
- ❑ SimCell site technology and communications check/technology requirements before exercise to ensure ready for exercise play. Have you identified a Plan B if this fails to help ensure the exercise is still a go?

Exercise Materials

- ❑ Additional Participant Needs (water, snacks, meals, sun block, restroom identification, etc.)
- ❑ Determine who,_____, will be responsible for getting the exercise documents to the site(s)? (These include the Situation manuals, PowerPoints, leader's guide, Participant Feedback Forms, etc.)
- ❑ Determine who, _____, will be responsible for collecting the exercise evaluation material?
- ❑ Determine where, _____, the exercise materials will be delivered to?

Attachment C – Final Exercise Task Considerations

- ❑ Exercise planning team should visit the site at least 1 day prior to the event to set up the site
- ❑ On the day of the exercise, the planning team members should arrive several hours before the scheduled start to handle any remaining logistical or administrative items pertaining to set-up and to arrange for registration
- ❑ Exercise Briefing sites should be selected and a walk-through performed prior to exercise start
- ❑ Verify A/V & multi-media presentations are on site and ready for exercise play (Discussion based exercises typically include a multi-media presentations to present the scenario and accompany the SitMan)
- ❑ Verify Briefing presentations are loaded and working (Operations based exercises will include briefings for controllers/evaluators, actors, players, and observers/media. These briefing should be utilized to distribute exercise documentation, provide necessary instructions and administrative information to include safety instructions, and answer any outstanding questions)
- ❑ Discussion Based exercises: layout is extremely important, final walk-through check may entail changing the room layout to facilitate discussion
- ❑ Operations Based exercises: planners should consider the assembly area, response route, response operations area, parking, registration, observer/media accommodations, and the Simulation Cell (SimCell)
- ❑ Other accommodations: restrooms and water must be available to all participants, observers, and actors
- ❑ Provide Identification to participants (badge, vest, etc.). A form of identification should be provided for the individuals permitted at the exercise site
- ❑ Perimeter security and site safety during setup and conduct are essential and should be considered

Attachment D – Exercise Scenario Development

1. **Developing the exercise scenario**
   A scenario is an outline or model of the simulated sequence of events for the exercise. It can be written as a narrative or depicted by an event timeline. For discussion-based exercises, a scenario provides the backdrop that drives participant discussion, and is contained in a **SitMan**. For operations-based exercises, a scenario provides background information about the incident catalyst(s) of the exercise. The overall scenario is provided in the **C/E Handbook**, and specific scenario events are contained in the **MSEL** (Master Series Event List).

   Exercise planners should select and **develop scenarios that enable an exercise to assess objectives and achievement levels**. All scenarios should be realistic, plausible, and challenging; however, designers must ensure the scenario is not so complicated that it overwhelms players.

   A scenario consists of three basic elements:
   (1) The general context or comprehensive story;
   (2) The required conditions that will allow players to demonstrate proficiency and competency in conducting critical tasks, demonstrating core capabilities, and meeting objectives; and
   (3) The technical details necessary to accurately depict scenario conditions and events. The exercise planning team ensures that the design effort is not characterized by a fixation on scenario development; rather, **the scenario facilitates assessment of exercise objectives and core capabilities.** Because of this, exercise planners should refrain from developing the scenario until after the scope and objectives of the exercise have been clearly defined.

2. **Storyline that drives the exercise**
   It is extremely important the scenario be as plausible and realistic as possible. This requires the involvement of subject matter experts on the planning team who can help to provide this realism based upon real-world and/or prior experiences as well as knowledge of plans, policies and procedures. Utilizing individuals with human and animal food expertise from your RRTs, the National Weather Service, law enforcement, academia, and emergency management backgrounds will collectively add to the realism of the event. To provide a higher level of realism, exercise planners may choose to develop additional details to infuse into the scenario if necessary. These details may also be useful if participants begin to fight the scenario.

   The storyline that emerges is the backdrop to your players responding or reacting to the scenario to meet the objectives and critical tasks identified early on in the initial exercise planning. The storyline should include dates, locations, and events that occur that should help to drive play (a response) from the player participants. At times you have to nationalize (spell out events that would occur, maybe by the player participants but because of the

condensed time line, you drive responses by including actions in the scenario development itself, that the players then need to respond to.

3. **Determining the type of threat or hazard to be used in an exercise**
   The first step in designing a scenario is determining the type of threat or hazard on which the exercise will focus. Each type of emergency has its own strengths and weaknesses when it comes to evaluating different aspects of prevention, protection, mitigation, response, and recovery found in the National Response Framework[4].

   The exercise planning team should choose a threat or hazard that best assesses the objectives and core capabilities on which the exercise will focus. This should be a realistic representation of potential threats and hazards faced by the exercising entity.

4. **Realistically stress the resources and staff**
   It is important when designing an exercise that the exercise planning team is conscientious of how and if the players can realistically perform these actions/the required response/task(s). It is critical that the planning team take a building block approach: crawl, walk, and run by building from discussion based exercises to operational ones.

   The planning team should design the scenario to test, but not overwhelm, the player participants performing/responding to the human or animal food event.

[4] http://www.fema.gov/national-response-framework

Attachment E – Initial Planning Meeting (IPM) Worksheet—RRT Exercise Program

This worksheet summarizes the information gathered during the initial planning meeting (IPM)

When filling out, you will want to focus on RRT tasks (**how task will be performed**), conditions (**under what conditions**), and standards (**to the RRT standards outlined in the National or state specific Best Practice Manual(s)).** The core capabilities and capability targets in this form are gathered from the National Preparedness Goal (2011).

Final Exercise Core Capability and Objectives	
Core Capability: Planning (All Mission Areas)	
Capability Target: 1. Develop RRT food safety and food defense operational plans that adequately identify critical objectives based on the planning requirement, provide a complete and integrated picture of the sequence and scope of the tasks to achieve the objectives, and are implementable within the time frame contemplated in the plan using available resources.	
FINAL EXERCISE OBJECTIVES	

Final Exercise Core Capability and Objectives	
Core Capability: **Operational Coordination (All Mission Areas)**	
Capability Target: 1. Mobilize all critical RRT resources and establish command, control, and coordination structures within the affected community and other coordinating bodies in surrounding communities and maintain as needed throughout the duration of the incident. 2. Enhance and maintain National Incident Management System (NIMS)—compliant command, control, and coordination structures to meet basic human needs, stabilize the incident, and transition to recovery.	
FINAL EXERCISE OBJECTIVES	

Final Exercise Core Capability and Objectives	
Core Capability: **Public Information and Warning (All Mission Areas)**	
Capability Target: 1. Inform all affected segments of society by all means necessary, including accessible tools, of critical lifesaving and life-sustaining information to expedite the delivery of emergency services and aid the public to take protective actions. 2. Deliver credible messages (press releases, recall notices, etc.) to inform partner agencies and the public about protective measures and other life-sustaining actions and facilitate the transition to recovery.	
FINAL EXERCISE OBJECTIVES	

Final Exercise Core Capability and Objectives	
Core Capability: **Intelligence and Information Sharing (Protection Mission Area)**	
Capability Target: 1. Anticipate and identify emerging and/or imminent threats through the intelligence cycle. 2. Share relevant, timely, and actionable information and analysis with Federal, state, local, private sector, and international partners and develop and disseminate appropriate classified/unclassified products. 3. Ensure Federal, state, local, and private sector partners possess or have access to a mechanism to submit terrorism-related information and/or suspicious activity reports to law enforcement.	
FINAL EXERCISE OBJECTIVES	

Final Exercise Core Capability and Objectives	
Core Capability: **Screening Search and Detection (Protection Mission Area)**	
Capability Target: 1. Screen cargo, conveyances, mail, baggage, and people using information-based and physical screening technology and processes. 2. Detect WMD, traditional, and emerging threats and hazards of concern using: a. A laboratory diagnostic capability and the capacity for food, agricultural (plant/animal), environmental, medical products, and clinical samples b. Bio-surveillance systems c. CBRNE detection systems d. Trained healthcare, emergency medical, veterinary, and environmental laboratory professionals.	
FINAL EXERCISE OBJECTIVES	

Final Exercise Core Capability and Objectives	
Core Capability: **Supply Chain Integrity and Security (Protection Mission Area)**	
Capability Target: 1. Screen cargo, conveyances, mail, baggage, and people using information-based and physical screening technology and processes. 2. Detect WMD, traditional, and emerging threats and hazards of concern using: a. A laboratory diagnostic capability and the capacity for food, agricultural (plant/animal), environmental, medical products, and clinical samples b. Bio-surveillance systems c. CBRNE detection systems d. Trained healthcare, emergency medical, veterinary, and environmental laboratory professionals.	
FINAL EXERCISE OBJECTIVES	

Participants: Please list active participants in the exercises from your RRT and other local, state and federal partner agencies. Additional participants may be added as the final exercises planning progresses.

Exercise Participants	
Example: Venessa Sims, GDA	Example: Rita Johnson, FDACS

General Scenario:

Additional Planning Information:

Final Exercise Dates, Locations and Durations:

Dates	
Locations	
Addresses	
Durations ***(Give reasonable timeframes if not established in the plan)***	**Number of Days Established for Exercise Play:** **<u>Exercise Day Schedule</u>** **Registration:** **Safety Briefing:** **Start Ex:** **End Ex:** **Hotwash*:** **C/E De-Brief:** **Next Day Brief:**

Data Collection Forms: Separate forms will be provided for players and C/E participants. Forms will be collected immediately after each day of the exercise so player and C/E information can be incorporated into the after action report (AAR). If a multi-day exercise, data should be collected each evening and a briefing should occur with C/E members.

***Hotwashes should occur at each location of exercise play to obtain feedback from exercise participants.

Logistics:

Logistics	Agency/POC	Due Date
Coordinator		**Ongoing**
Notify Participants		
Develop Scenario		
Develop Exercise Documents and Coordinate Exercise Activities		
Secure Exercise Logistics		
Coordinate Refreshments		
Coordinate Registration (Badges and Sign-In Rosters)		
Identify and Procure Exercise Materials		
Facilitate Registration		
Exercise Lead Facilitator		
Exercise Lead Evaluator		
Print Exercise Documents and Stage Exercise Materials		
Develop After Action Report		

Project Schedule:

Mid-Term Planning Meeting	
Date	
Location	
Final Planning Meeting	
Date	
Location	
Draft AAR Due	
Date	
After Action Meeting	
Date	

Attachment F – Glossary & Acronyms

Glossary

TERM	Definition
Actors	A participant in an action or process
Drills	A coordinated, supervised activity usually employed to validate a specific function or capability in a single agency or organization
Exercise	An instrument to train for, assess, practice, and improve performance in prevention, protection, mitigation, response, and recovery capabilities in a risk-free environment.
Facilitator	A person responsible for leading or coordinating the work of a group.
Full Scale Exercises (FSE)	FSEs are typically the most complex and resource-intensive type of exercise. FSEs are usually conducted in a real-time, stressful environment that is intended to mirror a real incident. FSEs often include many players operating under cooperative systems such as the Incident Command System (ICS).
Functional Exercise (FE)	FEs are typically focused on exercising plans, policies, procedures, and staff members involved in management, direction, command, and control functions
Game	A simulation of operations that often involves two or more teams, usually in a competitive environment, using rules, data, and procedures designed to depict an actual or hypothetical situation.
Hotwash	A performance review, particularly after a training exercise. The hotwash is an opportunity for all participants to voice their opinions on the exercise and lessons learned.
Injects	Specific scenario event that prompt players to implement the plans, policies, procedures, and protocols that require testing that prompt players to implement the plans, policies, procedures, and protocols that require testing during the exercise, as identified in the capabilities-based planning process g during the exercise, as identified in the capabilities-based planning process.
Observers	Non-participants in testing exercise criteria
Operational-based Exercises	Operations-based exercises are characterized by actual reaction to an exercise scenario, such as initiating communications or mobilizing personal and resources.
Scope	An indicator of extent of the exercise. The key elements in defining exercise scope include exercise type, participation level, exercise duration, exercise location, and exercise parameters.
Seminar	Seminars generally orient participants to, or provide an overview of, authorities, strategies, plans, policies, procedures, protocols, resources, concepts, and ideas.
SimCell	A location from which controllers deliver messages representing actions, activities, and conversations of an individual, agency, or organization that is not participating in the exercise but would likely be actively involved during a real incident.

Tabletop Exercise	A tabletop exercise (TTX) is intended to generate discussion of various issues regarding a hypothetical, simulated emergency.
Target Capabilities List	The Target Capabilities List (TCL) defines and provides the basis for assessing preparedness. It also establishes national guidance for preparing the Nation for major all-hazards events, such as those defined by the National Planning Scenarios.
Workshop	A meeting at which a group of people engage in intensive discussion and activity on a particular subject or project.

Acronyms

Acronym	Term
AAR	After Action Report
A/V	Audio/Visual
C/E	Controller and Evaluator
EEG	Exercise Evaluation Guides
ExPlan	Exercise Plan
FE	Functional Exercise
FPM	Final Planning Meeting
FSE	Full Scale Exercise
ICS	Incident Command Systems
IPM	Initial Planning Meeting
MPM	Mid-term Planning Meeting
MSEL	Master Scenario Event List
POC	Point of Contact
RRT	Rapid Response Team
SitMan	Situation Manual
SMART	Specific, Measurable, Achievable, Relevant, and Time-bound
SMEs	Subject Matter Experts
SOPs	Standard Operating Procedures
StartEx	Start of Exercise
TCL	Target Capabilities List
TEP	Training and Exercise Plan
TEPW	Training and Exercise Planning Workshop
TTX	Tabletop Exercise

Attachment G – Resources for Planning and Executing Large Scale Exercises, MI RRT

Electronic copies can be obtained by going to FoodSHIELD or emailing OP.Feedback@fda.hhs.gov.

FoodSHIELD website information: https://www.foodshield.org/, RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Exercise, Training & Meeting Materials, File name: MI RRT Exercise Planning Kit Resource List 2016.doc.
Note that access to these documents is limited to personnel participating in the RRT Program.

RESOURCES FOR FUTURE LARGE SCALE EXERCISES

The intent of this document is to provide a set of resources created by the planners of the 2016 Sample Team exercise. These documents might serve as a reference or model for future exercises.

Description	Resource	Comments
Exercise Objectives	Sample objectives and goals.doc	May use some or all of these goals to drive the exercise development.
Timeline	Sample timeline.docx	This is a rough guideline for planning the exercise, actual event will vary.
Sample Agenda	sample team agenda.docx	If the presenters are different, consider preparing a site specific agenda. Timeframes were broad to allow for flexibility.
Training Slides	Sample STE 2016 MDARD PowerPoint 1	Slides can be tweaked for each session and updated between sessions if necessary.
Incident Check-in	Sample Check In LIst.docx ATL Check In LIst.docx	Prepare this 2-3 days prior to the exercise. Make sure everyone provides a cell phone number. Fill in the names and Team Leader positions ahead of time so it's easier to verify attendance the day of the exercise
Exercise Evaluation	STE 2016 evaluation.docx	Data from the hard copy surveys was entered into Survey-monkey. Consider using a survey-monkey link for participants.
Incident Action Plan	STE 2016 Incident Action Plan.pdf	Generic IAP covered all sessions. Might consider a specific IAP for each session.
Operational Briefing Agenda	STE 2016 IMT Operation briefing.do	Sample Agenda that was followed during operational briefing
Traceback Instructions and Form	STE 2016 TB instructions.docx	Traceback info provided to TB team leaders for review with their teams.
Sampler Instructions	STE 2016 sampling instructions.docx	Sampling info provided to all team leaders for review with their teams.
Chain of Custody Instructions and Form	Custody.docx	This was piloted during the sample team.

Description	Resource	Comments
Recall Audit Instructions and Form	STE 2016 RAC instructions.docx STE Kalamazoo recall.docx RAC form.pdf	Recall Audit check info provided to RAC team leaders for review with their teams.
Planning Session Instructions	STE 2016 IMT planning session.docx	Incident Management Team was instructed to go through a planning cycle to develop an IAP. If this is done again, consider expanding or providing more structure.
Planning P	STE 2016 planning p.docx	Planning p was provided to all participants.
ICS acronyms	Sample Team Acronyms and Definit	Incident Management Team Acronym list was compiled per request of participants.
Email notifications	Sample Email from Director.docx STE 2016 Sample Team Leaders.msg Sample Team Exercise.msg STE 2016 Incident Management Team M	Various emails detail the communications between the STE planners and various participants.
Participation List	Sample Team Participation List.docx	2016 list of participants by location
ICS 204	STE 204 Kalamazoo.docx	Example 204 that was created and used for each session. The original ICS 204 was modified to fit MDARD purposes

Electronic copies of these resources can be obtained by one of three ways: 1) going to the Attachments Panel of this PDF document; 2) going to FoodSHIELD; 3) or emailing OP.Feedback@fda.hhs.gov. FoodSHIELD website information: https://www.foodshield.org/, RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Exercise, Training & Meeting Materials, File name: MI RRT Exercise Planning Kit Resource List 2016.doc. Note that access to the RRT Program FoodSHIELD Workgroup is limited to personnel participating in the RRT Program.

Attachment H – Example Exercise & Materials (Small), WA RRT, "The Crisis of Spices"

- Attachment H-1: Participant Manual
- Attachment H-2: Initial Briefing Presentation
- Attachment H-3: Incident Briefing
- Attachment H-4: Incident Action Plan
- Attachment H-5: After Action Report

Electronic copies can be obtained by going to FoodSHIELD or emailing OP.Feedback@fda.hhs.gov.

FoodSHIELD website information: https://www.foodshield.org/, RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Exercise, Training & Meeting Materials, Subfolder: July 2016 WA RRT Exercise Materials.
Note that access to these documents is limited to personnel participating in the RRT Program.

Washington RRT Annual Exercise
July 12-13, 2016

The Crisis Of Spices

Courtesy of Zachary D. Lyons

Participant Manual

Exercise Introduction

Purpose

The purpose of this tabletop exercise is to review the foundational procedures for initiating a Washington Rapid Response Team (WA RRT) activation to a human foodborne illness outbreak involving multiple states and jurisdictions. Such preparedness measures would be applicable to incidents involving both intentional and unintentional food/feed contamination, ultimately providing participants with an overview of response activities while strengthening inter-agency relationships at the local, state, and federal levels.

To protect the health of the American public, it is crucial that we ensure that food products are safe for consumption. Everyone involved in the food chain, from farmer through consumer, has a responsibility to keep the food supply safe.

At any point during production or distribution, food can be contaminated either accidentally or on purpose. Regardless of the circumstances, the United States Food and Drug Administration (FDA), the Washington State Dept. of Agriculture (WSDA), Washington State Department of Health (WA DOH), and many other federal, state, tribal, and local agencies work together to protect the food and feed supply in Washington State.

Through this working relationship, FDA, WSDA, and WA DOH strive to continuously seek new ideas and strategies to reduce the incidence of human and animal health emergencies and to support food/feed defense-related innovation. In light of food/feed defense concerns, it is incumbent that local, State and Federal governments and industry partners understand the roles and responsibilities of all participating entities in a joint emergency response.

Objectives

- ❒ Simulate the steps for fully activating the WA RRT per documented procedures in the WA RRT Operations Manual v.4.0.
- ❒ Work through the Planning "P" to develop an Incident Action Plan (IAP) for the first operational period.
- ❒ Complete an After-Action Review and corresponding After-Action Report to evaluate the overall performance of the exercise.

Exercise Setting

Previous exercises for the WA RRT were held in a face-to-face setting with the majority of responders gathered in close proximity during the exercise activities. To further mimic real-life conditions, the current exercise will take place **virtually** with responders located at their normal work stations. Video conferencing will be used at times to address the exercise participants collectively.

Guidelines

This exercise is to be conducted in a safe learning environment so that all participants can share and explore concepts with one another while discussing multiple solutions and options for a given issue. The following guidelines are intended meet this end:

- This will be an open, low-stress, non-public learning environment and is not intended to set precedents.
- Participants will listen to and respect the varying viewpoints of all of the other participants while contributing according to the knowledge and understanding applicable to their position.
- Multiple options and outcomes may be presented while working through the incident scenario with participants from different agencies. Please view these situations as discussion-fostering opportunities.
- The scenario discussed is plausible and the events occur as presented. Keep the overall exercise objectives in mind when considering the information provided and avoid analysis paralysis from detail speculation. In other word, don't fight the scenario!
- Principles of the Incident Command System (ICS), including applicable terminology and forms, will be implemented during the exercise.
- Emails sent as part of the exercise activities must include "EXERCISE ONLY" in the subject line and the body of the email must being with: "The information in this email is for exercise purposes only".
- Lessons learned from today's activities may be shared with food safety and response colleagues in order to assist in the development of an effective and integrated food safety system.
- Participants are expected to be committed to learning from the activities of this exercise and apply the experience gained to strengthen the skills required for their position/function.
- Individual evaluations of the exercise will not be completed by the responders. Participants are encouraged to share comments and suggestions pertaining to the strengths and improvement areas during the After-Action Review.

Roles and Responsibilities

Lead Planners – The individuals who are responsible for the exercise, including convening the Planning Committee and coordinating all pre- and post-exercise needs.

Participants – Respond to the scenario based on their first-hand, experiential knowledge; current plans and procedures of their individual entity, agency or jurisdiction; and insights from training and experience.

Evaluators – Each participant is encouraged to provide feedback on the strengths and improvement needs captured during the exercise.

Tabletop Exercise Agenda

Tuesday July 12, 2016

Approx. Time	Activity
0900 hours[a]	Introduction and Briefing (WebEx)
0930 hours	Initial Incident Notification
0945 hours	WSDA Internal Coordination
1015 hours	WSDA to Notify WA DOH and FDA SEA-DO
1045 hours	WA RRT Management Meeting
1115 hours	Briefing with WSDA/FDA Agency Executives
1145 hours	RRT Activation Recommendation
1200 hours	WA RRT Work through ICS Planning “P”
1700 hours	Distribute SITREP and IAP to Response Agencies

[a]Times are listed according to Pacific Daylight Time (PDT).

Wednesday July 13, 2016

Approx. Time	Activity
0900 hours	After-Action Review with all participants
1000 hours	Adjourn

Exercise Instructions

As outlined in the above agenda, an initial briefing of the exercise will be provided to all participants via video conferencing on Tuesday July 12th. An individual from each response agency will serve as the primary point of contact during the exercise and will be identified at the time of the initial briefing.

Once the briefing is complete, the exercise will be carried out as follows:

- Initial notification from the Iowa RRT of illness cases possibly linked to a Washington State processor.
- The information will be assessed by WSDA management personnel to determine the proper next steps under normal operating conditions.
- WSDA will provide notification to FDA SEA-DO and WA DOH.
    - Epidemiological data for the Washington illness cases will be provided WA DOH.
- WA RRT Management consisting of WSDA and FDA SEA-DO personnel will hold a conference call during which the need for RRT activation is identified.
- A briefing will be held with WSDA and FDA SEA-DO Agency Executives.
- A formal decision will be made to activate the WA RRT according to jointly endorsed WSDA/FDA SEA-DO procedures (Figure 1) and a Letter of Expectation will be issued.
- Time permitting, WSDA Regional Managers and FDA SEA-DO SCSOs may choose to notify field staff.

During the afternoon of the 12th, WSDA and FDA SEA-DO staff normally involved in an illness outbreak response will work through the ICS Planning "P" to develop the initial Incident Action Plan (IAP) (Figure 2). The pre-identified FDA SEA-DO and WSDA Unified Commanders will collaborate with individuals assigned to the Planning and Operations Sections within the ICS structure to create the objectives/tactics in the IAP along with the Situation Report (SITREP) for the upcoming operational period. Planning meetings throughout the afternoon, such as conference calls or WebEx meetings, will be necessary to complete this process and may be combined as appropriate. The necessary ICS forms (201, 202, 203, 204, 205, 206, 208, 215, and 215A) are located on the WA RRT workgroup on FoodSHIELD and will need to be completed prior to 1700 hours on the 12th.

After-Action Review

The exercise will conclude with an After-Action Review on Tuesday the 13th from approximately 0900 hours to 1000 hours over WebEx. All participants are encouraged to attend and discuss strengths and development areas noted during the exercise activities. More contribution brings more value to the After-Action Review, an important tool for refining response capabilities. An After-Action Report will afterwards be generated and shared with participating agencies.

Supplementary Information

Figure 1. A flowchart outlining the steps included in the WA RRT formal activation process.

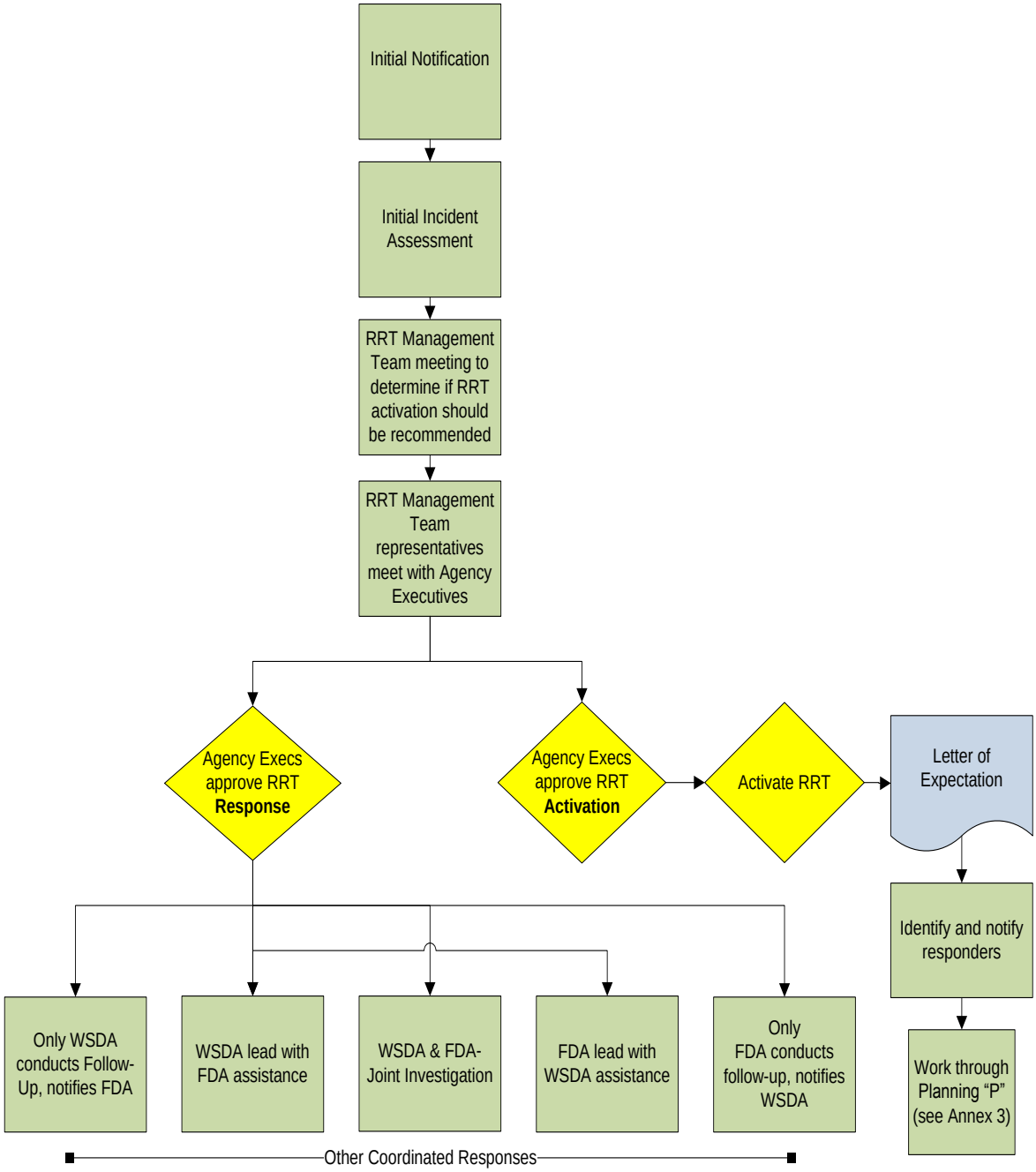
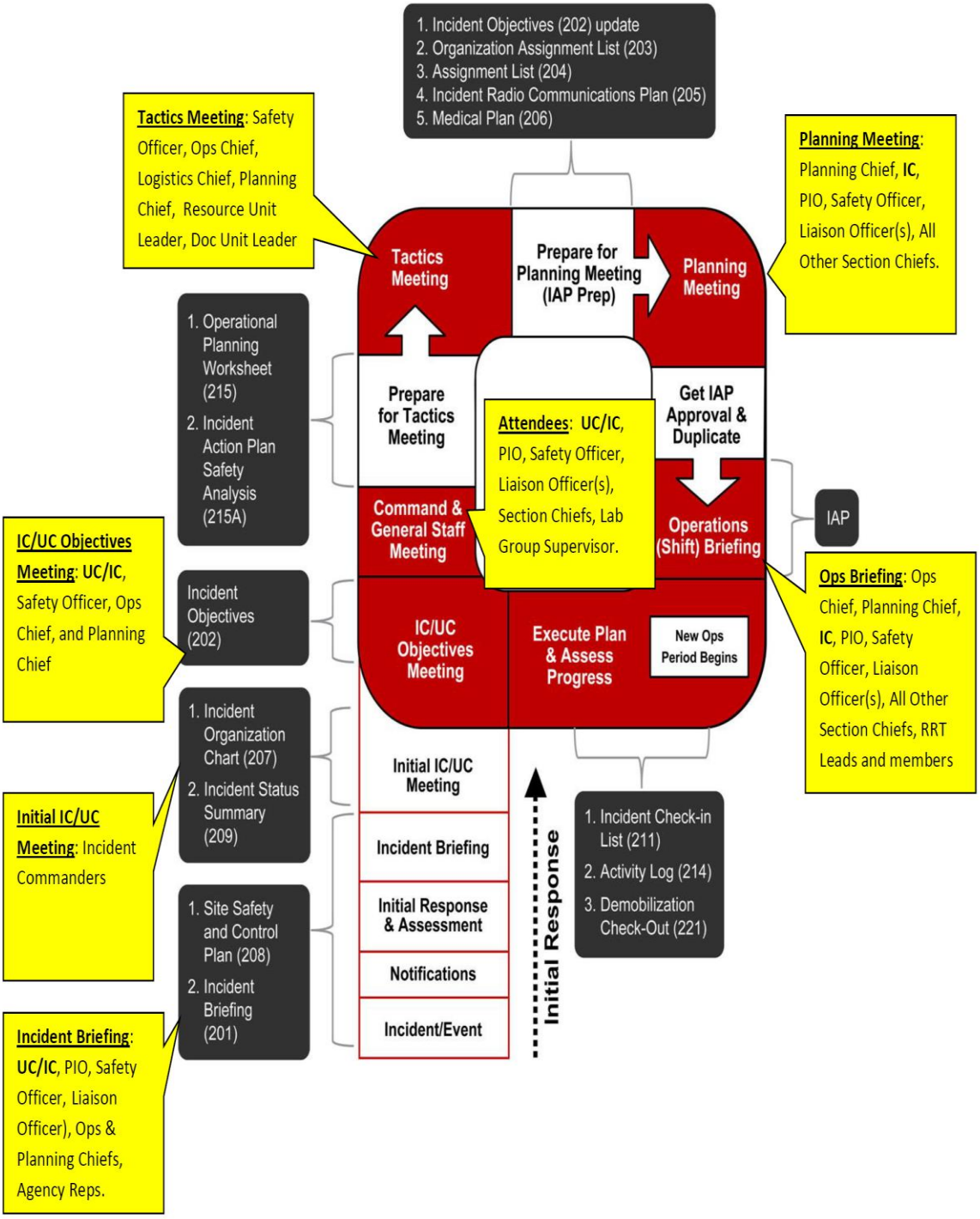


Figure 2. The ICS Planning "P" identifying relevant ICS personnel and forms.



Washington RRT Annual Exercise

RRT Activation Drill

July 12th, 2016

WashingtonRRT
Food Response

Scope

- Numerous agencies responsible for food/feed safety
- Intentional and/or unintentional contamination can occur at any point during farm-to-fork continuum
- Food/feed safety incidents can be complex, involving multiple states, agencies, and jurisdictions
  - Pre-established, inter-agency working relationships

WashingtonRRT
Food Response

Purpose

Practice WA RRT activation and joint agency response to a multi-state foodborne illness outbreak

WashingtonRRT
Food Response

Objectives

- Complete the steps for full RRT activation per the WA RRT Operations Manual v. 4.0
- Work through the Planning "P" to create an Incident Action Plan (IAP)
- Conduct an After-Action Review

WashingtonRRT
Food Response

Guidelines

- A continual improvement opportunity
- ICS principles and terminology will be used
- Don't fight the scenario!
- "EXERCISE ONLY" in the subject line of emails
  - Email body must begin with: "The information in this email is for exercise purposes only"

WashingtonRRT Food Response

Agenda

Tuesday July 12th: Table Top Exercise

Time	Activity
0900 hours	Introduction and Briefing (WebEx)
0930 hours	Initial Incident Notification
0945 hours	WSDA Internal Coordination
1015 hours	WSDA to Notify WA DOH and FDA SEA-DO
1045 hours	WA RRT Management Meeting
1115 hours	Briefing with WSDA/FDA Agency Executives
1145 hours	RRT Activation Recommendation
1200 hours	WA RRT Work through ICS Planning "P"
1700 hours	Distribute SITREP and IAP to Response Agencies

Wednesday July 13th: After-Action Review (0900-1000 hours)

- We appreciate your feedback!

WashingtonRRT Food Response

Incident Scenario

- Iowa Salmonella illness cluster associated with dry spice
  - Linked to Pierre's Finest, Inc. in Chehalis, WA
- Illness cases in Washington with matching PFGE pattern
  - Linked to Charlie's Stop-N-Chow restaurants
- Product and environmental sampling underway
  - Salmonella CRO's reported
- Multiple deaths and hospitalizations reported

WashingtonRRT
Food Response

Role and Responsibilities

- Iowa RRT
  - Initial incident notification
- WA Dept. of Health
  - Epi data for Washington illnesses
- WSDA Food Safety/RRT
  - Response planning and coordination with appropriate FDA SEA-DO personnel
- FDA-SEA DO
  - Response planning and coordination with appropriate WSDA personnel

WashingtonRRT
Food Response


Questions?
WashingtonRRT
Food Response

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Salmonella Illness Cluster-July 2016 (EXERCISE)	2. Incident Number: (EON num. if applicable) N/A	3. Date/Time Initiated: Date: 07/12/2016 Time: 1100 hours

4. Map/Sketch (include sketch, showing the total area of operations, the incident site/area, impacted and threatened areas, overflight results, trajectories, impacted shorelines, or other graphics depicting situational status and resource assignment)**:**

FOR EXERCISE PURPOSES ONLY

No Maps have been created yet for this incident.

Situation Report:

On the morning of 7/12/2016, the Iowa RRT notified the Washington RRT that they are tracking seven (7) confirmed cases of Salmonella in their state. Preliminary epidemiological information indicated that five of the seven (71%) of the cases reported to have eaten at Charlie's Stop-N-Chow restaurant locations, with all of those cases consuming the "Fiery Fries" product. IA RRT has indicated that they have collected invoices at the retail locations and can provide to WA RRT upon request. This initial investigation revealed that the Fiery Pepper Spice applied to the Fiery Fries product was manufactured by Pierre's Finest, Inc. located in Chehalis, WA. Pierre's Finest, Inc. is a licensed food processor with WSDA. Review of the previous inspection report revealed minor structural and cleaning violations. The report also included information on the ingredients for the Fiery Pepper Spice product, a dry mixture that contains chili powder, sea salt, paprika, onion powder, garlic powder, and ground black pepper.

WSDA as indeed requested the invoices from Iowa RRT along with additional information related to any case hospitalizations and/or deaths at this time.

WA RRT notified WA DOH Communicable Disease Epi on the morning of 7/12/16 to inform them of the illness cluster in IA and to inquire of any associated epi illness information collected in Washington State. WA DOH Epi indicated that a total of nine (9) illness cases of *Salmonella rissen* have been confirmed in Washington State, with 7 of those 9 cases (78%) being located in Lewis County. One additional case is located in King County and another single case located in Pierce County. Preliminary epi information from WA DOH indicates that of the 4 cases that ate at the Charlie's Stop-N-Chow locations in WA, all 4 (100%) consumed the Fiery Fries.

Four of the nine (45%) of the current cases in Washington have been hospitalized. Currently, WA RRT is aware that some IA illness cases have been hospitalized, however the exact number is unknown at this time.

WA DOH has collected ingredient as well as environmental samples from the three Charlie's Stop-N-Chow locations in Lewis County. As of 1130 hours on 7/12/2016, two of the ingredient samples collected are Cannot-Rule-Out (CRO) for Salmonella. In addition, a total of five environmental samples collected at the three retail locations in Lewis County are CRO for Salmonella. Confirmation results are anticipated from WA DOH Public Health Lab within the next two days.

1400 hours Update, 07/12/2016:

At approximately 1045 hours on 7/12/16, the Washington RRT Management Team met to discuss current information related to the incident in order to determine possible activation of the Washington RRT. Based on the information presented, all representatives from WSDA and FDA SEA-DO recommended activation of the RRT.

1. Incident Name: Salmonella Illness Cluster-July 2016 (EXERCISE)	2. Incident Number: (EON num. if applicable) N/A	3. Date/Time Initiated: Date: 07/12/2016 Time: 1100 hours

Agency Executives from both WSDA and FDA SEA-DO were briefed on the current information and on the Management Team's recommendation to activate the RRT. Both agency executives were in agreement and the RRT was fully activated at approximately 1200 hours on 7/12/16. The finalized Letter of Expectation was received by the IMT at approximately 1530 hours on 7/12/16.

At approximately 1130 hours on 7/2/2016, WSDA received notice from WA DOH that Lewis County Environmental Health (EH) had closed Charlie's Stop-N-Chow locations within their jurisdiction and placed a hold order on the Fiery Pepper Spice so it would not be used or discarded. In order to reopen, Lewis County placed the following conditions on the facilities:

1. **Thoroughly clean and sanitize the restaurant**
2. **Allow all food employees to be interviewed by Lewis County Epi to identify possible cases**
3. **Discontinue use of the Fiery Pepper Spice blend until situation is resolved and Lewis County allows them to resume using the ingredient.**

WA DOH also reported that Lewis County EH would be collecting additional investigational product and ingredient samples from the retail locations which will be sent to WA DOH Public Health Lab in Shoreline, WA for analysis.

At approximately 1230 hours on 7/12/2016, IA RRT updated WA RRT that two of the illness cases that were hospitalized had died. Additionally, the initial traceback investigation conducted by the IA RRT did not associate any other food products other than the Fiery Fries.

At 1245 hours on 7/12/2016, Washington RRT Command and General Staff held a joint objectives and tactics call in order to determine next steps. The upcoming operational period was identified as 0000 hours on 7/13/2016 through 0000 hours on 7/15/2016.

5. Situation Summary and Health and Safety Briefing (for briefings or transfer of command)**:** Recognize potential incident Health and Safety Hazards and develop necessary measures (remove hazard, provide personal protective equipment, warn people of the hazard) to protect responders from those hazards.

Possible safety hazards exist for deployed field staff that are inherent to a large-scale food production facility including moving equipment, conveyor belts, slips/trips/falls, loud noises, extreme heat/cold environments, and inclined/elevated surfaces. Deployed personnel have been provided appropriate PPE to conduct inspection and sampling activities in these environments (e.g. ear plugs, smocks, gloves, eye protection, etc.)

If additional PPE is required, please report to the Operations Section Chief of your respective agency.

6. Prepared by: Name: Randy Treadwell____ Position/Title: DPSC-WSDA_____Signature: 

ICS 201, Page 1	Date/Time: 1400 hours, 07/12/2016_____

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Salmonella Illness Cluster-July 2016 (EXERCISE)	2. Incident Number: (EON num. if applicable) N/A	3. Date/Time Initiated: Date: 07/12/2016 Time: 1100 hours

7. Current and Planned Objectives:

- **Ensure the safety of all RRT responders and associated personnel.**
- **Expedite the removal of all potentially contaminated product from commerce associated with the Salmonella illness cluster.**
- **Work to identify root cause or contributing factors related to product contamination.**
- **Ensure appropriate and timely information sharing among response agencies and general public.**

8. Current and Planned Actions, Strategies, and Tactics:

Time:	Actions:
	Incident Command
0000 hours on 7/13/2016 to 0000 hours on 7/15/2016	Provide responders with updated objectives as the focus of response elves.
Same as above	Provide overall safety messages and hazard analyses related to safety for the duration of the response.
	Operations Section:
Same as above	Determine source and receipt process for ingredients coming into the Pierre's Finest, Inc. processing facility in Chehalis, WA.
Same as above	Observe and document spice process flow at the Chehalis, WA facility and observe any root cause and/or contributing factors that may lead to possible product contamination.
Same as above	Review firm distribution records for product in question.
Same as above	Review consumer complaint records/logs maintained by the firm.
Same as above	Collect ingredient and finished product samples at processing facility, based on availability and investigation group recommendations.
	Planning Section:
Same as above	Maintain response documentation and distribute IAPs to participating responders and appropriate agency liaisons for future operational periods
Same as above	Coordinate and facilitate call between firm representatives and WSDA/FDA SEA-DO after the arrival of investigation team at facility in the morning of 7/13/2016.
Same as above	Coordinate and facilitate joint planning calls for future operational periods.

6. Prepared by: Name: Randy Treadwell____ Position/Title: DPSC-WSDA_____Signature: Randy Treadwell

ICS 201, Page 2 Date/Time: 1400 hours; 07/12/2016_____

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Salmonella Illness Cluster-July 2016 (EXERCISE)	2. Incident Number: (EON num. if applicable) N/A	3. Date/Time Initiated: Date: 07/12/2016 Time: 1100 hours

9. Current Organization (fill in additional organization as appropriate)**:**

WSDA:

Unified Commander: Mike Tokos
Planning Section Chief: Caleb James
Deputy Planning Section Chief-WSDA: Randy Treadwell
Deputy Operations Section Chief: Linda Condon
Agency Executive: Candace Jacobs
PIO: Hector Castro

FDA:

Unified Commander: Victor Meo
Deputy Planning Section Chief-FDA: Alicia Schroder
Agency Executive: Miriam Burbach

WA DOH-Food Safety Program:

Agency Liaison: Joe Graham

WA DOH-Communicable Disease Epidemiology:

Agency Liaison: Beth Melius

Iowa Rapid Response Team:

Agency Liaison: Melanie Harris

WSDA Microbiology Laboratory:

Liaison: Yong Liu

DOH Public Health Laboratory:

Liaison: Beth Melius

Lewis County Environmental Health:

Liaison: Joe Graham

6. Prepared by: Name: Randy Treadwell____ Position/Title: DPSC-WSDA_____Signature: Randy Treadwell

ICS 201, Page 3 Date/Time: 1400 hours; 07/12/2016_____

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Salmonella Illness Cluster-July 2016 (EXERCISE)	2. Incident Number: (EON num. if applicable) N/A	3. Date/Time Initiated: Date: 07/12/2016 Time: 1100 hours

10. Resource Summary:

Resource	Resource Identifier	Date/Time Ordered	ETA	Arrived	Notes (location/assignment/status)
Food Safety Officers-WSDA	FSO	1500 hrs on 7/12/16	0800 hrs on 7/13/16	☐	Will meet with FDA CSO at 0800 hours at inspection location in Chehalis, WA.
Consumer Safety Officers-FDA SEA-DO	CSO	1500 hrs on 7/12/16	0800 hrs on 7/13/16	☐	Will meet with WSDA FSO at 0800 hours at inspection location in Chehalis, WA.
				☐	

6. Prepared by: Name: Randy Treadwell____ Position/Title: DPSC-WSDA_____Signature: Randy Treadwell

ICS 201, Page 4 Date/Time: 1400 hours; 07/12/2016_____

Updated by FDA 2/2011

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: Salmonella Illness Cluster-July 2016; WA RRT Exercise	2. Operational Period: Date From: 07/13/2016 Time From: 0000 hours	Date To: 07/15/2016 Time To: 0000 hours

3. Objective(s):

- **Ensure the safety of all RRT responders and associated personnel.**
- **Expedite the removal of all potentially contaminated product from commerce associated with the Salmonella illness cluster.**
- **Work to identify root cause or contributing factors related to product contamination.**
- **Ensure appropriate and timely information sharing among response agencies and general public.**

4. Operational Period Command Emphasis:

Emphasis for the initial operational period will include production and environmental sampling, gathering pertinent information (production/distribution/sanitation records, etc.), and conducting a general facility investigation at the Washington State-based production facility potentially associated with the suspected illness vehicle.

General Situational Awareness:

Ensure FDA/WSDA investigators are equipped with appropriate personal protective equipment (PPE), including hard hats, smocks, dust masks, and ear protection.

5. Site Safety Plan Required? Yes ☐ No ■

Approved Site Safety Plan(s) Located at: N/A

6. Incident Action Plan (the items checked below are included in this Incident Action Plan)**:**

■ ICS 203	☐ Map/Chart	Other Attachments:
■ ICS 204	☐ Weather Forecast/Tides/Currents	
■ ICS 205		☐ _____
■ ICS 206		☐ _____
■ ICS 208		☐ _____

7. Prepared by: Name: Caleb James Position/Title: Planning Section Chief Signature: Caleb James

8. Approved by Incident Commander: Name: Victor Meo/Michael Tokos Signature: **/Signed/**_____

ICS 202	IAP Page _1 of 6___	Date/Time: 07/13/2016 1700 hours

Updated by FDA 2/2011

ORGANIZATION ASSIGNMENT LIST (ICS 203), ADAPTED FOR FDA

1. Incident Name: Salmonella Illness Cluster-July 2016 (EXERCISE)	2. Operational Period:	Date From: 07/13/2016	Date To: 00:00 Hours
		Time From: 07/15/2016	Time To: 00:00 Hours

3. Incident Commander(s)/ Agency Incident Coordinator and Command Staff: (include location)	
X IMT IC/UCs	Mike Tokos, WSDA, Olympia
☐ IMG AIC	Victor Meo, FDA, Bothell
Deputy	
Safety Officer	
Public Info. Officer	Hector Castro, WSDA
Liaison Officer	

4. Agency/Organization Representatives:	
Agency/Organization	Name
WA DOH-Food Safety	Joe Graham, DOH
WSDA DOH-CD Epi	Beth Melius, DOH
IA RRT	Melanie Harris, Iowa DIA
WSDA Micro Lab	Yong Liu, WSDA
WA DOH Public Health Lab	Beth Melius, DOH

5. Planning Section:	
Chief	Caleb James, WSDA
Deputy	Alicia Schroder, FDA/Randy Treadwell, WSDA
Resources Unit	
Situation Unit	
Documentation Unit	
Demobilization Unit	
Technical Specialists	

6. Logistics Section:	
Chief	
Deputy	
Support Branch	
Director	
Supply Unit	
Facilities Unit	
Ground Support Unit	
Service Branch	
Director	
Communications Unit	
Medical Unit	
Food Unit	

7. Operations Section:		
Chief	Linda Condon	
Deputy	Alicia Schroder	
Staging Area		
Branch	WA RRT	
Branch Director		
Deputy		
Division/Group	Pierre's Investigation Group	Deanna Straayer-WSDA
Division/Group		
Division/Group		
Division/Group		
Division/Group		
Branch		
Branch Director		
Deputy		
Division/Group		
Division/Group		
Division/Group		
Division/Group		
Branch		
Branch Director		
Deputy		
Division/Group		
Division/Group		

8. Finance/Administration Section:	
Chief	
Deputy	
Time Unit	
Procurement Unit	
Comp/Claims Unit	
Cost Unit	

9. Prepared by: Name: Alicia Schroder Position/Title: Deputy PSC Signature: *Alicia Schroder*

ICS 203	IAP Page __2 of 6___	Date/Time: 07/12/2016 at 14:28 Hours

Updated by FDA 2/2011

ASSIGNMENT LIST (ICS 204), Adapted for FDA

1. Incident Name:	2. Operational Period:	3.
Salmonella Illness Cluster-July 2016 (EXERCISE)	Date From: 07/13/2016 Date To: 07/15/2016 Time From: 0000 Time To: 0000	**Branch:** **WA RRT** **Division:** **n/a** **Group: n/a**

4. Operations Personnel: Name — Contact Number(s)

Operations Section Chief: Linda Condon 360-810-0732

Branch Director: n/a

Division/Group Supervisor: Deanna Straayer-WSDA

5. Resources Assigned:		# of Persons	Contact (e.g., phone, pager, radio frequency, etc.)	Reporting Location, Special Equipment and Supplies, Remarks, Notes, Information
Resource Identifier	Leader			
Investigation Group-FSOs, CSOs	Deanna Straayer	5	FSO Hoffman: 206-473-2748 FSO Satak: 360-951-5086 CSO: TBD CSO: TBD	Pierre's Finest, Inc.

6. Work Assignments:

Tactical objectives:

a. FSOs/CSOs – gather data and documentation for:
   i. incoming ingredients, process flow, distribution
   ii. consumer complaint records/logs
   iii. sanitation evaluation
   iv. ingredient and product sampling
   v. environmental sampling

7. Special Instructions:

Inspection is for-cause in response to an ongoing illness outbreak. Please review the Incident Briefing (ICS form 201) for specific details related to the incident. A call is being coordinated between FDA SEA-DO, WSDA, and firm representatives after the inspection group arrives at the facility on the morning of 7/13/2016.

Fiery Pepper Spice product is a blend of 6 spice ingredients: chili powder, sea salt, paprika, onion powder, garlic powder, ground black pepper.

8. Communications (radio and/or phone contact numbers needed for this assignment)**:**

Name/Function	Primary Contact: indicate cell, pager, or radio (frequency/system/channel)
n/a / n/a	n/a
/	
/	
/	

9. Prepared by: Name: Linda Condon Position/Title: Operations Section Chief

Signature: Linda Condon

ICS 204	IAP Page _3 of 6___	Date/Time: 07/12/2016/1505

Updated by FDA 2/2011

INCIDENT COMMUNICATIONS PLAN (ICS 205), Adapted for FDA

1. Incident Name:	2. Date/Time Prepared:	3. Operational Period:
Salmonella Illness Cluster-July 2016 (EXERCISE)	Date: 7/12/2016 Time: 15:30	Date From: 07/13/2016 Date To: 00:00 Hours Time From: 07/15/2016 Time To: 00:00 Hours

4. Incident communication information:

Incident Assigned Position	Name (Last, First)	Primary Number	Secondary Number	Other Method (s) of Contact (pager, email, radio, etc.)	Remarks
Unified Commander-WSDA	Tokos, Mike	360-902-1965	360-951-6942	mtokos@agr.wa.gov	
Unified Commander-FDA	Meo, Victor	425-302-0464	206-696-2930	Victor.meo@fda.hhs.gov	
Operations Section Chief (OSC)	Condon, Linda	360-902-1860		lcondon@agr.wa.gov	
Planning Section Chief (PSC)	James, Caleb	509-808-0324		cjames@agr.wa.gov	
Deputy PSC-WSDA	Treadwell, Randy	509-413-3739		rtreadwell@agr.wa.gov	
Deputy PSC-FDA	Schroder, Alicia	425-302-0476	425-582-3148	Alicia.schroder@fda.hhs.gov	
WADOH CD-EPI POC	Melius, Beth	206-418-5432		Beth.melius@dhs.wa.gov	
WADOH Food Safety POC	Graham, Joe	360-236-3305		Joe.graham@doh.wa.gov	
IA DIA POC	Harris, Melanie	515-281-6096		Melanie.harris@dia.iowa.gov	
PIO-WSDA	Castro, Hector	360-902-1815	360-464-0118	hcastro@agr.wa.gov	
WSDA Micro Lab Liaison	Liu, Yong	360-664-8962		lyong@agr.wa.gov	

5. Special Instructions:

6. Prepared by (Communications Unit Leader)**:** Name: Alicia Schroder_____ Signature: *Alicia Schroder*_____

ICS 205	IAP Page __4 of 6___	Date/Time: 07/12/2016 15:30_____

Updated by FDA 2/2011

MEDICAL PLAN (ICS 206), Adapted for FDA

1. Incident Name: Salmonella Illness Cluster-July 2016 (EXERCISE)	**2. Operational Period:** Date From: 07/13/2016 Date To: 07/15/2016 Time From: 0000 Time To: 0000

3. Medical Aid Stations:

Name	Location	Contact Number(s)/Frequency	Paramedics on Site?
N/A			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No

4. Transportation:

Ambulance Service	Location	Contact Number(s)/Frequency	Level of Service
911			☐ ALS ☐ BLS
			☐ ALS ☐ BLS

5. Hospitals:

Hospital Name	Address	Contact Number(s)	Distance	Trauma Center	Burn Center	Helipad
Centralia Hospital	914 S. Scheuber Road Centralia, WA	ER: 360-827-8516	5 miles via car (approx. 10 min)	■ Yes Level: IV	■ Yes ☐ No	■ Yes ☐ No
Woodland Urgent Care	1299 Bishop Road, Chehalis, WA	360-748-9822 (Mon-Fri 0700-2000)	2.5 miles via car (approx. 10 min)	☐ Yes Level:_____	☐ Yes ■ No	☐ Yes ■ No

6. Special Medical Emergency Procedures:
Medical issues are not anticipated. Staff to be instructed to call 911.

7. Prepared by (Medical Unit Leader)**:** Name: Linda Condon Signature: Linda Condon

8. Approved by (Safety Officer)**:** Name: Michael Tokos Signature: Michael Tokos

ICS 206	**IAP Page _5 of 6___**	Date/Time: 07/12/2016 / 1525

Updated by FDA 2/2011

SAFETY MESSAGE/PLAN (ICS 208)

1. Incident Name: Salmonella Illness Cluster-July 2016 (EXERCISE)	2. Operational Period: Date From: 07/13/2016 Date To: 07/15/2016 Time From: 00:00 Time To: 00:00

3. Safety Message/Expanded Safety Message, Safety Plan, Site Safety Plan:

Safety Message: Ensure the safety of all RRT responder and associated personnel.

Safety Plan: This is an inspection of a manufacturer of spices. Use of normal inspectional PPE is required for this inspection. There is a potential for irritants either contact and/or breathing in spices.

-Have bottle water to hydrate and use as eye washes.
-Use of respirator or N95 dust mask as needed
-Use of gloves for protection of skin irritants.
-Use of lab coats/coveralls as needed.
-Use other appropriate PPE when needed.

Of note there are deaths associated with Salmonellosis potentially associated with this outbreak. People infected with Salmonella develop diarrhea, fever, and abdominal cramps between 12 and 72 hours after infection. The illness usually lasts 4 to 7 days, and most individuals recover without treatment. In some cases, diarrhea may be so severe that the patient needs to be hospitalized

Weather: For this operational period there is no known issue in the forecast.

Site Safety Plan: No known issues at the firm, therefore no site safety plan is required.

Washington Rapid Response Team 2016 Exercise

Activation Drill

After-Action Report/Improvement Plan

July 2016

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RESPONSE OVERVIEW

Response Name	EXERCISE: Salmonella Illness Cluster-July 2016
Response Dates	7/12/16
Scope	The exercise concentrated on formal activation of the WA RRT as well as joint agency response to a multi-state Salmonella illness outbreak associated with dry spices.
Mission Area(s)	Mitigation and Response.
Core Capabilities	Environmental Response/Health and Safety
Response Objectives	• Ensure the safety of all RRT responders and associated personnel. • Expedite the removal of all potentially contaminated product from commerce associated with the Salmonella illness cluster. • Work to identify root cause or contributing factors related to product contamination. • Ensure appropriate and timely information sharing among response agencies and general public.
Hazard	Foodborne human pathogen: Salmonella.
Response Organizations	WSDA Feed/Rapid Response Program, WSDA Food Safety Program, Washington State Department of Health (WA DOH) Communicable Disease Epidemiology, WA DOH Food Safety Program, Iowa RRT, FDA Seattle District Office (SEA-DO) FDA Coordinated Outbreak Response and Evaluation Network (CORE).
Point of Contact	Randy Treadwell Feed/Rapid Response Program Manager WSDA Feed/Rapid Response Program rtreadwell@agr.wa.gov

Incident Summary:

To initiate the exercise, the Washington Rapid Response Team (WA RRT) was notified by the Iowa RRT of a Salmonella illness cluster in Iowa associated with a dry spice product linked to a Washington State-based manufacturing facility. A restaurant chain with locations in Iowa and Washington was also implicated in the outbreak, which included seven illnesses in Iowa with a matching PFGE pattern to nine Washington illness cases. The incident scenario included two deaths and four hospitalizations associated with the outbreak.

The following objectives were identified during the initial briefing for the exercise:

- Complete the steps for full RRT activation per the WA RRT Operations Manual v. 4.0.
- Work through the Planning "P" to create an Incident Action Plan (IAP).
- Conduct an After-Action Review.

As the primary response partners of the WA RRT, WSDA and FDA SEA-DO worked closely to follow the steps identified in the jointly-endorsed Operations Manual to formally activate the WA RRT while operating under a Unified Command ICS structure. The IAP for the first operational period was created and shared with response agencies at the close of 7/12/16. An After-Action Review was held with the exercise participants on the following day to evaluate the overall exercise performance. An overview of the identified strengths and areas of improvement specific to three focus areas is provided in the following sections.

Focus Area #1: Exercise Format—Virtual vs. Face-to-Face

Strengths

Strength 1: Unlike previous WA RRT exercises held in a multi-day, face-to-face setting, the virtual exercise more closely mimicked real-life conditions as exercise participants were situated at their normal work stations during the response and planning activities.

Strength 2: Previously formed working relationships and good familiarity among exercise participants made it possible to hold the exercise in a virtual setting.

Strength 3: Participant Manual provided in advance included adequate detail regarding exercise guidelines, instructions, and roles and responsibilities for the activation drill.

Areas for Improvement

Area for Improvement 1: Personnel requirements were not clearly determined to the participating agencies early in the response, which made it difficult to fill some of the General Staff positions within the ICS structure.

Analysis: Though identified as an improvement area, this issue ultimately contributed to the real-life working conditions created by the virtual setting as staffing challenges are often faced during food/feed emergency responses. However, personnel needs will be more clearly communicated in the exercise announcement and participant manual for future exercises to allow for greater participation of individuals qualified to fill ICS General Staff positions.

Focus Area #2: Current WA RRT Procedures

Strengths

Strength 1: The procedures for formal activation of the WA RRT were closely followed in stepwise fashion and continue to be fit-for-use.

Strength 2: Exercise participants from WSDA and FDA SEA-DO had received the recently updated WA RRT Operations Manual v. 4.0 and were familiar with general RRT procedures, including the formal activation process.

Areas for Improvement

Area for Improvement 1: Potential safety concerns in a food/feed manufacturing facility can be difficult to quickly and thoroughly identify on the ICS Form 208 Safety Message/Plan.

Analysis: Field investigators are expected to take general safety precautions when doing any investigation/sampling work at a food/feed facility, however, developing pre-established, standardized medical statements for the ICS 208 Form may assist in quickly identifying additional safety considerations during a food/feed emergency response.

Area for Improvement 2: FDA SEA-DO personnel can only electronically sign documents in pdf format, which may create delays in document routing as well as formatting issues.

Analysis: The current electronic signature method does not allow for minor errors or typos to be corrected once the final document is signed and also can create formatting issues when compiling documents for the Incident Action Plan. Inquiring as to how other FDA District Offices electronically sign documents may produce a solution to this issue, which the Iowa RRT Coordinator agreed to pursue with FDA MIN-DO personnel.

Area for Improvement 3: Minor revisions were identified for the WA RRT Operations Manual v. 4.0, including:

- Check boxes contained in the Letter of Expectation template are misleading and should be replaced with an alternative bullet symbol or numbering system.
- Header information in Annex 14 is not current.
- Some web links to supplemental information in the Annexes were not current.

Analysis: The WA RRT Operations Manual is revised on a yearly basis. Developing a revision checklist may standardize the revision process and ensure all expired information is updated.

Focus Area #3: Execution of Current WA RRT Procedures

Strengths

Strength 1: The exercise conference calls were well organized and facilitated by Planning Section personnel which greatly assisted the Unified Commanders.

Strength 2: A field staff member was involved early in the ICS Planning "P" meetings, which provided the Unified Command and General Staff with helpful information to streamline the coordination efforts.

Areas for Improvement

Area for Improvement 1: Limited availability of qualified staff members for WSDA presented challenges when assigning an Operations Section Chief and Deputy.

Analysis: Continuing to build depth within the WA RRT through ICS position-specific training may serve to strengthen the continuity of operations during food/feed emergency responses. Additionally, revising the WA RRT membership process to extend beyond the current RRT Core Members would allow for a greater number of WSDA staff to become familiar with WA RRT procedures.

Area for Improvement 2: Reminders were needed related to the electronic storage location of the ICS forms; tactics for multiple groups/sections were included on the same ICS 204 Form.

Analysis: All ICS forms are located in the WA RRT Workgroup on FoodSHIELD, however, member login information may not be conveniently located. WSDA and FDA SEA-DO must separately identify a storage location so that the forms are readily available during a food/feed emergency response. Additionally, tactics specific to each group/section should be listed on a separate ICS 204 Form to avoid incomplete work assignments or duplication of efforts.

Area for Improvement 3: The purpose and intent of the conference calls was not always made clear prior to the start of the call.

Analysis: In an effort to promote planning efficiency, attendees should be made aware of the purpose and intent of a conference call well in advance, if possible, to allow necessary preparation time. Providing a brief meeting agenda along with the meeting announcement was discussed as a possible solution in addition to developing a standard conference call agenda template. The sample agendas included in the NIMS field guide and/or the FDA Incident Management Handbook may provide basic agenda templates.

Area for Improvement 3: Briefing with Agency Executives to recommend RRT activation occurred later than anticipated on the exercise agenda.

Analysis: Once the need for RRT activation is identified during the WA RRT Management meeting, adequate time should be allowed to compile the current incident information into a single document, such as a Situation Report (SITREP), to facilitate the briefing with Agency Executives.

APPENDIX A: IMPROVEMENT PLAN

This IP has been developed specifically for the Washington Rapid Response Team (RRT) as a result of the Annual Exercise-Activation Drill in July 2016.

Core Capability	Issue/Area for Improvement	Corrective Action	Capability Element[1]	Primary Responsible Organization	Organization POC	Start Date	Projected Completion Date
Core Capability 1: Exercise	1. Personnel requirements for exercise activities not clearly communicated	Personnel roles must be more clearly identified in future exercise announcements and participant manuals	Exercise	WA RRT	WA RRT Program Manager/RRT Coordinator	7/2016	2017 Exercise
	2. Briefing with Agency Executives was delayed	Following RRT Management meeting, allow adequate time to compile incident briefing info into a single document	Exercise	WA RRT	WA RRT Program Manager/RRT Coordinator	7/2016	2017 Exercise
Core Capability 2: Planning	1. Safety concerns for food/feed processing environments not easily identified	Developing standard medical statements for ICS 208 Form to quickly and effectively identify safety issues during food/feed responses	Planning	WA RRT/WSDA Risk Management	WA RRT Program Manager/RRT Coordinator/WSDA Safety Officer	7/2016	Ongoing
	2. FDA SEA-DO personnel can only apply E-signature to pdf documents	Inquire about E-signature methods used by other FDA District Offices	Planning	FDA SEA-DO/Iowa RRT	Iowa RRT Coordinator	7/2016	Ongoing
	3. Minor revisions necessary to WA RRT Ops Manual v. 4.0	Check boxes replaced with alternative bullet symbol in Letter of Expectation. Develop checklist for standardized annual review of WA RRT Ops Manual	Planning	WA RRT	WA RRT Program Manager/RRT Coordinator	7/2016	4/2017
	4. Purpose/intent of conference calls was not always clear	Provide brief conference call agenda prior to call. Develop conference call agenda template.	Planning	WA RRT	WA RRT Coordinator	7/2016	8/2016

[1] Capability Elements are: Planning, Organization, Equipment, Training, or Exercise.

	5. Reminders were needed for the electronic storage location of ICS forms	A designated and readily accessible electronic storage location for ICS forms must be separately identified by WSDA and FDA SEA-DO	Planning	WA RRT	WA RRT Coordinator/FDA SEA-DO ERC	7/2016	Ongoing
Core Capability 3: Training	1. Continuity of operations when qualified number of WSDA staff is limited	Provide ICS position-specific and WA RRT procedure training to additional WSDA staff	Training	WSDA Food Safety Program/WA RRT	Program Manager or designees	7/2016	Ongoing

APPENDIX B: RESPONSE PARTNERS

Participating Organizations
Federal
Food and Drug Administration; Seattle District Office (FDA SEA-DO)
FDA Coordinated Outbreak Response and Evaluation Network (CORE)
State
Washington State Dept. of Agriculture (WSDA) Feed/Rapid Response Program
WSDA Food Safety Program
Washington State Department of Health (WA DOH) Food Safety Program
WA DOH Communicable Disease Epidemiology
Iowa Rapid Response Team (IA RRT)
AAR Development Team
State
FDA SEA-DO
WSDA Feed/Rapid Response Program
WSDA Food Safety Program
WA DOH Food Safety Program
WA DOH Communicable Disease Epidemiology
IA RRT

Attachment I – Example Exercise & Materials (Complex/HSEEP), IN RRT, "Insider Addition at the Campus Café"

- Attachment I-1: Controller-Evaluator Handbook
- Attachment I-2: Exercise Plan
- Attachment I-3: Situation Manual
- Attachment I-4: Master Scenario Events List
- Attachment I-5: Food Handler Actor Script
- Attachment I-6: Case Definition
- Attachment I-7: Complaint Interview Evaluation
- Attachment I-8: Group Exercise Generating Hypothesis
- Attachment I-9: Blueberry Crisp Recipe
- Attachment I-10: Campus Café Buffet Menu
- Attachment I-11: Invoice
- Attachment I-12: Shellfish Tags
- Attachment I-13: Completed Complaint Form 1
- Attachment I-14: Completed Complaint Form 2

Electronic copies can be obtained by going to FoodSHIELD or emailing OP.Feedback@fda.hhs.gov.

FoodSHIELD website information: https://www.foodshield.org/, RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Exercise, Training & Meeting Materials, Subfolder: IN RRT 2015 Exercise Materials - Insider Addition at the Campus Cafe.
Note that access to these documents is limited to personnel participating in the RRT Program.

INSIDER ADDITION AT THE CAMPUS CAFE

CONTROLLER/EVALUATOR HANDBOOK

The Controller/Evaluator (C/E) Handbook describes the roles and responsibilities of exercise controllers and evaluators, and the procedures they should follow. Because the C/E Handbook contains information about the scenario and about exercise administration, it is distributed to only those individuals specifically designated as controllers or evaluators; it should not be provided to exercise players. The C/E Handbook may supplement the Exercise Plan (ExPlan) or be a standalone document.

Rev. April 2013

HSEEP-DD07

EXERCISE OVERVIEW

Exercise Name	Insider Addition at the Campus Café
Exercise Dates	
Scope	These drills focus on response capabilities and collaboration between agencies during a foodborne illness outbreak utilizing procedures in place.
Mission Area(s)	Investigation response
Capabilities	Information Sharing Public Health Surveillance and Epidemiological Investigation
Objectives	Practice communication flow between jurisdictions during a Foodborne Outbreak Investigation according to procedures. Practice Foodborne Outbreak Investigation processes according to procedures.
Threat or Hazard	Foodborne illness intoxications where intentional contamination is suspected.
Scenario	Several students and staff members experienced (symptoms) shortly after eating at a popular campus food facility. The quantity and severity of cases prompts the LHDs to seek assistance from the state. Early in the investigation intentional contamination is suspected and law enforcement is brought into the investigation.
Sponsor	
Point of Contact	

GENERAL INFORMATION

EXERCISE OBJECTIVES AND CAPABILITIES

The following exercise objectives in Table 1 describe the expected outcomes for the exercise. The objectives are linked to capabilities, which are distinct critical elements necessary to achieve the specific mission area(s). The objectives and aligned capabilities are guided by elected and appointed officials and selected by the Exercise Planning Team.

Exercise Objective	Capability
Practice communication flow between jurisdictions during a Foodborne Outbreak Investigation according to procedures.	Information Sharing
Identify intra-jurisdictional stakeholders across public health, public safety, private sector, law enforcement, and other disciplines to determine information-sharing needs during an incident	Information Sharing
Practice Foodborne Outbreak Investigation processes according to procedures. (F2 P1-5)	Public Health Surveillance and Epidemiological Investigation
Conduct public health and epidemiological investigations according to procedures (F1/2 S1)	Public Health Surveillance and Epidemiological Investigation
Determine public health mitigation and actions to be recommended for the mitigation of the incident based upon data collected in the investigation and on applicable science-based standards (F3)	Public Health Surveillance and Epidemiological Investigation
Conduct investigation of disease and ensure coordination of investigation with jurisdictional partner agencies according to procedures.	Public Health Surveillance and Epidemiological Investigation

TABLE 1. EXERCISE OBJECTIVES AND ASSOCIATED CAPABILITIES

PARTICIPANT ROLES AND RESPONSIBILITIES

The term *participant* encompasses many groups of people, not just those playing in the exercise. Groups of participants involved in the exercise, and their respective roles and responsibilities, are as follows:

- **Players.** Players are personnel who have an active role in discussing or performing their regular roles and responsibilities during the exercise. Players discuss or initiate actions in response to the simulated emergency.
- **Controllers.** Controllers plan and manage exercise play, set up and operate the exercise site, and act in the roles of organizations or individuals that are not playing in

the exercise. Controllers direct the pace of the exercise, provide key data to players, and may prompt or initiate certain player actions to ensure exercise continuity. In addition, they issue exercise material to players as required, monitor the exercise timeline, and supervise the safety of all exercise participants.

- **Evaluators.** Evaluators evaluate and provide feedback on a designated functional area of the exercise. Evaluators observe and document performance against established capabilities.
- **Actors.** Actors simulate specific roles during exercise play, typically victims or other bystanders.
- **Observers.** Observers visit or view selected segments of the exercise. Observers do not play in the exercise, nor do they perform any control or evaluation functions. Observers view the exercise from a designated observation area and must remain within the observation area during the exercise. Very Important Persons (VIPs) are also observers, but they frequently are grouped separately.
- **Support Staff.** The exercise support staff includes individuals who perform administrative and logistical support tasks during the exercise (e.g., registration, catering).

Exercise Assumptions and Artificialities

In any exercise, assumptions and artificialities may be necessary to complete play in the time allotted and/or account for logistical limitations. Exercise participants should accept that assumptions and artificialities are inherent in any exercise, and should not allow these considerations to negatively impact their participation.

Assumptions

Assumptions constitute the implied factual foundation for the exercise and, as such, are assumed to be present before the exercise starts. The following assumptions apply to the exercise:

- The exercise is conducted in a no-fault learning environment wherein capabilities, plans, systems, and processes will be evaluated.
- The exercise scenario is plausible, and events occur as they are presented.
- Exercise simulation contains sufficient detail to allow players to react to information and situations as they are presented as if the simulated incident were real.
- Participating agencies may need to balance exercise play with real-world emergencies. Real-world emergencies take priority.

Artificialities

During this exercise, the following artificialities apply:

- Exercise communication and coordination is limited to participating exercise organizations, venues, and controllers.

EXERCISE LOGISTICS

SAFETY

Exercise participant safety takes priority over exercise events. The following general requirements apply to the exercise:

- A Safety Controller is responsible for participant safety; any safety concerns must be immediately reported to the Safety Controller. The Safety Controller and Exercise Director will determine if a real-world emergency warrants a pause in exercise play and when exercise play can be resumed.
- For an emergency that requires assistance, use the phrase **"real-world emergency."** The following procedures should be used in case of a real emergency during the exercise:
  - Anyone who observes a participant who is seriously ill or injured will immediately notify emergency services and the closest controller, and, within reason and training, render aid.
  - The controller aware of a real emergency will initiate the "real-world emergency" broadcast and provide the Safety Controller, Senior Controller, and Exercise Director with the location of the emergency and resources needed, if any.

SITE ACCESS

SECURITY

If entry control is required for the exercise venue(s), the sponsor organization is responsible for arranging appropriate security measures. To prevent interruption of the exercise, access to exercise sites is limited to exercise participants. Players should advise their venue's controller or evaluator of any unauthorized persons.

OBSERVER COORDINATION

Organizations with media personnel and/or observers attending the event should coordinate with the sponsor organization for access to the exercise site. Media/Observers are escorted to designated areas and accompanied by an exercise controller at all times. Sponsor organization representatives and/or the observer controller may be present to explain exercise conduct and answer questions. Exercise participants should be advised of media and/or observer presence.

POST-EXERCISE AND EVALUATION ACTIVITIES

DEBRIEFINGS

Post-exercise debriefings aim to collect sufficient relevant data to support effective evaluation and improvement planning.

Hot Wash

At the conclusion of exercise play, controllers facilitate a Hot Wash to allow players to discuss strengths and areas for improvement, and allow evaluators to seek clarification regarding player actions and decision-making processes. All participants may attend; however, observers are not encouraged to attend the meeting. The Hot Wash should not exceed 30 minutes.

Controller and Evaluator Debriefing

Controllers and evaluators attend a facilitated C/E Debriefing immediately following the exercise. During this debriefing, controllers and evaluators provide an overview of their observed functional areas and discuss strengths and areas for improvement.

Participant Feedback Forms

Participant Feedback Forms provide players with the opportunity to comment candidly on exercise activities and exercise design. Participant Feedback Forms should be collected at the conclusion of the Hot Wash.

Evaluation

After Action Report (AAR)

The AAR summarizes key information related to evaluation. The AAR primarily focuses on the analysis of capabilities, including capability performance, strengths, and areas for improvement. AARs also include basic exercise information, including the exercise name, type of exercise, dates, location, participating organizations, mission area(s), specific threat or hazard, a brief scenario description, and the name of the exercise sponsor and POC.

Improvement Planning

Improvement planning is the process by which the observations recorded in the AAR are resolved through development of concrete corrective actions, which are prioritized and tracked as a part of a continuous corrective action program.

After-Action Meeting

The After-Action Meeting (AAM) is a meeting held among decision- and policy-makers from the exercising organizations, as well as the Lead Evaluator and members of the Exercise Planning Team, to debrief the exercise and to review and refine the draft AAR and Improvement Plan (IP). The AAM should be an interactive session, providing attendees the opportunity to discuss and validate the observations and corrective actions in the draft AAR/IP.

Improvement Plan

The IP identifies specific corrective actions, assigns them to responsible parties, and establishes target dates for their completion. It is created by elected and appointed officials from the organizations participating in the exercise, and discussed and validated during the AAM.

SUBJECT MATTER EXPERT INFORMATION AND GUIDANCE

EXERCISE RULES

The following general rules govern exercise play:

- Real-world emergency actions take priority over exercise actions.
- Exercise players will comply with real-world emergency procedures, unless otherwise directed by the control staff.
- All communications (including written, radio, telephone, and e-mail) during the exercise will begin and end with the statement **"This is an exercise."**

PLAYERS INSTRUCTIONS

Players should follow certain guidelines before, during, and after the exercise to ensure a safe and effective exercise.

BEFORE THE EXERCISE

- Review appropriate organizational plans, procedures, and exercise support documents.
- Be at the appropriate site at least 30 minutes before the exercise starts. Wear the appropriate uniform and/or identification item(s).
- Sign in when you arrive.
- If you gain knowledge of the scenario before the exercise, notify a controller so that appropriate actions can be taken to ensure a valid evaluation.
- Read your Player Information Handout, which includes information on exercise safety.

DURING THE EXERCISE

- Respond to exercise events and information as if the emergency were real, unless otherwise directed by an exercise controller.
- Controllers will give you only information they are specifically directed to disseminate. You are expected to obtain other necessary information through existing emergency information channels.
- Do not engage in personal conversations with controllers, evaluators, observers, or media personnel. If you are asked an exercise-related question, give a short, concise answer. If you are busy and cannot immediately respond, indicate that, but report back with an answer as soon as possible.
- If you do not understand the scope of the exercise, or if you are uncertain about an organization's participation in an exercise, ask a controller.

Parts of the scenario may seem implausible. Recognize that the exercise has objectives to satisfy and may require incorporation of unrealistic aspects. Every effort has been made by the

exercise's trusted agents to balance realism with safety and to create an effective learning and evaluation environment.

- All exercise communications will begin and end with the statement **"This is an exercise."** This precaution is taken so that anyone who overhears the conversation will not mistake exercise play for a real-world emergency.
- Speak when you take an action. This procedure will ensure that evaluators are aware of critical actions as they occur.
- Maintain a log of your activities. Many times, this log may include documentation of activities that were missed by a controller or evaluator.

After the Exercise

- Participate in the Hot Wash at your venue with controllers and evaluators.
- Complete the Participant Feedback Form. This form allows you to comment candidly on emergency response activities and exercise effectiveness. Provide the completed form to a controller or evaluator.

Provide any notes or materials generated from the exercise to your controller or evaluator for review and inclusion in the AAR.

Controller Information and Guidance

Exercise Control Overview

Exercise control maintains exercise scope, pace, and integrity during exercise conduct. The control structure in a well-developed exercise ensures that exercise play assesses objectives in a coordinated fashion at all levels and at all locations for the duration of the exercise.

Exercise Control Documentation

Controller Package

The controller package consists of the C/E Handbook, activity logs, badges, and other exercise tools (e.g., MSEL) as necessary. Controllers must bring their packages and any additional professional materials specific to their assigned exercise activities.

Scenario Tools

The MSEL outlines benchmarks and injects that drive exercise play. It also details realistic input to exercise players, as well as information expected to emanate from simulated organizations (i.e., nonparticipating organizations or individuals who usually would respond to the situation). The MSEL consists of the following two parts:

- **Timeline.** This is a list of key exercise events, including scheduled injects and expected player actions. The timeline is used to track exercise events relative to desired response activities.
- **Injects.** An individual event inject is a detailed description of each exercise event. The inject includes the following pieces of information: scenario time, intended recipient, responsible controller, inject type, a short description of the event, and the expected player action.

CONTROLLER INSTRUCTIONS

BEFORE THE EXERCISE

- Review appropriate emergency plans, procedures, and protocols.
- Review appropriate exercise package materials, including the objectives, scenario, injects, safety and security plans, and controller instructions.
- Attend required briefings.
- Report to the exercise check-in location at the time designated in the exercise schedule, meet with the exercise staff, and present the Player Briefing.
- Be at the appropriate location at least 15 minutes before the exercise starts.
- Obtain, locate and test necessary communications equipment.

DURING THE EXERCISE

- Wear controller identification items (e.g., badge).
- Avoid personal conversations with exercise players.
- If you have been given injects, deliver them to appropriate players at the time indicated in the MSEL (or as directed by the Exercise Director). **Note:** If the information depends on some action to be taken by the player, do not deliver the inject until the player has earned the information by successfully accomplishing the required action.
- When you deliver an inject, notify the [Senior Controller] and note the time that you delivered the inject and player actions.
- Receive and record exercise information from players that would be directed to nonparticipating organizations.
- Observe and record exercise artificialities that interfere with exercise realism. If exercise artificialities interfere with exercise play, report it to the Exercise Director.
- Begin and end all exercise communications with the statement, **"This is an exercise."**
- Do not prompt players regarding what a specific response should be, unless an inject directs you to do so. Clarify information but do not provide coaching.

- Ensure that all observers and media personnel stay out of the exercise activity area. If you need assistance, notify the Exercise Director.
- Do not give information to players about scenario event progress or other participants' methods of problem resolution. Players are expected to obtain information through their own resources.

AFTER THE EXERCISE

- Distribute copies of Participant Feedback Forms and pertinent documentation.
- All controllers are expected to conduct a Hot Wash at their venue and, in coordination with the venue evaluator, take notes on findings identified by exercise players. Before the Hot Wash, do not discuss specific issues or problems with exercise players.
- At exercise termination, summarize your notes from the exercise and Hot Wash, and prepare for the Controller and Evaluator Debriefing. Have your summary ready for the Exercise Director.

Controller Responsibilities

The following table details controller responsibilities. For controller assignment details, see [Appendix G].

Controller Responsibilities
Exercise Director
• Oversees all exercise functions • Oversees and remains in contact with controllers and evaluators • Oversees setup and cleanup of exercise, and positioning of controllers and evaluators
Senior Controller
• Monitors exercise progress • Coordinates decisions regarding deviations or significant changes to the scenario • Monitors controller actions and ensures implementation of designed or modified actions at the appropriate time • Debriefs controllers and evaluators after the exercise • Oversees setup and takedown of the exercise
Safety Controller
• Monitors exercise safety during exercise setup, conduct, and cleanup • Receives any reports of safety concerns from other controllers or participants
Public Information Officer (PIO)
• Provides escort for observers • Provides narration and explanation during exercise events, as needed • Performs pre-exercise and post-exercise public affairs duties • May act as media briefer and escort at exercise site • Serves as safety officer for his or her site
Venue Controller
• Issues exercise materials to players • Monitors exercise timeline • Provides input to players (i.e., injects) as described in MSEL • Serves as safety officer for his or her site

Table 2. Controller Responsibilities

EVALUATOR INFORMATION AND GUIDANCE

EXERCISE EVALUATION OVERVIEW

Exercise evaluation assesses an organization's capabilities to accomplish a mission, function, or objective. Evaluation provides an opportunity to assess performance relative to exercise objectives and capabilities. Evaluation is accomplished by the following means:

- Observing the event and collecting supporting data;
- Analyzing collected data to identify strengths and areas for improvement; and
- Reporting exercise outcomes in the AAR.

EVALUATION DOCUMENTATION

EVALUATOR PACKAGE

The evaluator package contains this C/E Handbook and other items as necessary. Evaluators should bring the package to the exercise. They may reorganize the material so information that is critical to their specific assignment is readily accessible. Evaluators may bring additional professional materials specific to their assigned activities.

AFTER ACTION REPORT/IMPROVEMENT PLAN

The main focus of the AAR is the analysis of capabilities. For each capability exercised, the AAR includes a rating of how the exercise participants performed, as well as strengths and areas for improvement.

Following completion of the draft AAR, elected and appointed officials confirm observations identified in the AAR, and determine which areas for improvement require further action. As part of the improvement planning process, elected and appointed officials identify corrective actions to bring areas for improvement to resolution and determine the appropriate organization with responsibility for those actions. Corrective actions are consolidated in the IP, which is included as an appendix to the AAR.

EVALUATOR INSTRUCTIONS

GENERAL

- Avoid personal conversations with players.
- Do not give information to players about event progress or other participants' methods of problem resolution. Players are expected to obtain information through their own resources.

BEFORE THE EXERCISE

- Review appropriate plans, procedures, and protocols.
- Attend required evaluator training and other briefings.

- Review appropriate exercise materials, including the exercise schedule and evaluator instructions.
- Review any supporting materials for your area of responsibility to ensure that you have a thorough understanding of the capabilities you are assigned to evaluate.
- Report to the exercise check-in location at the time designated in the exercise schedule, and meet with the exercise staff.
- Obtain or locate necessary communications equipment, and test it to ensure that you can communicate with other evaluators and the Exercise Director.

During the Exercise

- Wear evaluator identification items (e.g., badge).
- Stay in proximity to player decision-makers.
- Use the MSEL to document performance relative to exercise objectives and capabilities.
- Document performance relative to exercise objectives and capabilities.
- Your primary duty is to document performance of capabilities. After the exercise, that information will be used to determine whether the exercise capabilities were effectively met and to identify strengths and areas for improvement.

After the Exercise

- Participate in the Hot Wash, and take notes on findings identified by players. Before the Hot Wash, do not discuss specific issues or problems with participants. After the Hot Wash, summarize your notes and prepare for the Controller and Evaluator Debriefing. Have your summary ready for the Lead Evaluator.
- Complete and submit any requested documentation to the Lead Evaluator at the end of the exercise.

Exercise Evaluation

Terminology

- **Capabilities:** The distinct critical elements necessary to achieve a specific mission area (e.g., prevention).

Documenting Observations

Observation notes should include *if* and *how* outcomes were met. Evaluators should also note if an obvious cause or underlying reason resulted in players not performing to expectations relative to exercise objectives and capabilities. However, the evaluators should not include recommendations. As part of the after-action and improvement planning processes, elected and appointed officials will review and confirm observations documented in the AAR and determine areas for improvement requiring further action.

Placement and Monitoring

Evaluators should be located so they can observe player actions and hear conversations without interfering with those activities. In certain conditions, more than one evaluator may be needed in a particular setting or area.

For specific evaluator assignments, see [Appendix G].

For exercise site maps highlighting key locations, see [Appendix D].

APPENDIX A: EXERCISE SCHEDULE

Time	Personnel	Activity	Location
November 10, 2015; 2:00pm			
1400 - 1445	Controllers, evaluators, and exercise staff	Controller and Evaluator Briefing Set up and walkthrough	Ivy Tech Conference Room
November 12, 2015			
0730 - 0800	Controllers and exercise staff	Check-in for final instructions and communications check	Ivy Tech Main Conference Room
0800-0820	VIPs and selected exercise staff	VIP Controller Briefing, Controllers provide player briefs	Ivy Tech Main Conference Room
0830 - 1200	All	Exercise starts	Ivy Tech Main Conference Room
1200 - 1300	All	Lunch Break	Ivy Tech Main Conference Room
1300 - 1330	All	Exercise Resumes, Four Groups Assigned, and Groups 1, 2, 3, and 4 Move to Designated Areas (See Appendix F for Group Details)	Ivy Tech Main Conference Room
1330 - 1445	All	Gp 1+2: Communication Drill & Press Release Drill / Gp 3+4: Environmental Assessment & Sample Collection Demonstration	Ivy Tech Main Conference Room / Kitchen Penthouse
1445-1500	All	Report to Designated Areas	In Transition
1500 - 1615	All	Gp 3+4: Communication Drill & Press Release Drill / Gp 1+2: Environmental Assessment & Sample Collection Demonstration	Ivy Tech Main Conference Room / Kitchen Penthouse
1615-1630	All	Return to Main Conference Room	In Transition
1630-1645	All	Exercise paused – Conclusion and Summary	Ivy Tech Main Conference Room
1645-1715	Controllers, evaluators, and exercise staff	Controller and Evaluator Debriefing	Ivy Tech Main Conference Room
November 13, 2015			
0730-0800	Controllers and exercise staff	Check-in for final instructions and communications check	Ivy Tech Main Conference Room
0800-0820	Controllers and exercise staff	Controller/Evaluator Briefing	Ivy Tech Main Conference Room

Time	Personnel	Activity	Location
0800-0830	All	Member Arrival, Check-in, and Free Discussion	Ivy Tech Main Conference Room
0830-0840	All	Greetings	Ivy Tech Main Conference Room
0840-0900	All	Ivy Tech Discusses Culinary Arts Center	Ivy Tech Main Conference Room
0900-0915	All	Summary of where we left off and what we will do today	Ivy Tech Main Conference Room
0915	All	Exercise Starts	Ivy Tech Main Conference Room
0915-0945	All	Law Enforcement Drill	Ivy Tech Main Conference Room
1030-1130	All	Hot Wash / Panel Discussion	Ivy Tech Main Conference Room
1130	All	Exercise Ends	Ivy Tech Main Conference Room
1130	All	Conclusions / Evaluations	Ivy Tech Main Conference Room
TBD			
TBD	Controllers, Evaluators and Observers	Controller and Evaluator After Action Review	TBD

APPENDIX B: TASK FORCE MEMBERS

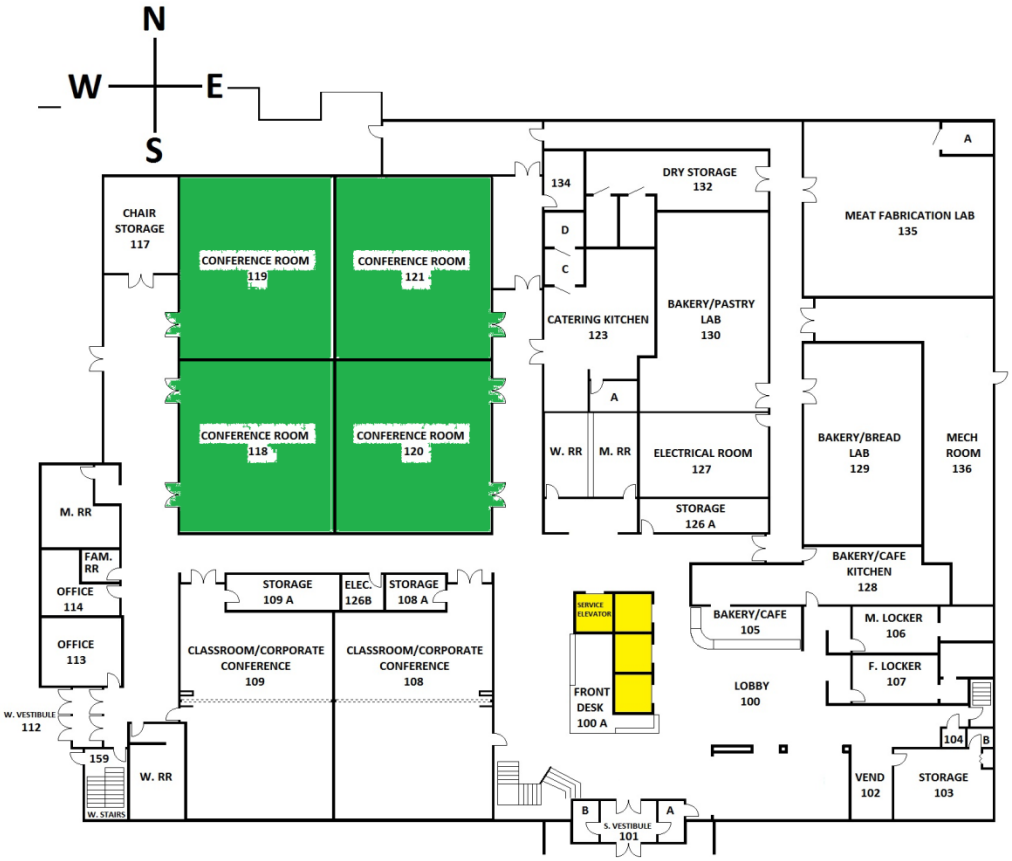
APPENDIX C: COMMUNICATIONS PLAN

Exercise staff will communicate with each other using the mobile phone numbers listed below during the exercise:

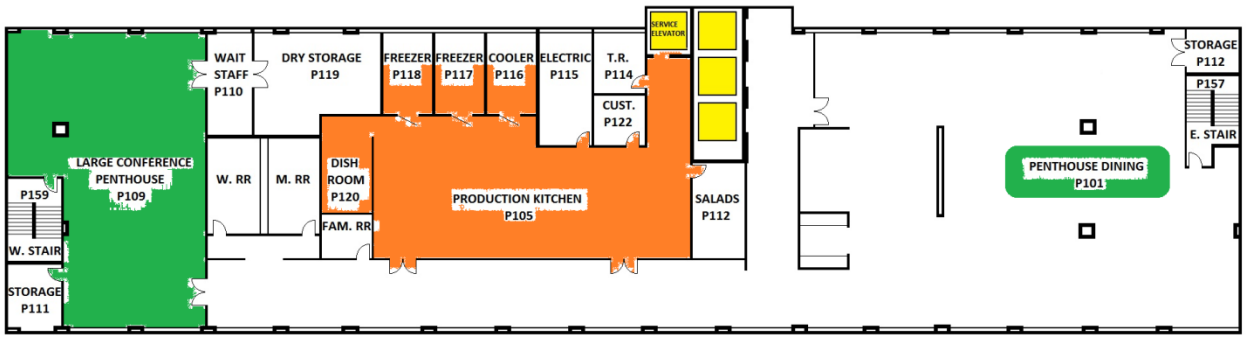
Name	E-mail	Mobile Phone	Position

APPENDIX D: EXERCISE SITE MAPS

Figure D.1: Map to Conference Rooms

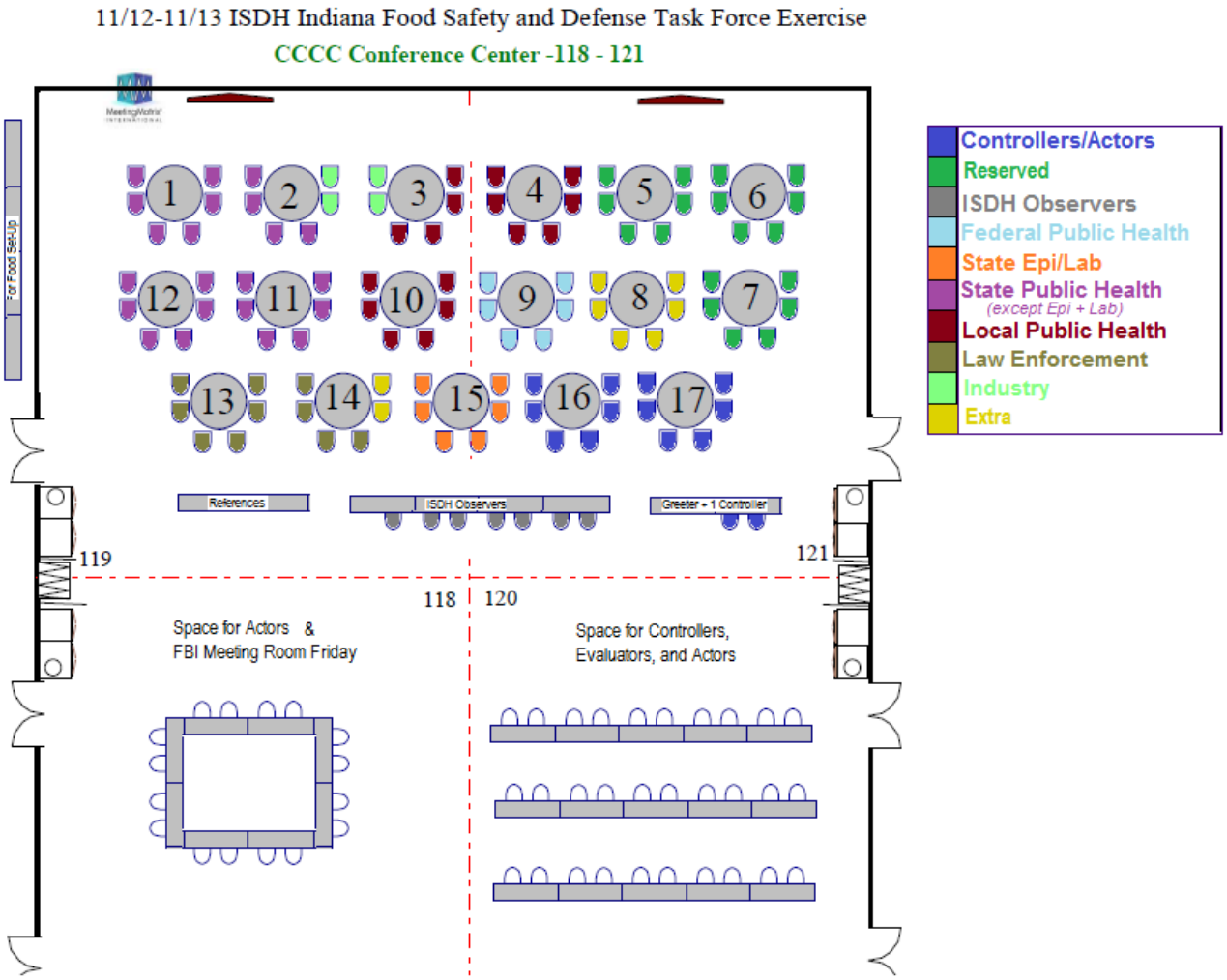


First Floor Meeting Rooms (Shaded Green)



Penthouse Meeting and Dining Rooms (Shaded Green)

Penthouse Kitchen (Shaded Orange)


11/12-11/13 ISDH Indiana Food Safety and Defense Task Force Exercise
CCCC Conference Center -118 - 121
For Food Set-Up
1
2
3
4
5
6
12
11
10
9
8
7
13
14
15
16
17
References
ISDH Observers
Greeter - 1 Controller
119
121
118
120
Space for Actors &
FBI Meeting Room Friday
Space for Controllers,
Evaluators, and Actors
Controllers/Actors
Reserved
ISDH Observers
Federal Public Health
State Epi/Lab
State Public Health
(except Epi + Lab)
Local Public Health
Law Enforcement
Industry
Extra

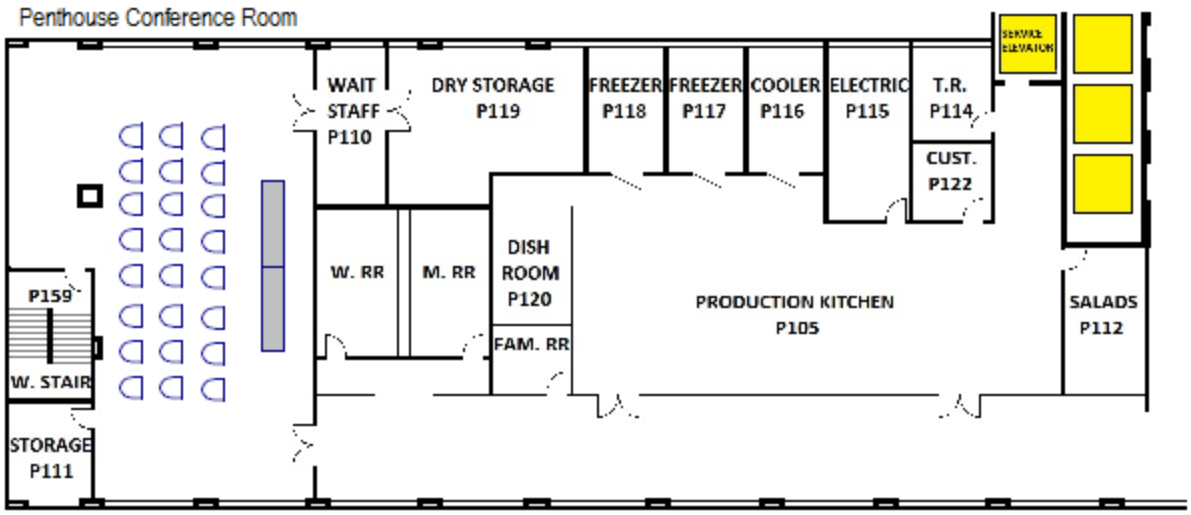

Penthouse Conference Room
WAIT STAFF P110
DRY STORAGE P119
FREEZER P118
FREEZER P117
COOLER P116
ELECTRIC P115
T.R. P114
CUST. P122
SERVICE ELEVATION
W. RR
M. RR
DISH ROOM P120
FAM. RR
PRODUCTION KITCHEN P105
SALADS P112
P159
W. STAIR
STORAGE P111

Figure D.2: Picture of Conference Rooms

1st Floor Rooms

Penthouse Rooms

Figure D.3: Penthouse Kitchen

APPENDIX E: EXERCISE SCENARIO

SCENARIO

THERE ARE SEVERAL STUDENTS AND STAFF MEMBERS EXPERIENCING VOMITING, DIARRHEA, MUSCLE TWITCHING AND WEAKNESS SHORTLY AFTER EATING AT A POPULAR CAMPUS FOOD FACILITY. THE CASES BEGIN TO EXPERIENCE WORSENING SYMPTOMS (ALTERED MENTAL STATES AND IRREGULAR HEART RHYTHM ETC.) AND TWO ARE ADMITTED TO THE ICU AFTER EXPERIENCING SEIZURES AND COMA. THE QUANTITY AND SEVERITY OF CASES PROMPTS THE LOCAL HEALTH DEPARTMENT TO SEEK ASSISTANCE FROM STATE AND FEDERAL PARTNERS. LATER INTENTIONAL CONTAMINATION IS SUSPECTED AND LAW ENFORCEMENT IS BROUGHT INTO THE INVESTIGATION.

MAJOR EVENTS

ALL PARTICIPANTS – MAIN CONFERENCE ROOM

(Exercise Start Point 12 November 2015)

12 Nov 15; 0730: Controllers, evaluators, and exercise staff Check-in

12 Nov 15; 0800: Member arrival, check-in, and free discussions

Seating Arrangements: Divide groups into equal representations of each discipline and have them seated at round tables. Assign seating by agency/discipline using the registration list. Identify groups that are present before beginning the exercise.

12 Nov 15; 0830: Greetings and Summary of the Day

- - - - - - - - - - - - - - - - (Scenario Day 1: November 12, 2015) - - - - - - - - - - - - - - - -

(01) 12 Nov 15; 0840: Scenario Details Given – Controller: *Add Controller Initials*
Around 2pm a Local Health Department (LHD) Food Protection Program receives a call from **one student** who reported experiencing ongoing symptoms of nausea, diarrhea, and cramping approximately 1.5 hours after eating from the buffet at the Campus Cafe. An Agency Complaint Form was completed; the complainant had no leftovers available for collection. The complainant reported eating the roast beef, pulled pork, green beans, and salad.

Discussion:

(ENV) Would you investigate one complaint? Why or why not? What actions would you consider?

(EPI) If the complaint was reported to the public health nurse or epidemiologist would you investigate this complaint? Why or why not? Would you refer it back to the food program since it was a food establishment complaint? What actions would you consider?

This may be dependent upon the jurisdiction. If the LHD does take the complaint they should collect a 72 hour food history.

(LAB) What involvement at this point would you have?

Probably very little involvement at this point unless left over-food is available and they decide to do an analysis.

(IND) What if the complaint was reported back to the establishment, what actions would you take? Do any of the industry representatives have a process for receiving complaints? If so what does it entail?

Often times the industry will receive and investigate complaints within their organizations, they may investigate and if issues are identified make changes as needed.

(02) 12 Nov 15; 0900: Complaint Interview Drill - Controller: *Add Controller Initials*

Drill Instructions: Utilize the FPP Complaint Interview Form and food history. Identify an interviewer, complainant, and observer in each group. Groups must have a minimum of three people.

(03) 12 Nov 15; 0920: Scenario Details Given
Around 3pm "an hour later" **a second call** is received from another student who reported experiencing ongoing symptoms of nausea, vomiting, diarrhea, and abdominal cramping approximately 1 hour after eating from the buffet at the Campus Cafe. An Agency Complaint Form was completed; again no leftovers were available from this complainant. The complainant reported eating pulled pork, beef brisket, salad, and blueberry crisp. However, he stated that he only ate a bite of the blueberry crisp because it tasted funny.

Discussion:

(ENV/EPI) Now that two complaints have been received, is this considered an outbreak? What actions should be taken for the complaint investigation and who should be involved at this point? Assuming that the Campus Café was the cause of the illness, what pathogens could be potential causes of the illness?

Most jurisdictions would respond at this point since they have two complaints that both share the same common exposure (making it an outbreak). They may want to focus on shared food or conduct a 72 hour food history since they may share other common exposures since they are both students at the same university. It is a short incubation period and would most likely be attributed towards an entero-toxin or chemical exposure.

(LAB) What involvement at this point would you have? What would you do to prepare for possible incoming food/clinical samples?

It would not be a bad idea to give them a heads up at this point, although with two complaints they should not be overly burdened with food or clinical samples. This would provide time for the lab to make media and manage new sampling into routine samples.

(IND) Now that two complaints have been received, what potential actions would you take? Do any industry representatives have foodborne illness outbreak procedures, contact lists, or other preparations in place?

This will be interesting to see how many industry members have developed protocols when they become aware of a potential foodborne illness and if they have POCs in their regulatory agencies to contact.

(04) 12 Nov 15; 0940: Scenario Details Given – Controller: *Add Controller Initials*
A food inspector from the LHD arrived at the Campus Café at 4:00pm to conduct an environmental assessment of the establishment. At the time of the incident the buffet line served pork loin, roast beef, pulled pork, oysters, salad, green beans, blueberry crisp dessert, pork & beans, pork cutlets, pasta noodles, and broasted chicken; and no other foods were provided to patrons. The food inspector observed no indication of time/temperature abuse, bare hand contact, improper chemical storage, or other practices that may have attributed to the illness. Several samples from the buffet were collected to include the pulled pork, salad, and blueberry crisp. The establishment was also asked to hold the buffet line items that were served that day in case additional samples were required.

Discussion:

(ENV/EPI/LAB) Should other samples have been collected? What laboratory analysis should be requested? What additional actions should be considered?

Since we are dealing with such a short incubation period, we would probably be looking at a preformed toxin, natural toxin, or chemical exposure. The analysis requested should include staph organism/toxin and b. cereus organism. With only two complaints it would be difficult to choose an "implicated food" so we would use what we know about those types of illnesses to chose possible food vehicles. The salad and blueberry crisp are reasonable due to possible pesticide contamination. You could also look into improperly held and refrigerated meats, potatoes, pasta's and such for staphylococcus and b. cereus preformed toxins. Clinical samples may also be requested for the two cases and analyzed for staphylococcus and bacillus cereus bacteria and preformed toxins.

(IND) What actions should the implicated establishment take while the inspector is at the establishment? How and what would you communicate with your employees and/or higher management?

Provide information and documentation to the inspector so that potential problems can be identified and corrected. Holding any ingredients or foods while the regulatory authority continues its investigation, ensure that these products are not used, or held improperly etc.

(05) 12 Nov 15; 1000: Scenario Details Given – Controller: *Add Controller Initials*
Around 2pm the Special Care Hospital saw **10 patients** who reported experiencing nausea, vomiting, diarrhea and abdominal cramping approximately 30 minutes to one hour after eating from the buffet at the Campus Cafe. Due to the amount of people who reported eating at the same location, the treating physician contacted the Public Health (PH) Nurse at the LHD and reported the incident on **Wednesday November 12, 2015 around 4:15pm.**

Meanwhile the College Clinic also saw **10 students** with similar symptoms around 3pm. Several had also reported additional symptoms to include muscle twitching and weakness. These symptoms also appeared approximately 30 minutes to one hour after eating at the Campus Café. Due to the amount of people who ate at the same location and experienced similar symptoms, the treating physician contacted the PH Nurse at the LHD and reported the incident on **Wednesday November 12, 2015 around 4:30pm.**

Discussion:

Note: Do not go to in-depth into the environmental assessment or mitigation actions during this section (05-10) because that will be covered later during the Env Assessment portion of the exercise.

(ENV/EPI) Now that we have 20 individuals reported to the LHD PH Nurse; and 2 individuals reported to the EHS Food Protection Program who experienced similar symptoms after eating at the Campus Café how would this change your view of the situation (agents/associated risk factors)? What additional actions should be considered? Do you think that the PH Nurses and Food Protection partners would be talking? What information should be provided to the establishment?

Now that we have 22 cases all experiencing similar symptoms and incubation periods after eating at the same food establishment we are likely looking at an outbreak. Additionally, we are seeing additional symptoms that are more neurological in nature combined with the short incubation period which makes sense with a toxin/chemical agent.
This would make investigators look into food items that may contain chemicals/pesticides (produce or foods or beverages that may come in contact with chemicals) and preformed (RTE foods, meats, pastas, potatoes), environmental and natural toxins (oysters/mushrooms). Partners would be talking and sharing information at this point. You may contact the establishment to inform them that they are implicated in an outbreak and discuss possible actions.

(LAB) Now that there are 22 individuals involved in the outbreak how would this change your involvement? What clinical and food laboratory testing should be accomplished? What actions would you take at this time?

The Laboratory could conduct staphylococcus and bacillus cereus clinical tests. The lab could also conduct these tests on the food samples and look for those toxins (staph) as well. A VOC or pesticide analysis may also be requested to identify any other toxins or chemical agents in the food.

(IND) Once you are aware of the significantly higher number of cases; what actions would you take? What information would you collect so that it is available if requested?

At this point the industry representatives should be cooperating with their regulatory authority and may decide to do additional actions like an internal investigation or a voluntary closure until they determine what caused the illness.

- - - - - - - - - - - - - - - - (Scenario Day 2: November 13, 2015) - - - - - - - - - - - - - - - -

(06) 12 Nov 15; 1020: Scenario Details Given – Controller: *Add Controller Initials*
First thing in the morning the LHD PH Nurse requests all of the case records from the hospital; and was informed that that shortly after being released several of the cases returned to the hospital after experiencing confusion, dizziness, urinary incontinence, heart palpitations, and trouble breathing. The patients were found to have wheezing and coughing, pinpointed pupils, drowsiness, and confusion. Two of the patients began experiencing weakness, pulmonary edema and respiratory distress and were intubated due to pulmonary reasons. The two were admitted to the critical care unit; while the others were kept overnight for observation. Tests completed included a CBC, CMP, CXR, ABG, and a toxicology screen.

The PH Nurse communicates the incident with their Food Protection office and they share information regarding the recent complaints from the Campus Café. The LHD also notifies the State Department of Health and informs them of the situation. The state contacts the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to report this on-going event.

Discussion:

(ENV/EPI/LAB)What do these additional symptoms suggest? What additional actions should be considered? Now that several cases reported serious symptoms, would temporarily closing the establishment be a consideration? What experts would you contact when dealing with a toxin or chemical exposure?

These additional symptoms are not suggestive of common preformed toxins like staph or b. cereus. Investigators may look into seeing if natural or environmental toxins have symptoms that are consistent with what is being reported. Additionally, chemicals or pesticides could be the cause of the illnesses as well. Experts from the state toxicologists, poison control, and toxicology specialists from the CDC, FDA may be contacted to assist with the investigation.

(IND) Now that the establishment has been implicated in an outbreak involving several serious cases requiring hospitalization, how should they respond? How and what would you communicate with your employees and/or higher management?

Industry should comment on what policies and procedures they have in place if any to respond to an outbreak. ***We will have a copy of the CIFOR Industry Guidelines as a reference on the reference table.*** *Again industry may decide to do an internal investigation, hold any of the implicated products, voluntarily close, or maybe conduct training with employees.*

(07) 12 Nov 15; 1040: Case Definition Drill – Controller: *Add Controller Initials*

Drill Instructions: Identify an epidemiologist/PH Nurse for each section and have them lead in the development of a case definition. A worksheet will be provided that assists in its development. Have groups write their responses on the paper provided and present to the group.

(08) 12 Nov 15; 1100: Scenario Details Given - Controller: *Add Controller Initials*
The PH Nurse began interviewing all **20 cases**, as well as the friends/family members of the **two individuals** that were unable to be interviewed due to extreme symptoms. The cases reported eating from a buffet line that served pork loin, roast beef, steamed oysters, pulled pork,

salad, green beans, blueberry crisp dessert, pork & beans, pork cutlets, pasta noodles, and broasted chicken.

Symptoms initially include nausea, vomiting, diarrhea, abdominal cramping and some mentioned increased salivation. Symptoms then progressed to confusion, pinpointed pupils, muscle twitching, dizziness, heart palpitations, and trouble breathing. In two of the cases symptoms developed to pulmonary edema and respiratory distress.

While interviewing the cases many individuals reported experiencing a funny (garlic/solvent-like) taste and smell while eating the fruit crisp. Most individuals stopped eating the fruit crisp after not liking the taste. However, friends/family members of the patients with the more severe symptoms stated that their relatives had eaten more
of the dessert.

The LHD Food Inspector contacted the Campus Café and requested the list of patrons that ate lunch that day. The Campus Café keeps record of student/staff when they purchase food. A symptom/food history survey was developed and sent to all of the names on the patron list**. The survey was completed by 80 students and identified an additional five ill individuals that hadn't been seen by a medical provider making 27 ill cases in total.**

Discussion:

(ALL) What are your thoughts on the situation? What additional actions should be considered? What other local, state, federal agencies would you now involve in the investigation? Would a press release be appropriate at this point?

These symptoms are moving further away from appearing to be preformed toxins. Look into natural toxins, pesticides, and chemicals. At this point a LHD should request involvement from state and federal partners due to the severity of the illnesses. Also, since in many cases medical treatment has been required a press release may be needed.

- - - - - - - - - - - - - - - - (Scenario Day 3: November 14, 2015) - - - - - - - - - - - - - - - -

(09) 12 Nov 15: 1120: Scenario Details Given - Controller: *Add Controller Initials*
After receiving interview and survey results from all of the staff and students that ate lunch at the Campus Café the following epidemiological study and symptoms percentages were identified. Since the students and staff are a well defined group the Public Health Nurse decided to do a Cohort Study by determining the attack rates and relative risk.

Table E1: Food Specific Attack Rates

Food Item	Ate This Food			Did not eat this Food			
	Ill	Well	A.R.	Ill	Well	A.R.	R.R.
Pork Loin	17	20	45.9	8	35	18.6	2.5
Pulled Pork	11	33	25	14	22	38.8	0.64
Pork Cutlet	6	30	16.6	19	25	43.1	0.38
Pork and Beans	2	13	13.3	23	42	35.3	0.37
Roast Beef	8	12	40	17	43	28.3	1.41
Steamed Oysters	15	8	65.2	8	49	14	4.66
Broasted Chicken	15	45	25	10	10	50	0.5
Pasta Noodles	2	12	14.2	23	43	34.8	0.4
Green Beans	16	30	34.7	9	25	26.4	1.31
Salad	12	45	21	13	10	56.5	0.37
Blueberry Crisp	22	12	64.7	3	43	6.5	9.95

A.R. = Attack Rate R.R. = Relative Risk

Table E2: Symptoms of Cases (n=27)

Symptom	Number	Percent (%)
Nausea	23	85
Vomiting	18	66
Diarrhea	21	77
Abdominal cramps	21	77
Dizziness	20	74
Pinpointed Pupils	20	74
Muscle Twitching	10	37
Mental Confusion	6	22
Trouble Breathing	5	18
Heart Palpitations	3	11
Pulmonary Edema	2	7
Respiratory Distress	2	7

Note: Increased salivation was not included here. Perhaps it was thought to be inconsequential?

(10) 12 Nov 15; 1130: Hypotheses Drill – Controller: *Add Controller Initials*

Drill Instructions: Use available information to make an educated guess about the cause and source of the outbreak. This will help direct immediate control measures, focus studies, and

determine partners. Use the worksheet provided that explains how to develop a hypothesis. Use the large post it paper to present your hypotheses.

Currently the two foods of interest would be the steamed oysters and the blueberry crisp. At this point some type of toxin or chemical contamination involving the seafood or the blueberries. This could be due to shellfish poisoning related t o the oysters or could be chemical contamination of a food at the establishment or before arriving.

Note: no beverages were included in the epidemiological study; beverages from tap have been contaminated in the past due to contamination from cleaning chemicals.

12 Nov 15; 1200 - 1300: Lunch

(11) 12 Nov 15; 1300: Scenario Details Given *(See Communication Drill):* Controller: The local health authorities and the State Health Department hold a call with all involved jurisdictions. County and university health officials report the possible link to the Campus Cafe, due to the cluster from the clinic and the hospital. Experts agree that due to the rapid onset of acute symptoms that are atypical of bacterial foodborne illness; a chemical agent or toxin may be the cause, but it is unknown at this time.

Local Health Department Food Safety Inspectors contact the Campus Cafe management and indicate a ***possible*** association with their restaurants. The Campus Cafe management begins an internal investigation. The story appears on the news detailing the incident.

Discussion:

(IND) What investigation actions would you take if this was occurring at your establishment?

Industry members should investigate the facility, employees, and product. They should also be in contact with their regulatory authorities, and if needed the media. They should be communicating with their own employees in regards to the situation and possible actions. The facility should also be considering mitigation and control actions to include facility closure, product hold/remove/replace, and employee training.

(12) 12 Nov 15; 1310: Environmental Assessment Plan of Action Drill – Controller:

Drill Instructions: Review current information on the outbreak and determine investigation actions. Use the Environmental Assessment Generic form for guidance and complete the attached worksheet. Establish what individuals need to be involved in the environmental assessment. Discuss individual tasks and identify who will interview, collect samples, conduct food flows, and collect documents. Determine potential causes and sources of contamination. Specify the targeted food, the sampling plan, interview questions, and the documents that should be collected.

Review the known information regarding the outbreak, the implicated foods, agents, and hypothesis. Teams may also request information on the regulatory history of the Campus Café. Establish the team, assign tasks, determine focus, and prepare for the environmental assessment drill. Players may use their own reference, or references provided on the reference table. The plan of action should focus on blueberry crisp/oysters and a chemical agent.

12 Nov 15; 1330: Concurrent Environmental Assessment/Sample Demonstration and Communication/Press Release Drills (See Attachment F)

Concurrent Drill Instructions: Separate the players into four groups of equal numbers containing equal representation from each discipline (as much as possible). Groups 1 and 2 report to the main conference room, Groups 3 and 4 report to the penthouse kitchen or meeting room. Groups in the penthouse will either conduct the Environmental Assessment drill or the Sample Collection Demonstration; they will switch places half way through. The group in the main conference room will participate in a Communication and Press release drill. See Appendix F: Day 1 – 1330 Break out Flow Chart for group details. A brief summary is listed below:

Group 1 + Group 2
1330: Main Conference Room – Communication & Press Release Drills
1445: 15 Minute Break – Groups Move to Designated Areas
1500: Penthouse – Environmental Assessment Drill & Sample Collection Demonstration
[at 1500: Group1 to kitchen, Group 2 to penthouse meeting room; at 1405: switch]

Group 3 + Group 4
1330: Penthouse – Environmental Assessment Drill & Sample Collection Demonstration
[at 1330: Group 3 to kitchen, Group 4 to penthouse meeting room; at 1535: switch]
1445: 15 Minute Break – Groups Move to Designated Areas
1500: Main Conference Room – Communication & Press Release Drills

(13/14) 12 Nov 15; 1330/1500: Communication / Press Release Drill: Controller: *Add Controller Initials*; Actor: *Add Actor Initials* - Main Room

1. Communication Drill Instructions (45 min): Have groups separate by discipline/agency and have an empty table in the center of the room. Have each group decide what information they will provide and who will be their spokesperson. A table used to simulate a conference call will be at the center of the room and the state agency (who will be coordinating the conference call) will help decide what agencies will be invited to the table. JJ will play the management for the Campus Café.

2. Press Release Drill (30 min): Individuals not participating in the conference call will work on developing a press release and/or other responses to address increased concern among the community.

(15/16) 12 Nov 15; 1330/1410/1500/1540: Environmental Assessment/Sample Collection Drill: **Controllers:** *Add Controller(s) Initials***; and Actor** *Initials* **-** Penthouse 13th Floor

1. **Environmental Assessment Drill (25 min):** Controllers: *Add Controller Initials*; Actor *Add Actor Initials* - Begin with a discussion regarding the environmental assessment. Perform tasks assigned at the plan of action drill. At least four food handlers and *actor* will play kitchen management for the Campus Café identifiable by actor badges.

    - Food flow diagram of the implicated foods
    - Gather documentation (SOPs, shipment receipts, oyster tags etc.)
    - Look for evidence of chemical contamination
    - Sample collection – identify what foods would be collected?
    - Interview management and staff members (intentional contamination becomes evident).
    - Law Enforcement will then begin their investigation by interviewing staff.

1a. Discuss EA Findings (10 min): During the environmental assessment samples were collected, observations were made regarding chemical storage, records were collected, and a food flow diagram was created in regards to the blueberry crisp. While interviewing a food handler it was discovered that another employee was a student currently being removed from his *select admit* program for cheating. This employee was heard mentioning that he/she would contaminate the food to get back at the university. At this point law enforcement should be brought in and they will start their own investigation by interviewing the food handler that had originally reported the information. The food handler that made the statement was not present at the time of the environmental assessment.

Discussion:

(ENV/EPI) Now that there is suspicion of an intentional contamination would law enforcement be contacted? If so who would you contact? Does your jurisdiction have procedures and contact lists to follow? How would you notify law enforcement without putting yourself in danger or alerting the suspect?

Law enforcement should be contacted and the names and contact information should be listed in procedures and contact lists. Inspectors should be mindful about not placing themselves in a situation where they would confront the suspect or inform the suspect of their suspicions.

(IND) Now that there is suspicion of intentional contamination what actions would you consider? Do you have food defense procedures and/or training that can be utilized?

Many manufacturing firms have food defense plans in place, smaller retail establishments may or may not. This would be a great time to assess who has established procedures and/or training that can be used.

(LAW) Since you have been now included in the investigation what actions would you consider? Once a suspect has been identified how would you respond?

They would likely respond by going to the establishment and interviewing staff members at the campus café. They would also coordinate with public health investigators to gather information on cases, implicated foods, food samples, and staff interviews implicating intentional contamination. They would also gather evidence to include the foods and the pesticide used to contaminate the food.

2. **Sample Demonstration (25 min.):** Controllers: *Add Controller Initials* - A composite sample will be demonstrated; paperwork, packaging, and transport information will also be presented. The laboratory will also provide some information on clinical samples and discuss what analyses may have been completed during this investigation. *Controller* will bring sampling supplies and coordinate with the other *controller*.

2a. Discuss Sample Demonstration (10 min): This is where players can ask questions regarding sample collection, storage, packaging and transportation. Ask industry representatives if they have procedures to keep potential food samples for investigators to collect when an outbreak is suspected. Law enforcement representatives should pay special attention to sample collection since it will be important evidence.

12 Nov 15; 1615: Break

12 Nov 15; 1630: Pause Exercise – Conclusion and Summary

Scenario Continues 13 November 2015

13 Nov 15; 0730: Controllers, evaluators, and exercise staff Check-in

13 Nov 15; 0800: Member arrival, check-in, and free discussions

13 Nov 15; 0830: Greetings

13 Nov 15; 0840: Ivy Tech to discuss educational offerings at the Culinary Arts Center

13 Nov 15; 0900: Summary of where we left off and what we'll do today

- - - - - - - - - - - - - - - - (Scenario Day 4: November 15, 2015) - - - - - - - - - - - - - - - -

(17) 13 Nov 15; 0910: Law Enforcement Drill (40 min): Controller: *Add Controller Initials*

Law Enforcement Drill Instructions: A law enforcement representative/intern will be acting as the suspect while the law enforcement player(s) interview the suspect. While interviewing the suspect, the student admits to contaminating the blueberry crisp with a pesticide because he was angry after being kicked out of the university for cheating. The pesticide was labeled as

Dursban, which is an organophosphate pesticide that was purchased at a local agricultural store. The pesticide was collected as evidence and the information was provided to investigatory partners as well as the medical staff that has been treating the cases.

Law Enforcement Discussion: A presentation will be conducted regarding personal safety and important points to consider while assisting law enforcement investigations when intentional contamination becomes apparent. All controllers will also provide insight into working and communicating with law enforcement agencies during an intentional contamination incident.

Discussion:

(All) Discuss what you would do with the establishment during the criminal investigation.

Now it has turned into a criminal investigation the establishment may be considered a crime scene. Before reopening investigators may have to decide what actions are to be taken whether it be to throw out just the implicated foods or all of the foods before reopening.

(18) 13 Nov 15; 0950: Scenario Details Given: Controller: *Add Controller Initials*
This new information is then forwarded to all investigatory partners, to include the appropriate law enforcement agencies, the state FUSION Center, FBI, FDA OCI, and the state Department of Homeland Security. Laboratory results for the initial food samples come back negative for *Staphylococcus* organism/toxin and the *Bacillus cereus* organism.

With the added information from the suspect and the signs and symptoms that have been documented by medical providers a presumptive diagnosis of organophosphate poisoning has been determined. After discussing with a toxicology/poison control experts a serum cholinesterase level and RBC Cholinesterase level tests were completed. Laboratory testing showing decreased serum cholinesterase levels (24 hour turnaround) supporting the diagnosis; however, clinical laboratory results for the RBC Cholinesterase level test will take approximately one to two weeks for results.

Discussion: What do these results suggest? What should we test the food samples for with this new information? What further actions should be considered for law enforcement?

(ALL) Laboratory analysis for pesticides and VOCs are already being conducted on the food, they may want a sample of the pesticide as well. Contact the chemistry laboratory to discuss additional analysis and collection. The laboratory and investigatory partners may want to compare results from clinical, food, and pesticide analysis to ensure that they appear to be the same agent. Communicate with law enforcement to potentially coordinate additional investigation actions and sampling.

(19) 13 Nov 15; 1005: Scenario Details Given: Controller: *Add Controller Initials*
The laboratory food and clinical results appear to all point towards an organophosphate pesticide. The suspect that admitted to contaminating the food has been taken into custody after being charged with level 5 battery and is awaiting a hearing while law enforcement officials

continue their investigation. All of the ill individuals recovered including the two that were in critical care. Many of the individuals are looking into taking legal action against both the Campus Café and the suspect individual that contaminated the food. Briefly discuss After Action Reviews and the Panel Discussion

13 Nov 15; 1015: Break
Time to allow volunteers and key players to prepare for Panel Discussion

13 Nov 15; 1030: Hot Wash / Panel Discussion
Panel discussion by multiple key players and a few volunteers from various sectors including Ivy Tech kitchen management/academia; also include students.

Discussion:

(All) Discuss the fact that many of the actions that were taken during the exercise would be the same whether the situation was intentional or unintentional. This scenario provided several opportunities to test investigation procedures for each discipline and/or agency that represents the Food Safety and Defense Task Force.

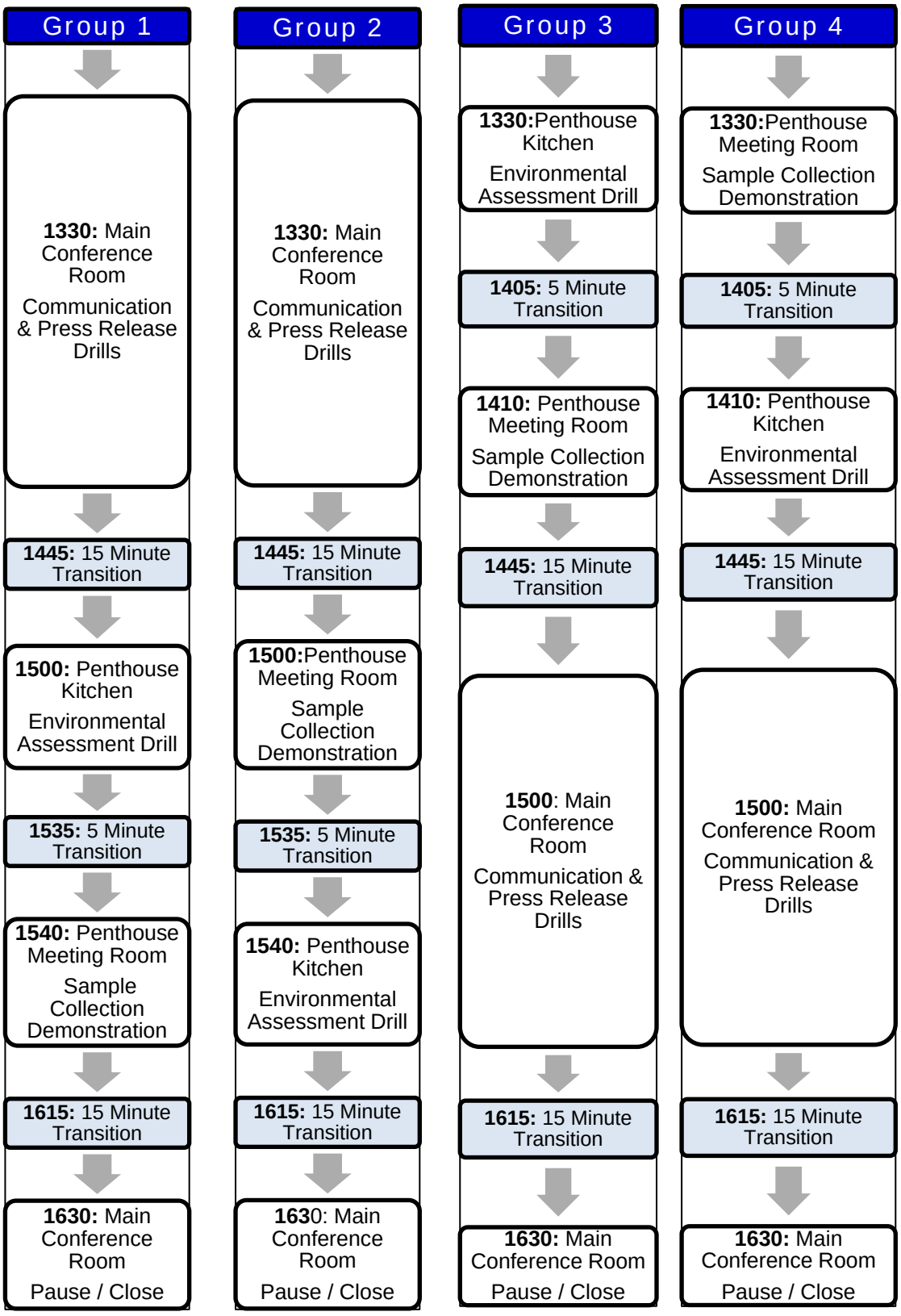
The after action review will allow players to discuss the process, its usefulness, ask questions, and discuss what went well and what should have been done differently.

1. Ask each agency/industry member what will be done at their agencies after a scenario of this nature?
    - With the information compiled
    - With the lessons learned
    - To prevent/lessen risks in the future
    - To help train employees to watch their co-workers for signs
2. Ask players to discuss how they will use lessons learned moving forward in his/her career.

13 Nov 15; 1130: Conclusion/Evaluations
Thank participants for attending. Recognize Ivy Tech for their help and the FDA for funding the exercise. Recognize volunteers/controllers for their hard work. Ask for evaluations to be placed in a box provided on their way out. Tell them that we will update the members list and send the 2016 meeting dates at the start of next year.

13 Nov 15; 1145: Controller and Evaluator After Action Review

APPENDIX F: DAY 1 – 1330 BREAK OUT FLOW CHART



APPENDIX G: CONTROLLER AND EVALUATOR ASSIGNMENTS

This is a list of controller and evaluator assignments. Both controllers and evaluators may be assigned to a second area if play has been completed in the first.

APPENDIX H: ACRONYMS

Acronym	Term
A.R.	Attack Rate
C/E	Controller/Evaluator
ENV	Environmental
EPI	Epidemiology/Public Health Nurses
ExPlan	Exercise Plan
HSEEP	Homeland Security Exercise and Evaluation Program
IND	Industry
LAB	Laboratory
MSEL	Master Scenario Events List
R.R.	Relative Risk
SME	Subject Matter Expert
DHS	U.S. Department of Homeland Security

Insider Addition at the Campus Cafe

Exercise Plan

Date

The Exercise Plan (ExPlan) gives elected and appointed officials, observers, media personnel, and players from participating organizations information they need to observe or participate in the exercise. Some exercise material is intended for the exclusive use of exercise planners, controllers, and evaluators, but players may view other materials that are necessary to their performance. All exercise participants may view the ExPlan.

Rev. April 2013
HSEEP-DD06

EXERCISE OVERVIEW

Exercise Name	Insider Addition at the Campus Café
Exercise Dates	
Scope	These drills focus on response capabilities and collaboration between agencies during a foodborne illness outbreak utilizing procedures in place.
Mission Area(s)	Investigation response
Capabilities	Information Sharing Public Health Surveillance and Epidemiological Investigation
Objectives	Practice communication flow between jurisdictions during a Foodborne Outbreak Investigation according to procedures. Practice Foodborne Outbreak Investigation processes according to procedures.
Threat or Hazard	Foodborne illness intoxications where intentional contamination is suspected.
Scenario	Several students and staff members experienced (symptoms) shortly after eating at a popular campus food facility. The quantity and severity of cases prompts the LHDs to seek assistance from the ISDH.
Sponsor	
Point of Contact	

GENERAL INFORMATION

Exercise Objectives and Capabilities

The following exercise objectives in Table 1 describe the expected outcomes for the exercise. The objectives are linked to capabilities, which are distinct critical elements necessary to achieve the specific mission area(s). The objectives and aligned capabilities are guided by elected and appointed officials and selected by the Exercise Planning Team.

Exercise Objective	Capability
Practice communication flow between jurisdictions during a Foodborne Outbreak Investigation according to procedures.	Information Sharing
Identify intra-jurisdictional stakeholders across public health, public safety, private sector, law enforcement, and other disciplines to determine information-sharing needs during an incident	Information Sharing
Practice Foodborne Outbreak Investigation processes according to procedures.	Public Health Surveillance and Epidemiological Investigation
Conduct public health and epidemiological investigations according to procedures	Public Health Surveillance and Epidemiological Investigation
Determine public health mitigation and actions to be recommended for the mitigation of the incident based upon data collected in the investigation and on applicable science-based standards	Public Health Surveillance and Epidemiological Investigation
Conduct investigation of disease and ensure coordination of investigation with jurisdictional partner agencies according to procedures.	Public Health Surveillance and Epidemiological Investigation

Table 1. Exercise Objectives and Associated Capabilities

Participant Roles and Responsibilities

The term *participant* encompasses many groups of people, not just those playing in the exercise. Groups of participants involved in the exercise, and their respective roles and responsibilities, are as follows:

- **Players.** Players are personnel who have an active role in discussing or performing their regular roles and responsibilities during the exercise. Players discuss or initiate actions in response to the simulated emergency.
- **Controllers.** Controllers plan and manage exercise play, set up and operate the exercise site, and act in the roles of organizations or individuals that are not playing in the exercise. Controllers direct the pace of the exercise, provide key data to players, and may prompt or initiate certain player actions to ensure exercise continuity. In addition, they issue exercise material to players as required, monitor the exercise timeline, and supervise the safety of all exercise participants.

- **Simulators.** Simulators are control staff personnel who role play nonparticipating organizations or individuals.
- **Evaluators.** Evaluators evaluate and provide feedback on a designated functional area of the exercise. Evaluators observe and document performance against established capability targets and critical tasks, in accordance with the Exercise Evaluation Guides (EEGs).
- **Actors.** Actors simulate specific roles during exercise play, typically victims or other bystanders.
- **Observers.** Observers visit or view selected segments of the exercise. Observers do not play in the exercise, nor do they perform any control or evaluation functions. Observers view the exercise from a designated observation area and must remain within the observation area during the exercise. Very Important Persons (VIPs) are also observers, but they frequently are grouped separately.
- **Media Personnel.** Some media personnel may be present as observers, pending approval by the sponsor organization and the Exercise Planning Team.
- **Support Staff.** The exercise support staff includes individuals who perform administrative and logistical support tasks during the exercise (e.g., registration, catering).

Exercise Assumptions and Artificialities

In any exercise, assumptions and artificialities may be necessary to complete play in the time allotted and/or account for logistical limitations. Exercise participants should accept that assumptions and artificialities are inherent in any exercise, and should not allow these considerations to negatively impact their participation.

Assumptions

Assumptions constitute the implied factual foundation for the exercise and, as such, are assumed to be present before the exercise starts. The following assumptions apply to the exercise:

- The exercise is conducted in a no-fault learning environment wherein capabilities, plans, systems, and processes will be evaluated.
- The exercise scenario is plausible, and events occur as they are presented.
- Exercise simulation contains sufficient detail to allow players to react to information and situations as they are presented as if the simulated incident were real.
- Participating agencies may need to balance exercise play with real-world emergencies. Real-world emergencies take priority.

Artificialities

During this exercise, the following artificialities apply:

- Exercise communication and coordination is limited to participating exercise organizations, venues, and controllers.

EXERCISE LOGISTICS

Safety

Exercise participant safety takes priority over exercise events. The following general requirements apply to the exercise:

- A Safety Controller is responsible for participant safety; any safety concerns must be immediately reported to the Safety Controller. The Safety Controller and Exercise Director will determine if a real-world emergency warrants a pause in exercise play and when exercise play can be resumed.
- For an emergency that requires assistance, use the phrase **["real-world emergency."]** The following procedures should be used in case of a real emergency during the exercise:
  - Anyone who observes a participant who is seriously ill or injured will immediately notify emergency services and the closest controller, and, within reason and training, render aid.
  - The controller aware of a real emergency will initiate the ["real-world emergency"] broadcast and provide the Safety Controller, Senior Controller, and Exercise Director with the location of the emergency and resources needed, if any.

Site Access

Security

To prevent interruption of the exercise, access to exercise sites is limited to exercise participants. Players should advise their venue's controller or evaluator of any unauthorized persons.

Observer Coordination

Organizations with observers attending the event should coordinate with the sponsor organization for access to the exercise site. Observers are escorted to designated areas and accompanied by an exercise controller at all times. Sponsor organization representatives and/or the observer controller may be present to explain exercise conduct and answer questions. Exercise participants should be advised of media and/or observer presence.

Exercise Identification

Exercise staff may be identified by badges and vests to clearly display exercise roles; additionally, uniform clothing may be worn to show agency affiliation.

POST-EXERCISE AND EVALUATION ACTIVITIES

Debriefings

Post-exercise debriefings aim to collect sufficient relevant data to support effective evaluation and improvement planning.

Hot Wash

At the conclusion of exercise play, controllers facilitate a Hot Wash to allow players to discuss strengths and areas for improvement, and evaluators to seek clarification regarding player actions and decision-making processes. All participants may attend; however, observers are not encouraged to attend the meeting. The Hot Wash should not exceed 30 minutes.

Controller and Evaluator Debriefing

Controllers and evaluators attend a facilitated C/E Debriefing immediately following the exercise. During this debriefing, controllers and evaluators provide an overview of their observed functional areas and discuss strengths and areas for improvement.

Participant Feedback Forms

Participant Feedback Forms provide players with the opportunity to comment candidly on exercise activities and exercise design. Participant Feedback Forms should be collected at the conclusion of the Hot Wash.

Evaluation

Exercise Evaluation Guides

EEGs assist evaluators in collecting relevant exercise observations. EEGs document exercise objectives and aligned capabilities, capability targets, and critical tasks. Each EEG provides evaluators with information on what they should expect to see demonstrated in their functional area. The EEGs, coupled with Participant Feedback Forms and Hot Wash notes, are used to evaluate the exercise and compile the After-Action Report (AAR).

After-Action Report

The AAR summarizes key information related to evaluation. The AAR primarily focuses on the analysis of capabilities, including capability performance, strengths, and areas for improvement. AARs also include basic exercise information, including the exercise name, type of exercise, dates, location, participating organizations, mission area(s), specific threat or hazard, a brief scenario description, and the name of the exercise sponsor and POC.

Improvement Planning

Improvement planning is the process by which the observations recorded in the AAR are resolved through development of concrete corrective actions, which are prioritized and tracked as a part of a continuous corrective action program.

After-Action Meeting

The After-Action Meeting (AAM) is a meeting held among decision- and policy-makers from the exercising organizations, as well as the Lead Evaluator and members of the Exercise Planning Team, to debrief the exercise and to review and refine the draft AAR and Improvement Plan (IP). The AAM should be an interactive session, providing attendees the opportunity to discuss and validate the observations and corrective actions in the draft AAR/IP.

Improvement Plan

The IP identifies specific corrective actions, assigns them to responsible parties, and establishes target dates for their completion. It is created by elected and appointed officials from the organizations participating in the exercise, and discussed and validated during the AAM.

PARTICIPANT INFORMATION AND GUIDANCE

Exercise Rules

The following general rules govern exercise play:

- Real-world emergency actions take priority over exercise actions.
- Exercise players will comply with real-world emergency procedures, unless otherwise directed by the control staff.
- All communications (including written, radio, telephone, and e-mail) during the exercise will begin and end with the statement **["This is an exercise."]**

Players Instructions

Players should follow certain guidelines before, during, and after the exercise to ensure a safe and effective exercise.

Before the Exercise

- Review appropriate organizational plans, procedures, and exercise support documents.
- Be at the appropriate site at least 30 minutes before the exercise starts. Wear the appropriate uniform and/or identification item(s).
- Sign in when you arrive.
- If you gain knowledge of the scenario before the exercise, notify a controller so that appropriate actions can be taken to ensure a valid evaluation.
- [Read your Player Information Handout, which includes information on exercise safety.]

During the Exercise

- Respond to exercise events and information as if the emergency were real, unless otherwise directed by an exercise controller.

- Controllers will give you only information they are specifically directed to disseminate. You are expected to obtain other necessary information through existing emergency information channels.
- Do not engage in personal conversations with controllers, evaluators, observers, or media personnel. If you are asked an exercise-related question, give a short, concise answer. If you are busy and cannot immediately respond, indicate that, but report back with an answer as soon as possible.
- If you do not understand the scope of the exercise, or if you are uncertain about an organization's participation in an exercise, ask a controller.
- Parts of the scenario may seem implausible. Recognize that the exercise has objectives to satisfy and may require incorporation of unrealistic aspects. Every effort has been made by the exercise's trusted agents to balance realism with safety and to create an effective learning and evaluation environment.
- All exercise communications will begin and end with the statement [**"This is an exercise."**] This precaution is taken so that anyone who overhears the conversation will not mistake exercise play for a real-world emergency.
- Speak when you take an action. This procedure will ensure that evaluators are aware of critical actions as they occur.
- Maintain a log of your activities. Many times, this log may include documentation of activities that were missed by a controller or evaluator.

After the Exercise

- Participate in the Hot Wash at your venue with controllers and evaluators.
- Complete the Participant Feedback Form. This form allows you to comment candidly on emergency response activities and exercise effectiveness. Provide the completed form to a controller or evaluator.
- Provide any notes or materials generated from the exercise to your controller or evaluator for review and inclusion in the AAR.

Simulation Guidelines

Because the exercise is of limited duration and scope, certain details will be simulated. The physical description of what would fully occur at the incident sites and surrounding areas will be relayed to players by simulators or controllers.

APPENDIX A: EXERCISE SCHEDULE

Time	Personnel	Activity	Location
November 10, 2015; 2:00pm			
1400 - 1445	Controllers, evaluators, and exercise staff	Controller and Evaluator Briefing Set up and walkthrough	Ivy Tech Conference Room
November 12, 2015			
0730 - 0800	Controllers and exercise staff	Check-in for final instructions and communications check	Ivy Tech Main Conference Room
0800-0820	VIPs and selected exercise staff	VIP Controller Briefing, Controllers provide player briefs	Ivy Tech Main Conference Room
0830 - 1200	All	Exercise starts	Ivy Tech Main Conference Room
1200 - 1300	All	Lunch Break	Ivy Tech Main Conference Room
1300 - 1330	All	Exercise Resumes, Four Groups Assigned, and Groups 1, 2, 3, and 4 Move to Designated Areas (See Appendix F for Group Details)	Ivy Tech Main Conference Room
1330 - 1445	All	Gp 1+2: Communication Drill & Press Release Drill / Gp 3+4: Environmental Assessment & Sample Collection Demonstration	Ivy Tech Main Conference Room / Kitchen Penthouse
1445-1500	All	Report to Designated Areas	In Transition
1500 - 1615	All	Gp 3+4: Communication Drill & Press Release Drill / Gp 1+2: Environmental Assessment & Sample Collection Demonstration	Ivy Tech Main Conference Room / Kitchen Penthouse
1615-1630	All	Return to Main Conference Room	In Transition
1630-1645	All	Exercise paused – Conclusion and Summary	Ivy Tech Main Conference Room
1645-1715	Controllers, evaluators, and exercise staff	Controller and Evaluator Debriefing	Ivy Tech Main Conference Room
November 13, 2015			
0730-0800	Controllers and exercise staff	Check-in for final instructions and communications check	Ivy Tech Main Conference Room
0800-0820	Controllers and exercise staff	Controller/Evaluator Briefing	Ivy Tech Main Conference Room
0800-0830	All	Member Arrival, Check-in, and Free Discussion	Ivy Tech Main Conference Room
0830-0840	All	Greetings	Ivy Tech Main Conference Room
0840-0900	All	Ivy Tech Discusses Culinary Arts Center	Ivy Tech Main Conference Room
0900-0915	All	Summary of where we left off and what we will do today	Ivy Tech Main Conference Room

Time	Personnel	Activity	Location
0915	All	Exercise Starts	Ivy Tech Main Conference Room
0915-0945	All	Law Enforcement Drill	Ivy Tech Main Conference Room
1030-1130	All	Hot Wash / Panel Discussion	Ivy Tech Main Conference Room
1130	All	Exercise Ends	Ivy Tech Main Conference Room
1130	All	Conclusions / Evaluations	Ivy Tech Main Conference Room
TBD			
TBD	Controllers, Evaluators and Observers	Controller and Evaluator After Action Review	TBD

APPENDIX B: PLAYERS

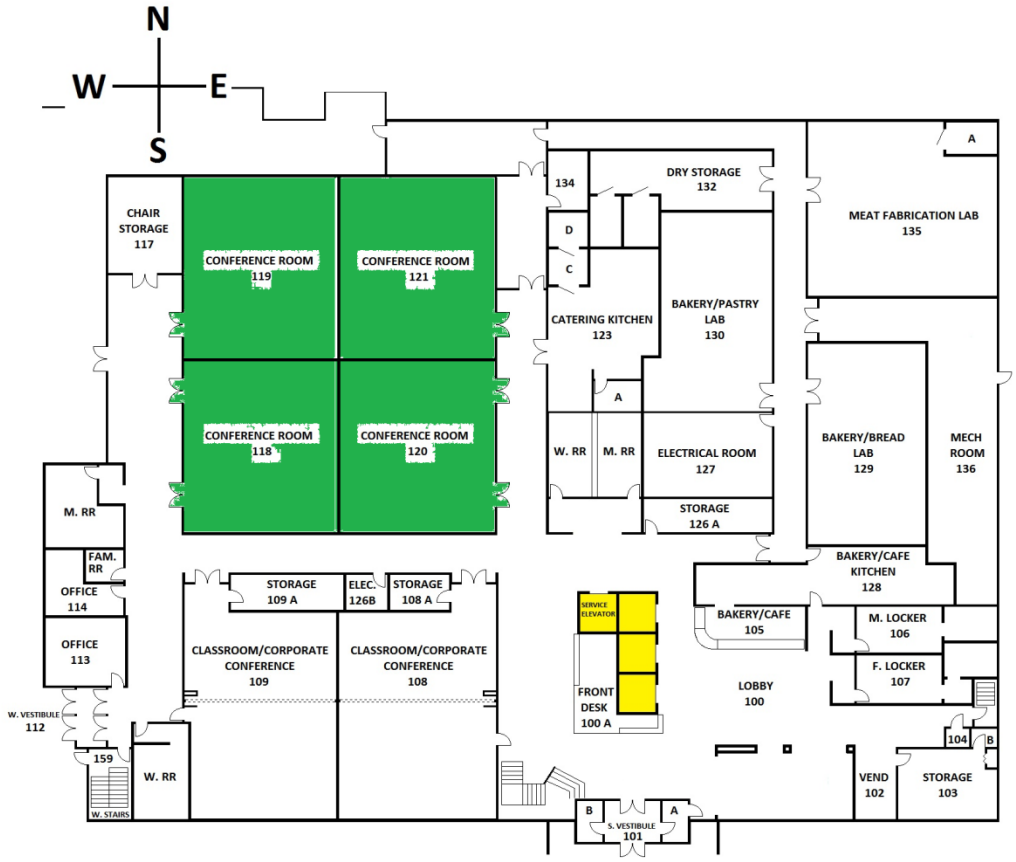
FIRST	LAST	Sector

APPENDIX C: CONTROLLER LIST

Name	Position
	Director/Senior Controller; Environmental Venue
	Safety Controller/Exercise Facilitator
	Greeter/Exercise Facilitator
	Actor/Actor Controller
	Industry Controller
	Environmental Health Controller/Evaluator
	Environmental Health Controller/Evaluator
	Law Enforcement Controller/Evaluator
	Epidemiology Controller/Evaluator
	Laboratory Controller/ Evaluator
	OPA & Communication Controller/Evaluator

APPENDIX D: EXERCISE SITE MAPS

Figure D.1: Map to Conference Rooms



First Floor Meeting Rooms (Shaded Green)

Penthouse Meeting and Dining Rooms (Shaded Green)
Penthouse Kitchen (Shaded Orange)

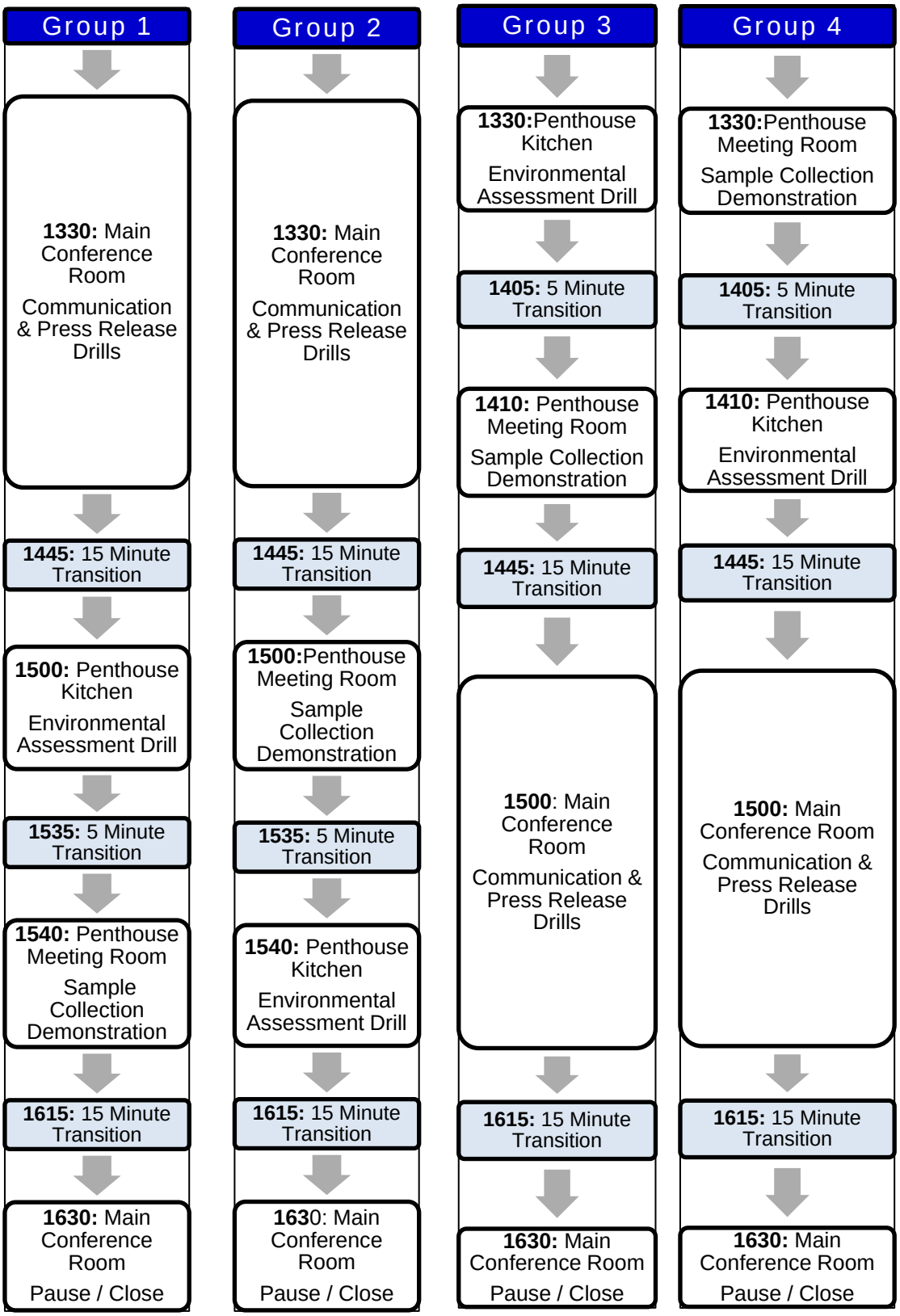
Figure D.2: Picture of Conference Rooms


1st Floor Rooms


Penthouse Rooms

Figure D.3: Penthouse Kitchen


APPENDIX E: DAY 1 – 1330 BREAK OUT FLOW CHART



APPENDIX F: ACRONYMS

Acronym	Term
A.R.	Attack Rate
C/E	Controller/Evaluator
ENV	Environmental
EPI	Epidemiology/Public Health Nurses
ExPlan	Exercise Plan
HSEEP	Homeland Security Exercise and Evaluation Program
IND	Industry
LAB	Laboratory
MSEL	Master Scenario Events List
R.R.	Relative Risk
SME	Subject Matter Expert
DHS	U.S. Department of Homeland Security

INSIDER ADDITION AT THE CAMPUS CAFE

SITUATION MANUAL

November 12-13, 2015

- (Scenario Day 1: November 12, 2015) -

(01) 12 Nov 15; 0840: Scenario Details Given
Around 2pm a LHD EHS Food Protection Program receives a call from **one student** who reported experiencing ongoing symptoms of nausea, diarrhea, and cramping approximately 1.5 hours after eating from the buffet at the Campus Cafe. An ISDH Complaint Form was completed; the complainant had no leftovers available for collection. The complainant reported eating the roast beef, pulled pork, green beans, and salad.

Discussion:

(ENV) Would you investigate one complaint? Why or why not? What actions would you consider?

(EPI) If the complaint was reported to the public health nurse or epidemiologist would you investigate this complaint? Why or why not? Would you refer it back to the food program since it was a food establishment complaint? What actions would you consider?

(LAB) What involvement at this point would you have?

(IND) What if the complaint was reported back to the establishment, what actions would you take? Do any of the industry representatives have a process for receiving complaints? If so what does it entail?

(02) 12 Nov 15; 0900: Complaint Interview Drill

Drill Instructions: Utilize the provided complaint forms (or your own) to interview a complainant and obtain a food history. Identify an interviewer, complainant, and observer in each group. Be prepared to discuss your experience from the interview.

(03) 12 Nov 15; 0920: Scenario Details Given
Around 3pm “an hour later” **a second call** is received from another student who reported experiencing ongoing symptoms of nausea, vomiting, diarrhea, and abdominal cramping approximately 1 hour after eating from the buffet at the Campus Cafe. An ISDH Complaint Form was completed; again no leftovers were available from this complainant. The complainant reported eating pulled pork, beef brisket, salad, and blueberry crisp. However, he stated that he only ate a bite of the blueberry crisp because it tasted funny.

Discussion:

(ENV/EPI) Now that two complaints have been received, is this considered an outbreak? What actions should be taken for the complaint investigation and who should be involved at this point? Assuming that the Campus Café was the cause of the illness, what pathogens could be potential causes of the illness?

(LAB) What involvement at this point would you have? What would you do to prepare for possible incoming food/clinical samples?

(IND) Now that two complaints have been received, what potential actions would you take? Do any industry representatives have foodborne illness outbreak procedures, contact lists, or other preparations in place?

(04) 12 Nov 15; 0940: Scenario Details Given
A food inspector from the LHD arrived at the Campus Café at 4:00pm to conduct an environmental assessment of the establishment. At the time of the incident the buffet line served pork loin, roast beef, pulled pork, oysters, salad, green beans, blueberry crisp dessert, pork & beans, pork cutlets, pasta

noodles, and broasted chicken; and no other foods were provided to patrons. The food inspector observed no indication of time/temperature abuse, bare hand contact, improper chemical storage, or other practices that may have attributed to the illness. Several samples from the buffet were collected to include the pulled pork, salad, and blueberry crisp. The establishment was also asked to hold the buffet line items that were served that day in case additional samples were required.

Discussion:

(ENV/EPI/LAB) Should other samples have been collected? What laboratory analysis should be requested? What additional actions should be considered?

(IND) What actions should the implicated establishment take while the inspector is at the establishment? How and what would you communicate with your employees and/or higher management?

(05) 12 Nov 15; 1000: Scenario Details Given
Around 2pm the Special Care Hospital saw **10 patients** who reported experiencing nausea, vomiting, diarrhea and abdominal cramping approximately 30 minutes to one hour after eating from the buffet at the Campus Cafe. Due to the amount of people who reported eating at the same location, the treating physician contacted the PH Nurse at the Local Health Department and reported the incident on **Wednesday November 12, 2015 around 4:15pm.**

Meanwhile the College Clinic also saw **10 students** with similar symptoms around 3pm. Several had also reported additional symptoms to include muscle twitching and weakness. These symptoms also appeared approximately 30 minutes to one hour after eating at the Campus Café. Due to the amount of people who ate at the same location and experienced similar symptoms, the treating physician contacted the PH Nurse at the Local Health Department and reported the incident on **Wednesday November 12, 2015 around 4:30pm.**

Discussion:

(ENV/EPI) Now that we have 20 individuals reported to the LHD PH Nurse; and 2 individuals reported to the EHS Food Protection Program who experienced similar symptoms after eating at the Campus Café how would this change your view of the situation (agents/associated risk factors)? What additional actions should be considered? Do you think that the PH Nurses and EHS Food Protection partners would be talking? What information should be provided to the establishment?

(LAB) Now that there are 22 individuals involved in the outbreak how would this change your involvement? What clinical and food laboratory testing should be accomplished? What actions would you take at this time?

(IND) Once you are aware of the significantly higher number of cases; what actions would you take? What information would you collect so that it is available if requested?

- (Scenario Day 2: November 13, 2015) -

(06) 12 Nov 15; 1020: Scenario Details Given
First thing in the morning the Local Health Departments PH Nurse requests all of the case records from the hospital; and was informed that that shortly after being released several of the cases returned to the hospital after experiencing confusion, dizziness, urinary incontinence, heart palpitations, and trouble breathing. The patients were found to have wheezing and coughing, pinpointed pupils, drowsiness, and confusion. Two of the patients began experiencing weakness, pulmonary edema and respiratory distress and were intubated due to pulmonary reasons. The two were admitted to the critical care unit;

while the others were kept overnight for observation. Tests completed included a CBC, CMP, CXR, ABG, and a toxicology screen.

The PH Nurse communicates the incident with their EHS Food Protection office and they share information regarding the recent complaints from the Campus Café. The LHD also notifies the State Department of Health and informs them of the situation. The state contacts the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to report this on-going event.

Discussion:

(ENV/EPI/LAB)What do these additional symptoms suggest? What additional actions should be considered? Now that several cases reported serious symptoms, would temporarily closing the establishment be a consideration? What experts would you contact when dealing with a toxin or chemical exposure?

(IND) Now that the establishment has been implicated in an outbreak involving several serious cases requiring hospitalization, how should they respond? How and what would you communicate with your employees and/or higher management?

07) 12 Nov 15; 1040: Case Definition Drill
Drill Instructions: An epidemiologist/PH Nurse will be identified for each group and will assist in the development of a case definition. A worksheet will also be provided to assists in its development. Groups will present their responses on the large post it paper provided.

(08) 12 Nov 15; 1100: Scenario Details Given
The PH Nurse began interviewing all **20 cases**, as well as the friends/family members of the **two individuals** that were unable to be interviewed due to extreme symptoms. The cases reported eating from a buffet line that served pork loin, roast beef, steamed oysters, pulled pork, salad, green beans, blueberry crisp dessert, pork & beans, pork cutlets, pasta noodles, and broasted chicken.

Symptoms initially include nausea, vomiting, diarrhea, abdominal cramping and some mentioned increased salivation. Symptoms then progressed to confusion, pinpointed pupils, muscle twitching, dizziness, heart palpitations, and trouble breathing. In two of the cases symptoms developed to pulmonary edema and respiratory distress.

While interviewing the cases many individuals reported experiencing a funny (garlic/solvent-like) taste and smell while eating the fruit crisp. Most individuals stopped eating the fruit crisp after not liking the taste. However, friends/family members of the patients with the more severe symptoms stated that their relatives had eaten more
of the dessert.

The LHD Food Inspector contacted the Campus Café and requested the list of patrons that ate lunch that day. The Campus Café keeps record of student/staff when they purchase food. A symptom/food history survey was developed and sent to all of the names on the patron list**. The survey was completed by 80 students and identified an additional five ill individuals that hadn't been seen by a medical provider making 27 ill cases in total.**

Discussion:

(ALL) What are your thoughts on the situation? What additional actions should be considered? What other local, state, federal agencies would you now involve in the investigation? Would a press release be appropriate at this point?

- (Scenario Day 3: November 14, 2015) -

(09) 12 Nov 15: 1120: Scenario Details Given

After receiving interview and survey results from all of the staff and students that ate lunch at the Campus Café the following epidemiological study and symptoms percentages were identified. Since the students and staff are a well defined group the Public Health Nurse decided to do a Cohort Study by determining the attack rates and relative risk.

Table 1: Food Specific Attack Rates

Food Item	Ate This Food			Did not eat this Food			
	Ill	Well	A.R.	Ill	Well	A.R.	R.R.
Pork Loin	17	20	45.9	8	35	18.6	2.5
Pulled Pork	11	33	25	14	22	38.8	0.64
Pork Cutlet	6	30	16.6	19	25	43.1	0.38
Pork and Beans	2	13	13.3	23	42	35.3	0.37
Roast Beef	8	12	40	17	43	28.3	1.41
Steamed Oysters	15	8	65.2	8	49	14	4.66
Broasted Chicken	15	45	25	10	10	50	0.5
Pasta Noodles	2	12	14.2	23	43	34.8	0.4
Green Beans	16	30	34.7	9	25	26.4	1.31
Salad	12	45	21	13	10	56.5	0.37
Blueberry Crisp	22	12	64.7	3	43	6.5	9.95

A.R. = Attack Rate R.R. = Relative Risk

Table 2: Symptoms of Cases (n=27)

Symptom	Number	Percent (%)
Nausea	23	85
Vomiting	18	66
Diarrhea	21	77
Abdominal cramps	21	77
Dizziness	20	74
Pinpointed Pupils	20	74
Muscle Twitching	10	37
Mental Confusion	6	22
Trouble Breathing	5	18
Heart Palpitations	3	11
Pulmonary Edema	2	7
Respiratory Distress	2	7

(10) 12 Nov 15; 1130: Hypotheses Drill

Drill Instructions: Use available information to make a hypothesis or an educated guess about the cause and source of the outbreak. This will help direct immediate control measures, focus studies, and determine partners. Use the worksheet provided that explains how to develop a hypothesis and use the large post it paper to present your hypotheses.

12 Nov 15; 1200 - 1300: Lunch

(11) 12 Nov 15; 1300: Scenario Details Given
The local health authorities and the State Health Department hold a call with all involved jurisdictions. County and university health officials report the possible link to the Campus Cafe, due to the cluster from the clinic and the hospital. Experts agree that due to the rapid onset of acute symptoms that are atypical of bacterial foodborne illness; a chemical agent or toxin may be the cause, but it is unknown at this time.

Local Health Department Food Safety Inspectors contact the Campus Cafe management and indicate a ***possible*** association with their restaurants. The Campus Cafe management begins an internal investigation. The story appears on the news detailing the incident.

Discussion:

(IND) What investigation actions would you take if this was occurring at your establishment?

(12) 12 Nov 15; 1310: Environmental Assessment Plan of Action Drill
Drill Instructions: Review current information on the outbreak and determine investigation actions. Use the Environmental Assessment Generic form for guidance and complete the attached worksheet. Establish what individuals need to be involved in the environmental assessment. Discuss individual tasks and identify who will interview, collect samples, conduct food flows, and collect documents. Determine potential causes and sources of contamination. Specify the targeted food, the sampling plan, interview questions, and the documents that should be collected.

(13 – 16) 12 Nov 15; 1330: Concurrent Environmental Assessment/Sample Demonstration and Communication/Press Release Drills
Concurrent Drill Overview: Players into four groups; groups 1 and 2 report to the main conference room, Groups 3 and 4 will report to the penthouse kitchen or meeting room. Groups in the penthouse will either conduct the Environmental Assessment drill or the Sample Collection Demonstration; they will switch places half way through. The group in the main conference room will participate in a Communication and Press release drill

Group 1 + Group 2

1330: Main Conference Room – Communication & Press Release Drills

1445: 15 Minute Break – Groups Move to Designated Areas

1500: Penthouse – Environmental Assessment Drill & Sample Collection Demonstration
[1500 breakdown: Group 1 to Kitchen (Room P105), Group 2 to Conference Room (Room P109); switch at 1535]

Group 3 + Group 4

1330: Penthouse – Environmental Assessment Drill & Sample Collection Demonstration
[1330 breakdown: Group 3 to Kitchen (Room P105), Group 4 to Conference Room (Room P109); switch at 1405]

1445: 15 Minute Break – Groups Move to Designated Areas

1500: Main Conference Room – Communication & Press Release Drills

12 Nov 15; 1615: Break

12 Nov 15; 1630: Pause Exercise – Conclusion and Summary

Scenario Continues 13 November 2015

13 Nov 15; 0730: Controllers, evaluators, and exercise staff Check-in

13 Nov 15; 0800: Member arrival, check-in, and free discussions

13 Nov 15; 0830: Greetings

13 Nov 15; 0840: Ivy Tech to discuss educational offerings at the Culinary Arts Center

13 Nov 15; 0900: Summary of where we left off and what we'll do today

- (Scenario Day 4: November 15, 2015) -

(17) 13 Nov 15; 0910: Law Enforcement Drill (40 min):
(All) Discuss what you would do with the establishment during the criminal investigation.

(18) 13 Nov 15; 0950: Scenario Details Given:
This new information is then forwarded to all investigatory partners, to include the appropriate law enforcement agencies, the FUSION Center, FBI, FDA OCI, and the Department of Homeland Security. Laboratory results for the initial food samples come back negative for *Staphylococcus* organism/toxin and the *Bacillus cereus* organism.

With the added information from the suspect and the signs and symptoms that have been documented by medical providers a presumptive diagnosis of organophosphate poisoning has been determined. After discussing with a toxicology/poison control experts a serum cholinesterase level and RBC Cholinesterase level tests were completed. Laboratory testing showing decreased serum cholinesterase levels (24 hour turnaround) support the diagnosis; however, clinical laboratory results for the RBC Cholinesterase level test will take approximately one to two weeks.

Discussion: What do these results suggest? What should we test the food samples for with this new information? What further actions should be considered for law enforcement?

(19) 13 Nov 15; 1005: Scenario Details Given: Controller: MT
The laboratory food and clinical results appear to all point towards an organophosphate pesticide. The suspect that admitted to contaminating the food has been taken into custody after being charged with level 5 battery and is awaiting a hearing while law enforcement officials continue their investigation. All of the ill individuals recovered including the two that were in critical care. Many of the individuals are looking into taking legal action against both the Campus Café and the suspect individual that contaminated the food. Briefly discuss After Action Reviews and the Panel Discussion

13 Nov 15; 1015: Break

13 Nov 15; 1030: After Action Review / Panel Discussion
A panel discussion will be conducted by multiple key players, volunteers, and controllers/evaluators.

Discussion:

(All) This scenario provided several opportunities to test investigation procedures for each discipline and/or agency that represents the Indiana Food Safety and Defense Task Force.

Discuss the exercise process, its usefulness, ask questions, and discuss what went well and what should have been done differently.

1. What will be done at your agency after exercising a scenario of this nature?
    - With the information compiled
    - With the lessons learned
    - To prevent/lessen risks in the future
    - To help train your employees to watch their co-workers for signs (see something say something campaign)
2. How will you use lessons learned in this exercise moving forward in your career.

13 Nov 15; 1130: Conclusion/Evaluations
Thank you for participating in the event. We would also like to thank Ivy Tech for their help and the FDA for funding the exercise. We would also like to thank our volunteers/controllers for their hard work. Please place your evaluations in a box before leaving.

Abbreviation Key:
EHC: Environmental Health Controllers
EC: Epidemiology Controllers
LC: Laboratory Controllers
PAC: Public Affairs Controllers
LE: Law Enforcement Controllers

Master Scenario Events List (MSEL)

Food Safety and Defense Task Force Table Top/Drill Exercise
Master Scenario Events List (MSEL)

This is drill is slated from 8:00am; November 12, 2015 – 11:00am; November 13, 2015. All Evaluators will evaluate the responses for their prospective disciplines regardless of who the controller is for the event.

Event #	Event Time	Event Description	Method of Delivery	Recipient Player(s)	Expected Outcome of Player Action	Comments
	7:30	Exercise set-up Main Conference Room			*Controllers/evaluators and exercise staff check-in.*	
	8:00	Player arrival and check-in Main Conference Room	Face to Face Controller: *Any*	Players	*Players will find their assigned seating.*	
	8:30	Greeting and Summary Main Conference Room	Face to Face Controller: *Any*	All	*Exercise Summary & Safety Brief*	
01	8:40	LHD EHS Food Protection Program receives a call from one student with symptoms 1.5 hours after eating from at the Campus Café. Main Conference Room	Face to Face Controller: *EHC*	All	***Env/Epi*** *response may be dependent upon the jurisdiction. If taken, collect a 72 hr food history.* ***Lab*** *would have limited involvement but may prepare for incoming samples.* ***Ind*** *may also receive & investigate complaints.*	
02	9:00	Complaint Interview Drill Main Conference Room	Face to Face Controller: *EHC*	Groups (3 People)	*Use complaint forms and conduct a food history. Utilize techniques discussed at the EpiReady Training.*	
03	9:20	LHD EHS receives a second call from another student experiencing similar symptoms after eating at the Campus Cafe. Main Conference Room	Face to Face Controller: *EHC*	All	***ENV/EPI*** *most jurisdictions would respond to two complaints with common exposures. It's a short incubation period and likely an entero-toxin or chemical. Focus on shared food or conduct a 72 hour food history.* ***Lab*** *should be informed.* ***Ind*** *may have procedures and/or POCs in their regulatory agencies.*	

Event #	Event Time	Event Description	Method of Delivery	Recipient Player(s)	Expected Outcome of Player Action	Comments
04	9:40	EA completed at the Campus Café. Collected documentation, found no evidence of risk factors. Main Conference Room	Face to Face Controller: *EHC*	All	***ENV/EPI/LAB*** *suspect preformed toxins, natural toxin, or chemical exposure. Look at what is known about those pathogens/vehicles. Test for b. cereus and staph.* ***Ind*** *may hold the buffet items for further invest.*	
05	10:00	Ten patients reported to the hospital, and ten patients reported to the student clinic reporting symptoms after eating at the Campus Café. LHD PH Nurse notified. Main Conference Room	Face to Face Controller: *EC*	All	***ENV/EPI*** *we have 22 cases with similar exposure, symptoms & incubation periods. Additional neurological symptoms appeared. Looks like a toxin or chemical agent.* ***Lab*** *can test for staph, B. cereus, pesticides, VOCs.* ***Ind*** *should be cooperative, may do an internal invest, voluntary closure.*	
06	10:20	The next morning it was and identified that several individuals returned to the hospital and were admitted after experiencing more severe symptoms; two were admitted to the ICU. Main Conference Room	Face to Face Controller: *EC*	All	***ENV/EPI/LAB*** *these symptoms are moving further away from preformed toxins. Look into natural toxins or pesticides/chemicals. LHD should request involvement from state and federal partners. Request SMEs. Also, due to medical treatment a press release may be needed.* ***IND*** *any policies in place?*	
07	10:40	Case Definition Drill Main Conference Room	Worksheet Controller: *EC*	Groups	*Each group should have an epi/ph nurse for the case definition drill.*	
08	11:00	PH Nurse interviews 20 cases and two family members (ICU). Menu items and symptoms were gathered. A survey was conducted on 80 students and identified 5 more cases. Main Conference Room	Face to Face Controller: *EC*	All	*The symptoms are moving further away from preformed toxins. Look into natural toxins, pesticides, and chemicals. Should prompt a request for involvement from state/federal partners. Discuss further actions (investigation, press release etc.)*	

Event #	Event Time	Event Description	Method of Delivery	Recipient Player(s)	Expected Outcome of Player Action	Comments
09	11:20	An epidemiological study and symptoms analysis was conducted. Main Conference Room	Face to Face Controller: *EC*	All	*The two foods of interest would be the oysters and blueberry crisp.*	
10	11:30	Hypothesis Drill Main Conference Room	Worksheet Controller: *EC*	Groups	*Develop a hypothesis from the information provided. References will be made available (if requested). Example - Appears to be toxin or chemical contamination. This could be due to shellfish poisoning related to the oysters or could be chemical contamination of a food at the establishment or before arriving.*	
	12:00	Lunch Location TBD		All		
11	1:00	LHD and ISDH hold a teleconference. Main Conference Room	Face to Face Controller: *EHC*	All	*Leads to the communication drill.* ***IND*** *investigate the facility, employees, and product. Contact with their regulatory authorities, and if needed the media. Communicating with their employees. Consider mitigation and control actions to include facility closure, product hold/remove/ replace, and training.*	
12	1:10	EA Plan of Action Drill Main Conference Room Insert	Worksheet Controller: *EHC – 2 to 3* Actor:	Groups	*Review the outbreak, implicated foods, agents, and hypothesis. Request regulatory history. Establish the team, assign tasks, determine focus, and prepare for the EA. Players may use their references, or those provided on the reference table.*	

Event #	Event Time	Event Description	Method of Delivery	Recipient Player(s)	Expected Outcome of Player Action	Comments
13	1:30 3:00	Communication Drill Main Conference Room	Drill Controller: *PAC – 2 to 3*	All	*Identify agency/discipline representatives and have them share and request information.*	
14	1:45 3:15	Press Release Drill Main Conference Room	Drill - Insert Controller: *PAC – 2 to 3*	All	*15 min into com drill insert public hysteria and need to develop a press release and/or call center.*	
15	1:30 2:15 3:00 3:45	Environmental Assessment (40 min) – 5 min transition Kitchen (TBD)	F2F Drill Controllers: *EHC – 2 to 3* Actor:	All Ind. Roles	*Interviewers, sample collectors, food flow, law enf, and observers.* *Actors play food handlers and management*	
16		Sample Demonstration (40 Min) – 5 min transition Conference Room 2	Demonstration Controllers: *EHC/LC – 1ea..*	All	*View demonstration and ask questions.*	
	4:15	Break Main Conference Room		All		
	4:30	Pause Exercise Main Conference Room			*Conclusion and Summary*	
	7:30	Exercise Staff Check-in Main Conference Room		Exercise Staff		
	8:00	Player arrival and check-in Main Conference Room	Face to Face Controller: *Any*	All		
	8:30	Greetings Main Conference Room	Face to Face Controller: *Any*	All		
	9:00	Summary of events Main Conference Room	Face to Face Controller: *Any*	All		
17	9:10	Law Enforcement Drill (30 min) Law Enforcement Discussion (10 min)	F2F Drill Controller: *LEC*	All	***LE** controllers will improvise while being a suspect for LE players to interview. **ALL** will discuss safety and all controllers will discuss working together for other disciplines when criminal activity is suspected.*	

Event #	Event Time	Event Description	Method of Delivery	Recipient Player(s)	Expected Outcome of Player Action	Comments
18	9:50	Results for the initial food samples came back neg for b. cereus/staph.	Face to Face Controller: *LC*	All	*Now that a pesticide is suspected we can conduct laboratory analysis for pesticides and VOCs. Contact the ISDH Chemistry lab to discuss analysis and collection. Communicate with law enforcement to coordinate investigation and sampling.*	
19	10:05	The laboratory now tests the food samples for VOCs and pesticides; discovers the organophosphate pesticides.	Face to Face Controller: *LC*	All	*This ends the scenario and opens into the after action and panel discussion portion of the exercise.*	
	10:15	Break				
	10:30	After Action and Panel Discussion	Face to Face Controller: *Any*	All	*Ask members what they may do differently in an event of this nature after this exercise, lessons learned, as well as food defense?*	
	11:30	Conclusions and Evaluations	Face to Face Controller: *Any*	All		

MSEL Inject - Drills

Event #	**10**	Event Time:	[1140] *(Expected)*	[Time] *(Actual)*
Via:	Face to Face	**Objective(s):**	Identify problem with epidemiological study	
Who Delivers?		*EC*	**Recipient Player(s):**	All
Event Description:				
Hypothesis Drill				
Inject:				
No beverages were included in the epidemiological study; beverages from tap have been contaminated in the past due to contamination from cleaning chemicals.				

Expected Action(s):	**Notes**
Discuss gathering this information or looking into the possibility during the environmental assessment.	
Expected Outcome:	**Notes**
Would like players to identify this issue. Especially since there have been many issues associated with beverages being contaminated with cleaning chemicals.	

MSEL Inject - Drills

Event #	**12**	Event Time:	[1320] *(Expected)*	[Time] *(Actual)*
Via:	Face to Face	**Objective(s):**	Allocating dwindling resources	
Who Delivers?		*EHC*	**Recipient Player(s):**	

Event Description:
Environmental Assessment Plan of Action Drill
Inject:
A message is received that many of our field staff are already engaged with a large event in another part of the state and the field staff member for that area is vacant. How would you reallocate dwindling resources to this outbreak?

Expected Action(s):	**Notes**
Discuss with management removing a field staff member from the event or another jurisdiction and having them partner with the local health department investigating the outbreak. The problem is that it may take a field staff member several hours to arrive at the location.	
Expected Outcome:	**Notes**
Make apparent dwindling resources and staffing and its affect on preparedness.	

Event #	**13/14**	Event Time:	[1345/1515] *(Expected)*	[Time] *(Actual)*
Via:	Face to Face	**Objective(s):**	Prompt a Press Release	
Who Delivers?		*PAC*	**Recipient Player(s):**	Kris Gasperic
Event Description:				
Communication and Press Release Drill				
Inject:				
Large amounts of people have been calling the university, local health department, and state health department due to the belief that they may have been exposed and are experiencing symptoms of anxiety, sweating, and heart palpitations.				

Expected Action(s):	**Notes**
Individuals not participating in the conference call will work on developing a press release and/or other responses to address increased concern among the community.	
Expected Outcome:	**Notes**
Press Releases and/or call centers etc..	

Event #	**13**	Event Time:	[1330/1500] *(Expected)*	[Time] *(Actual)*
Via:	Face to Face	**Objective(s):**	Request SMEs for the teleconference conference	
Who Delivers?		*PAC*	**Recipient Player(s):**	Teleconference players
Event Description:				
Communication Drill				
Inject:				
Have poison control and other SMEs stand up and offer what information and experience they can provide.				

Expected Action(s):	**Notes**
Ensure that toxicology/poison control representatives; in additional to all other local, state, and establishment representatives are invited to the teleconference.	
Expected Outcome:	**Notes**
SMEs and representatives that may have specific information to add are invited to the table to discuss the scenario.	

Event #	**13**	Event Time:	[1400/1530] *(Expected)*	[Time] *(Actual)*
Via:	Face to Face	**Objective(s):**	Intentional Contamination coordination	
Who Delivers?		*PAC*	**Recipient Player(s):**	Teleconference players
Event Description:				
Communication Drill				
Inject:				
If there was the suspicion of intentional contamination who (what law enforcement agency) would you request join the table for the teleconference.				

Expected Action(s):	**Notes**
Ensure that law enforcement representatives are then included and that they are provided with the appropriate information. Law enforcement should also bring appropriate questions and information to the table to ensure information is flowing.	
Expected Outcome:	**Notes**
LE SMEs and representatives that may have specific information to add are invited to the table to discuss the scenario.	

Script for a Food Handler being interviewed by the Police.

Police: Hi there. I'm investigating the incident of an alleged food poisoning that occurred here at the institution and as part of the investigation, we're talking with employees who were in the area. I need to ask you a few questions. Can I have your name please?

Employee: John Smith

Police: And what is your job here at the institution?

Employee: I'm a food handler. I bring the food from the kitchen area and place it in the serving area.

Police: Are you aware of the incident that occurred involving this alleged food poisoning?

Employee: I only know what's been said around the facility here.

Police: And what has been said?

Employee: Only that a lot of people have gotten sick and the administration believes that it's from the food.

Police: Do you know of any reason why the food would make people sick?

Employee: Only if it wasn't prepared correctly or maybe it was bad food to begin with.

Police: Is that an issue here where food isn't prepared correctly or it may be bad or spoiled.

Employee: Oh no! I've never known of any incidents like this and I've been here for about 2 years now.

Police: Do you know of anyone who would deliberately want to do something to the food to cause people to be sick?

Employee: Well, I don't want to get anybody in trouble. What would happen to someone if they really did poison the food? Will they go to jail? Would I be in trouble if I knew something but didn't say anything? 'Cause I really don't want any trouble. I'm on academic probation myself and I really don't need any more stress right now!

Police: Okay, slow down now. If you have information that would help in the investigation, we really need to have it. We have a lot of sick people right now and we need to find out what happened.

Employee: Well, I heard this one student talking about how the college had done him wrong and he said he was gonna get even. He got caught cheating on a test and he's been in a lot of trouble here since he started.

Police: Do you have the name of the student?

Employee: I only know him as "Rex." He works the line with me a couple days a week and he's always complaining about how the school hates him and they've been trying to kick him out of school for quite a while now.

Police: Tell me about the statement he made concerning getting even.

Employee: He just said that one of the instructors caught him cheating on an exam 'cause he had some answers written on his arm. The instructor picked up his exam and told him he had to leave the classroom. The next day he got called in to the Dean's Office and was told he was suspended pending an academic hearing.

Police: Where did this conversation occur that he was telling you all this?

Employee: Oh, he was cleaning out his locker. He looked really pissed off. He said they can't treat him like that and they'll be sorry.

Police: What else did he say?

Employee: Well…..he said… I'm not gonna get in trouble am I? I probably should have said something before….

Police: Look, I'm not trying to get you in trouble. But if you have information that can help us, it would be appreciated.

Employee: He said he was gonna put something in the food to make folks puke their guts out. I didn't think he'd really do it! I thought he was just running his mouth 'cause he was always doing that! I thought he was just kidding!

Police: Alright, try to calm down. You're okay. I appreciate what you've told me. You've been very helpful.

Employee: So what happens now? Am I in trouble? Am I going to jail 'cause I didn't say anything?

Small Group Exercise: Creating a Case Definition

Divide into groups and develop a case definition based off of the information provided in the scenario.

Consider the following questions as you create your case definition:

1) What symptoms are reported among ill persons (and what is their frequency)?
2) How many ill persons if any have a positive stool culture and/or diagnosis?
3) What restrictions by time, place, and person might help discriminate between outbreak-related illness and background illness?

CHECKLIST FOR EVALUATOR

Establish Rapport

☐ Did the interviewer identify themselves and explain why they were calling?

☐ Did the interviewer explain why the questions they were asking were important?

☐ Did the interviewer address last meal bias and explain that pathogens may take days to cause illness?

☐ Did the interviewer explain that they may need to re-contact the case and did they ask when a good time to call back is?

☐ Did the interviewer thank the complainant for reporting the illness and providing information?

Purposeful Directed Information Gathering

☐ Was the interview structured and "flowing"?

☐ Did the interviewer use a data collection form and focus on the appropriate period of exposure?

☐ Did the interviewer use any strategies to help the complainants remember what they ate?

Collection of Exposure Information

☐ Did the interviewer collect a 5-day food history?

☐ Did the interviewer collect information on foods eaten in their home; foods eaten at restaurants, fast food establishments, delis; and foods eaten at the homes of friends and family?

☐ Did the interviewer collect the necessary details about events during the period of interest (e.g., name and contact information for the organizer or where the event was held) and for commercial establishments (e.g., name, address)?

☐ Did the interviewer ask about non-food exposures that might also result in a gastrointestinal illness?

☐ Did the interviewer ask about other persons who might have had the same exposures?

☐ Did the interviewer record dates and times of exposures?

Other items of note?

Group Exercise: Generating Hypotheses about an Outbreak

Question 1: Using the references brought and/or provided, identify suspect causative agent(s). List the corresponding incubation period, signs and symptoms, duration, laboratory testing, and treatment.

Question 2: Identify causative agents associated foods and their corresponding sources and factors associated with contamination.

Question 3: What is the population at risk, mode of transmission, and period of interest?

Question 4: Using the information from Questions 1-3, develop a hypothesis that includes the suspected causative agent, people at risk, mode of transmission, vehicle, and period of interest.

Blueberry Crisp Recipe

- 1 quart fresh blueberries (about 4 cups)
- ¾ cup sugar (or (to taste)
- 2 tablespoons cornstarch
- 1 cup water
- 2 -3 tablespoons lemon juice
- ½ teaspoon vanilla
- 1 cup all-purpose flour
- ¾ cup regular oats
- 1 cup brown sugar
- 1 ½ teaspoons cinnamon
- ½ cup butter, melted

1. Set oven to 350 degrees F.
2. Prepare an 11 x 7-inch baking dish (can use a 13 x 9-inch but it will not be as high).
3. Spread the blueberries in the bottom of the prepared baking pan.
4. In a small saucepan over medium heat combine the sugar, cornstarch, water and 2-3 Tbsp lemon juice; cook and stir until thick and clear, then add in the vanilla.
5. Pour over, then gently stir in the cooked mixture with the blueberries.
6. In a bowl combine the flour with oats, brown sugar and cinnamon.
7. Add in the melted butter; mix until crumbly (I start mixing with a spoon then finish mixing with my hands).
8. Sprinkle over the top of blueberries (there will be a couple of empty spots that is okay, there may seem like a lot of crumble but it will settle when baking).
9. Bake for 30-35 minutes, or until blueberry mixture bubbles and the topping is brown.

Campus Café Buffet Menu

November 4, 2015

Pork Loin

~

Roast Beef

~

Steamed Oysters

~

BBQ Pulled Pork

~

Pork Cutlets

~

Broasted Chicken

~

Fresh Garden Salad

~

Country Green Beans

~

Texas Style Pork & Beans

~

Pasta Noodles

~

Blueberry Crisp Dessert

Campus Café
False Address
City, State Zip
Phone #

INVOICE 216784 11/1/2015

University Food Suppliers
City, State, Zip
Phone #

Delivery Date: 11/2/2015

Prepaid

10 EA	1111167234890890	Whole Boneless Pork Loin Roast	EA	$20.00	$200.00
21 LB	1142361234890890	Roast Beef	LB	$8.00	$168.00
5 EA	1111154372890890	Whole leaf lettuce 10CT	EA	$7.50	$37.50
5 EA	1165367234890890	Tomato Large 30CT	EA	$10.00	$50.00
5 EA	5438967234890890	Cucumbers CTN 24CT	EA	$7.00	$35.00
5 EA	56347116720890	Blue Point Oysters 60CT	EA	$12.00	$60.00
10 EA	155116727890890	BBQ Pulled Pork	EA	$8.00	$80.00
8 EA	1177167288890590	Frozen Green Beans	EA	$7.50	$37.50
20 PT	66118834800890	Fresh Blueberries	PT	$3.00	$60.00
15 EA	116554234877790	Whole Chicken	EA	$7.00	$105.00
1 EA	A56239	Freight DL: 46795-3627	EA	$232.67	$232.67

$1,065.67

Kidwell Shellfish Farms

1234 State Road, City, State, Zip
PH: 123-245-5678 Fax 123-345-5678
State Certification # 111FF

60 Count Blue Points

Original Harvest Cert #:
Original Harvest Date: 10/15/2015
Final Harvest Date: 10/15/2015
Harvested in: State
Harvest Area: Location

Ship to:
Whatever Shellfish Farms
City State

Kidwell Shellfish Farms
City, State

Final Harvest Date: 10/15/2015
Harvested in: State
Harvest Area: Location

Kidwell Shellfish Farms

1234 State Road, City, State, Zip
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Whatever Shellfish Farms
City State

Kidwell Shellfish Farms
City, State

Final Harvest Date: 10/15/2015
Harvested in: State
Harvest Area: Location

CONSUMER COMPLAINT REPORT

State Form 14993 (R3/6-04)

INDIANA STATE DEPARTMENT OF HEALTH
FOOD PROTECTION PROGRAM

Health Department

EHS LHD

1.

- ☐ Bacterial
- ☐ Chemical
- ☐ Foreign Material
- ☐ Suspected Tampering
- ☒ Foodborne Illness
- ☐ Mislabeling
- ☐ Establishment
- ☐ Other _____

Date	Reported by	Phone
1/12/2015	Laurie Kidwell	

Complainant	Phone (H)	Phone (Other)
Pharmacy Student	317-222-2222	

Address	City	State	Zip
Student Dorms A	Indianapolis	IN	12345

Complaint

A student reports experiencing ongoing symptoms of nausea, vomiting, abdominal cramping, and diarrhea approximately 1 hour after eating from the buffet at the Campus Cafe. No leftovers were available from this complainant. The complainant reported eating pulled pork, beef brisket, salad, and blueberry crisp. However, he stated that he only ate a bite of the blueberry crisp because it tasted funny.

Injury/Illness	If yes, symptoms
☒ Yes ☐ No	N, V, D, AC

Date/Time of meal	Date/Time of symptoms	Number exposed	Number ill
1/12/15 12pm	1/12/15 1pm	1	1

Duration of illness	Physician/hospital	Address
ongoing	N/A	

2. Establishment Name Campus Cafe — Food involved: Buffet

Address	County	Date of visit	Time of Visit
Address, City, State, Zip	County	1/12/15	11am

3. Product label	Code/expiration date	
Mfg. ☐ Name Dist. ☐	Address	Pkg. size

Place of purchase	Address

Date of purchase	Number purchased	Number on hand

Police/firm notified	Contact

Additional info.

Sample collected	Complaint taken by
☐ Yes ☐ No	

ESTABLISHMENT FOLLOW-UP

Establishment name	Phone	
Person contacted	Title	
Action: ☐ LHD ☐ Retail ☐ Wholesale ☐ Other _____	Number on hand	Other complaints
Findings/comments		
Follow-up sample collected ☐ Yes ☐ Not	*Environmental Health Specialist*	

Note: Complaint form should be used for initial complaint even if a sample is not involved. If a manufactured food product or foodborne illness is involved, please forward to ISDH.

INDIANA STATE DEPARTMENT OF HEALTH

Food Protection Program
2 North Meridian Street
Indianapolis, IN 46204

SAMPLE RELEASE DOCUMENT

I, _____ _____
(Name) (Street Address)

_____ _____
(City) (State and Zip Code)

hereby agree to release the sample(s) described below into the custody of the authorized representative of the Food Protection Program, Indiana State Department of Health, for investigation and/or analysis:

_____ , _____
(Customer Signature) (Date)

_____ , _____
Protection Representative) (Date)

CONSUMER COMPLAINT REPORT

State Form 14993 (R3/6-04)

INDIANA STATE DEPARTMENT OF HEALTH
FOOD PROTECTION PROGRAM

Health Department

EHS LHD

1.

☐ Bacterial ☐ Suspected Tampering ☐ Establishment
☐ Chemical ☒ Foodborne Illness ☐ Other _____
☐ Foreign Material ☐ Mislabeling

Date	Reported by	Phone
1/12/2015	Kris Gasperic	

Complainant	Phone (H)	Phone (Other)
Information Technology Student	317-222-3333	

Address	City	State	Zip
Student Dorms B	Indianapolis	IN	12345

Complaint

A student reports experiencing ongoing symptoms of nausea, cramping, and diarrhea approximately 1.5 hours after eating from the buffet at the Campus Cafe. An ISDH Complaint Form was completed; the complainant had no leftovers available for collection. The complainant reported eating the roast beef, pulled pork, green beans, and salad.

Injury/Illness	If yes, symptoms	Date/Time of meal	Date/Time of symptoms	Number exposed	Number ill
☒ Yes ☐ No	N, D, AC	1/12/15 12pm	1/12/15 1:30pm	1	1

Duration of illness	Physician/hospital	Address
ongoing	N/A	

2. Establishment Name Campus Cafe | Food involved: Buffet

Address	County	Date of visit	Time of Visit
Address, City, State, Zip	County	1/12/15	11am

3. Product label | Code/expiration date

Mfg. ☐ Dist. ☐ Name	Address	Pkg. size

Place of purchase	Address

Date of purchase	Number purchased	Number on hand

Police/firm notified	Contact

Additional info.

Sample collected	Complaint taken by
☐ Yes ☐ No	

ESTABLISHMENT FOLLOW-UP

Establishment name	Phone	
Person contacted	Title	
Action: ☐ LHD ☐ Retail ☐ Wholesale ☐ Other _____	Number on hand	Other complaints
Findings/comments		
Follow-up sample collected ☐ Yes ☐ Not	*Environmental Health Specialist*	

Note: Complaint form should be used for initial complaint even if a sample is not involved. If a manufactured food product or foodborne illness is involved, please forward to ISDH.

INDIANA STATE DEPARTMENT OF HEALTH

Food Protection Program
2 North Meridian Street
Indianapolis, IN 46204

SAMPLE RELEASE DOCUMENT

I, _____ _____
(Name) (Street Address)

_____ _____
(City) (State and Zip Code)

hereby agree to release the sample(s) described below into the custody of the authorized representative of the Food Protection Program, Indiana State Department of Health, for investigation and/or analysis:

_____ , _____
(Customer Signature) (Date)

_____ , _____
Protection Representative) (Date)

Chapter 5. Tools for Program Analysis and Improvement: Council to Improve Foodborne Illness Outbreak Response (CIFOR) Manual and Toolkit

Table of Contents

1. PURPOSE

This Chapter provides an overview of the Council to Improve Foodborne Illness Outbreak Responses (CIFOR) "Guidelines for Foodborne Disease Outbreak Response" and the CIFOR Toolkit, which allows agencies to evaluate organizational structures and program capacity, related to foodborne illness (FBI) outbreak investigations. Rapid Response Teams (RRTs) are designed to have an integral role in the emergency response to outbreaks. As such, these tools used alongside other process evaluation and management resources should be used to integrate RRTs with partner FBI responding agencies, evaluating the individual capacities then supplementing for improved coordination in a unified emergency response.

2. SCOPE

CIFOR Guidelines provide a framework for multi-disciplinary and multi-agency collaboration between public health (epidemiology and environmental health),

laboratory, and regulatory agencies involved in a FBI investigation. This chapter focuses on the specific response actions and considerations outlined in the CIFOR "Guidelines for Foodborne Disease Outbreak Response" and related Toolkit, and where they may be integrated across organizations to create a plan for and execute a unified response to FBI outbreaks. This evaluation process may be useful for Rapid Response Teams (RRT), agencies with established outbreak response procedures, and for those assessing programmatic gaps with the goal of building upon existing plans and capabilities.

3. RESPONSIBLITY

3.1. Agency/Organization Leadership

Prior to initiation of the evaluation process, leadership of federal, state, and local agencies involved in responses to human and animal food incidents should be made aware of the process, outcomes, and what their individual and collaborative roles would be in supporting the evaluation's findings and advancing improvements.

3.2. RRT Members and Partners

Participate in all phases of the focus area selection, evaluation and reporting processes. For the purposes of the Toolkit and the "Investigation of Clusters and Outbreaks" focus area, participants should include representatives of environmental health, laboratory, and epidemiology units.

Apprise leadership of federal, state and local agencies involved in response to human and animal food incidents of the process, outcomes, and what their potential role would be in supporting findings and advancing improvements

Invite experts in information technology, retail food, legal issues, infectious disease etc., as needed to participate in the evaluation. This may be necessary as other elements of the CIFOR Toolkit are used, or when specific areas for improvement are identified.

3.3. Other Partners

Additional participants in an evaluation, including experts in information technology, retail food, legal issues, infectious disease experts etc., should be invited to the process particularly as other elements of the CIFOR Toolkit are used or when specific areas for improvement are identified.

4. DEFINITIONS

4.1. Internal v. External

4.1.1. Internal – Internal to the agency initiating use of the CIFOR Toolkit and having primary or coordinate responsibility for initiating an FBI investigation.

4.1.2. External – Agencies or other entities that would participate in an FBI investigation but are not part of the original, initiating agency for a response or for the evaluation process.

4.2. CIFOR – Council to Improve Foodborne Outbreak Response

4.3. FBI – Foodborne Illness

4.4. RRT – Rapid Response Team

4.5. MFRPS – Manufactured Food Regulatory Program Standards

5. BACKGROUND

RRTs may take advantage of several different tools available to improve the effectiveness and efficiencies of their organizational structures, response capacity, regulatory foundation, and other critical aspects of a human and animal food protection and response program. In addition to CIFOR's Guidelines for Foodborne Disease Outbreak Response, other program improvement initiatives include the MFRPS, and the Voluntary National Retail Food Regulatory Program Standards. These initiatives evaluate food programs primarily from the regulatory and food protection levels. Some elements of each of these tools may seem to overlap with or mirror those in other evaluation tools; however, each serves a specialized purpose in evaluating human and animal food protection and response programs.

In contrast, the CIFOR Guidelines are not focused on the evaluation of core food protection and response programs, but on critical elements of FBI outbreak and cluster investigations and the response. The CIFOR Guidelines and the associated CIFOR Toolkit examine the roles of regulatory, laboratory, public health organizations at the federal, state, and local levels with respect to an integrated outbreak response. Use of the CIFOR recommendations and tools will aid food protection and response programs and related agencies in understanding organizational models and best practices that may help integrate investigation activities and improve the overall performance of the RRT and associated investigation partners.

In this respect CIFOR Guidelines expand upon the foundation provided in other regulatory program evaluation tools. For example, while Standard 5 of the MFRPS, "Food Related Illness, Outbreak, and Hazards Response" examines capabilities related to foodborne illness outbreaks, MFRPS focus primarily on the regulatory element of a program. Use of the CIFOR Toolkit will contribute to programmatic efforts to meet MFRPS #5, though it emphasizes on other elements of FBI investigations.

Human and animal food protection and response programs and RRTs that are interested in using this evaluation tool should use the CIFOR Guidelines and the Toolkit together. The CIFOR Guidelines describe the major functions that need to occur during an FBI outbreak including planning and preparation, disease surveillance and outbreak detection, investigation of clusters and outbreaks, and control measures. The CIFOR Toolkit provides a mechanism for using the concepts in the CIFOR publication to evaluate existing state and local human and animal food protection and response programs and their associated

operations and capabilities. Use of the Toolkit will help these human and animal food protection programs to become more familiar with the CIFOR Guidelines, and identify and improve practices and capabilities that affect the performance of the RRT.

CIFOR Toolkit worksheets provide a valuable starting point for systematically assessing activities related to various components of outbreak investigation. Once completed, these worksheets provide a basis for use of other RRT manual elements including recall procedures, working with other agencies, and additional capabilities. Additional tools, job aids, and model protocols may be found in other chapters of the RRT Manual and in the CIFOR Clearinghouse on-line (see Comparison Table at the end of this chapter).

The CIFOR Toolkit facilitates an analysis of the different components and factors contributing to an effective FBI investigation. Of the four "Tracks" described in the Toolkit, It is suggested that the first one that should be evaluated for RRTs is "Investigation of Clusters and Outbreaks" including constituent Focus Areas within that Track: Environmental Health Investigations, Epidemiology Investigation, and Laboratory Investigation. (See Document E, "Selecting Focus Areas Worksheet" and CIFOR Guidelines Chapter 5.) RRTs should review information found in Chapter 5 of the CIFOR Guidelines that discusses the investigation process, in addition to the using the appropriate CIFOR Toolkit worksheets as described below. Chapter 6 of the manual, "Control Measures-Debriefings, Procedures for Removing Food from the Market" also discusses a key element of FBI response that should be examined and used for planning, protocol development and FBI investigation efforts.

The "Keys to Success" in each section of the CIFOR Toolkit discuss the core capabilities necessary for different elements of an FBI investigation, including specific activities, communication, relationships, resources and other factors that contribute to the improvement of response team capabilities. Ongoing use of the Toolkit and evaluation process will support efforts to improve and maintain overall RRT capacity.

6. SAFETY

N/A

7. EQUIPMENT/MATERIALS

- **7.1.** Texts referenced in this document
- **7.2.** Conferencing equipment, phones, email/internet/computer/blackberry, fax machines, scanners, and/or mail
- **7.3.** Access/use of FoodSHIELD
- **7.4.** Local area networks
- **7.5.** Meeting rooms
- **7.6.** Contact list

8. PROCESS DESCRIPTION

The following documents are developed with the intention of facilitating the integration of RRTs into existing human and animal food protection and response programs enhancing the ability to rapidly respond to human and animal food incidents through coordinating the activities and supplementing the capacity of all organizations involved. Use of the national FBI outbreak investigation process and evaluation standard, CIFOR Guidelines and Toolkit, provides a consistent nationwide basis for evaluating the mechanism of integrating and coordinating the RRT with partner organizations and the impact of these actions on process improvements and FBI investigation outcomes. The toolkit provides a mechanism for continued improvement through consistent evaluation of the outbreak response process for participants. Use of the process described advances the goal of full integration of the national human and animal food safety system across all levels.

The CIFOR Guidelines and Toolkit are the result of a multi-year process and are consensus recommendations for FBI outbreak investigation. The toolkit provides a mechanism for continued process improvement through consistent evaluation of outbreak responses. Use of the process described can result in improved and better aligned multi-agency and multi-disciplinary FBI investigations leading to a more nationally integrated human and animal food safety system.

8.1. Initiate Workgroup on Use of CIFOR Toolkit

To effectively use the CIFOR Toolkit, a workgroup should be formed to carry out the overarching assessment of the program and specific areas needing further evaluation. The workgroup should comprise members of at least the three core response areas (i.e., environmental health, epidemiology and laboratory) and others familiar with the outbreak response process. Additional expertise may be brought to the workgroup as well. Information on past outbreak investigations and after action summary reports from formal exercises may be used to provide information for the initial CIFOR evaluation tool, as described in Document E of the Toolkit, “Selecting Focus Areas Worksheet”.

This process narrows the number of areas for evaluation, although multiple sub-workgroups may be formed to address other response issues.

8.2. Refine Workgroup as Necessary

Assess workgroup expertise and experience and determine if additional members may be needed.

8.3. Prepare Background Resources

Familiarize partners with the CIFOR Toolkit worksheets, identify additional needed resources, and review historical information prior to use of actual worksheet. To use the worksheets effectively, participants should review previous outbreak response reports, plans, and activities. A complete background information sheet

will be developed based on these resources as part of the evaluation process which will inform conclusions about the RRT and FBI Investigation.

A review of the CIFOR Guidelines by all members is also essential to the success of the Workgroup and evaluation process.

The RRT manual, including the introductory chapter "Working with Other Agencies", "Communication Standard Operating Procedures", "Tracebacks", "Incident Action Plans, Situation Reports, and After Action Reports" and other sections relevant to your objectives and RRT should be evaluated.

Additional process and subject matter evaluation tools should also be reviewed and discussed prior to use of the CIFOR Guidelines so that findings and issues relevant to the RRT and FBI response can be introduced.

Historical documents on past FBI response efforts, and formal after action reports, should be examined to identify issues for discussion and evaluation.

8.4. Utilize CIFOR Toolkit Guidelines to Identify Strengths and Weaknesses

Following the selection of specific capabilities to be assessed, use the CIFOR worksheets individually then as a group to identify core strengths, weaknesses and resources in the food protection and response program areas. Use the appropriate portions of the CIFOR Toolkit to support your analysis and evaluation. Avoid duplication of effort, i.e., between two separate program evaluation processes such as MFRPS and CIFOR, and tailor your use of the CIFOR Toolkit to the specific needs and issues of your agency.

8.5. Share Findings with Contributing Partners and Leadership

Upon completing worksheets and use of the CIFOR Toolkit, assemble analysis and core findings and distribute to members of Workgroup and internal and external leadership as appropriate.

8.6. Comments and Reviews

Distribute CIFOR worksheets to members of the workgroup and internal leadership for feedback and comments. Once all comments are reviewed and incorporated as appropriate, distribute to appropriate parties.

8.7. Crosswalk Findings to Other Program Standards

In addition to completion of the Toolkit evaluation, findings should be cross walked when possible to the MFRPS and to the Retail Program Standards. Such standards help form the basis for foodborne illness outbreak response through strengthening of the core regulatory program. The Crosswalk may be found at the following address:
http://www.cifor.us/clearinghouse/uploads/Document%20H_Crosswalks%20betw

een%20National%20Initiatives%20and%20CIFOR%20Toolkit.pdf?CFID=42475325&CFTOKEN=78980292&jsessionid=A2FA380C84B33F21162553C983863F0D.cfusion

8.8. Develop Strategic Plan

Based on the findings from use of the CIFOR Toolkit, and evaluation of other best practice tools and resources, consider outlining areas for improvement and develop a strategic plan.

8.9. Continue Evaluations in Other Focus Areas

Carry out evaluations of other areas (e.g., communications) that contribute to the overall success of FBI investigations. See Metrics chapter of RRT Best Practices Manual.

8.10. Measure Improvement Through Actual Events and Exercises

Consider the development of, or adoption of, metrics to measure improvement in specified areas of FBI outbreak response and assess following actual events and exercises. Develop plans to address gaps, resources, and capabilities based on after action reports and metrics assessments.

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

The levels assume that agencies with higher level capacities meet all the elements, while agencies with lower level capacities meet only some of them

Level	Description
1	No awareness or familiarity with CIFOR Guidelines and CIFOR Toolkit. No FBI investigation process or capabilities have been evaluated using the CIFOR Toolkit.
2	Knowledge of FBI response capabilities. CIFOR Toolkit is used to assess one or more FBI response elements and a draft evaluation report is produced.
3	Engage with partner agencies, industry, and other FBI responders. Key parties[1] review and provide input on the draft evaluation report.
4	Capacity built to implement the development of an integrated human and animal food protection and response program (through assessment, corrective action plans, and strategic planning). The evaluation report is used to guide development of protocols for the RRT/human and animal food protection and response program, planning, and responses to exercises or actual incidents.
5	Full use of CIFOR Guidelines and Toolkit and RRT Chapters and related resources. FBI investigation protocols undergo routine[2] evaluation using CIFOR toolkit process.

9.2. Process Overview

[1] As determined by the RRT member agency leading this effort or the RRT Steering Committee/equivalent.
[2] As agreed upon by RRT member agencies involved in the evaluation. CIFOR suggests a yearly evaluation.

9.2.1. Identify Achievement level (table above). Identify agency goals and existing commitments to one or more process improvement initiatives (e.g., Manufactured Food Regulatory Program Standards (MFRPS), etc.). Review crosswalk (attached) that identifies similarities and differences of key initiatives related to human and animal food emergency response and process improvements.

9.2.2. Review CIFOR Guidelines (especially Chapter 5) and introductory CIFOR "Toolkit" sections including "Toolkit Overview – Document A" and "Selecting Focus Areas Worksheet – Document E".

9.2.3. Form a workgroup, including members of the RRT where appropriate, to carry out the evaluation process to identify potential focus areas where improvements may be needed. Ensure familiarity of all participants with the CIFOR Guidelines and related documents (the RRT Manual and CIFOR guidelines complement each other and should be used in tandem for the process).

9.2.4. Once the primary focus areas for a full evaluation have been identified, select the appropriate CIFOR Toolkit worksheet to guide the analysis (e.g., Focus Area 8 Worksheet: Environmental Health Investigation" CIFOR Toolkit worksheet)

9.2.5. Use the CIFOR tools and the findings from the analyses to develop a strategic improvement plan. Prioritize areas for improvement and develop plans to address other outstanding issues.

9.2.6. Modify and revise existing protocols and procedures as necessary based on findings.

9.2.7. Assess advances related to the CIFOR criteria in annual exercises and/or after action reports on actual incidents.

10. RELATED DOCUMENTS

10.1. RRT Best Practices Manual, US Food and Drug Administration, 2011

10.2. Council to Improve Foodborne Outbreak Response (CIFOR). Guidelines for Foodborne Disease Outbreak Response. Atlanta: Council of State and Territorial Epidemiologists, 2009

10.3. Voluntary National Food Retail Food Regulatory Program Standards

10.4. Manufactured Food Regulatory Program Standards (MFRPS)

10.5. Food Related Emergency Exercise Bundle (FREE-B)

11. REFERENCES AND OTHER RESOURCES

11.1. Manufactured Food Regulatory Program Standards (MFRPS) https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf

11.2. Voluntary National Retail Food Regulatory Program Standards https://www.fda.gov/food/guidanceregulation/retailfoodprotection/programstandards/ucm245409.htm

11.3. National Association of State Departments of Agriculture Food Emergency Response Plan Guidance http://www.nasda.org/Policy/6460/9885/6138/11681.aspx

11.4. Council to Improve Foodborne Outbreak Response *Guidelines for Foodborne Disease Outbreak Response* and related resources

11.4.1. Guidelines http://www.cifor.us/

11.4.2. Toolkit http://www.cifor.us/toolkit.cfm

11.4.3. Clearinghouse http://www.cifor.us/clearinghouse/keywordsearch.cfm

11.4.4. Crosswalk http://www.cifor.us/clearinghouse/uploads/Document%20H_Crosswalks%20between%20National%20Initiatives%20and%20CIFOR%20Toolkit.pdf?CFID=42475325&CFTOKEN=78980292&jsessionid=A2FA380C84B33F21162553C983863F0D.cfusion

11.5. FoodSHIELD https://www.foodshield.org/

12. ATTACHMENTS

12.1. Attachment A – Comparison Table: RRT Best Practices Manual to CIFOR Guidelines

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	10/11/2012	RRT CIFOR WG (TX**, MA, MI)
1.1	R	1/24/2013	ORA OP
1.2	R	5/26/2017	ORA/OP

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)

**Workgroup Lead

Change History

1.1 – Minor editorial revisions made to Achievement Levels and Attachment A for clarification purposes.

1.2 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.

Attachment A – Comparison Table: RRT Best Practices Manual to CIFOR Guidelines

This table aims to identify related sections between the RRT Best Practices Manual and the CIFOR Guidelines and Toolkit, and should not be interpreted as interchangeable. Please note that while these documents may contain content that touches on similar topics or is complementary, each of these documents serve a specific program or constituency. While it is encouraged for human and animal food regulatory and public health programs to leverage multiple response tools as appropriate for their program, human and animal food regulatory and public health programs receiving federal funding for response capacity development should always defer to the requirements set forth in that funding agreement.

DESCRIPTION OF CHAPTER		CIFOR GUIDELINES AND TOOLKIT
Chapter 1	Working with Other Agencies	Chapter 3.1 – Agency Roles
Chapter 2	Federal-State Cooperative Programs	No corresponding CIFOR content at this time
Chapter 3	Industry Relations	Chapter 3.6 – Communication Chatper 6.5.4 – Communication with the Industry
Chapter 4	Exercises	No corresponding CIFOR content at this time
Chapter 5	CIFOR	
Chapter 6	Food Emergency Response Plans (FERPs)	Chapter 3 – Planning and Preparation
Chapter 7	Communication Standard Operating Procedures (SOPs)	Chapter 3.6 – Communication
Chapter 8	Incident Command System Concepts in RRTs	Chapter 3.10 – Incident Command System
Chapter 9	Rapid Response Team (RRT) Training	Chapter 3.2 – Outbreak Investigation and Control Team
Chapter 10	Tracebacks	Chapter 6.2 – Control of the Source
Chapter 11	Joint Inspections & Investigations	Chapter 5.2.5 – Coordinate Investigation Activities Chapter 7 – Special Considerations for Multijurisdictional Outbreaks
Chapter 12	Environmental Sampling & Records Collection	Chapter 3.2 – Outbreak Investigation and Control Team
Chapter 13	Recalls	Chapter 6 – Control Measures
Chapter 14	After Action Reviews	Chapter 5.2.8 – Conduct a Debriefing at End of Investigation Chapter 6.7 – After-Action Meetings and Reports Chapter 7.5 – Multijurisdictional Outbreak Investigations After-Action Reports and Reporting to eFORS
Chapter 15	Metrics	Chapter 8 – Performance Indicators for Foodborne Disease Programs

DESCRIPTION OF CHAPTER		CIFOR GUIDELINES AND TOOLKIT
Relevant Concepts & Tools	Subsection A: RRT Capacity Building Process & Framework for Developing Rapid Response Capability	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection B: Response Concepts/Framework	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection C: Crosswalks of Frameworks/Concepts	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection D: Useful Tools in Improving Foodborne Outbreak Response	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection E: Conference Call Etiquette	Chapter 3.6 – Communication
Relevant Concepts & Tools	Subsection F: Overview: Incident Action Plans, Situation Reports, and After Action Reports	Chapter 7.5 – Multijurisdictional Outbreak Investigations After-Action Reports and Reporting to eFORS
Reference	Subsection A: Acronyms	No corresponding CIFOR content at this time
Reference	Subsection B: Glossary of Key Terms (Definitions)	Appendix 1 – Glossary
Reference	Subsection C: List of Reference Documents	Appendix 3 – List of Key Websites and Resources Cited
Reference	Subsection D: About the RRT Program	No corresponding CIFOR content at this time

Chapter 6. Food Emergency Response Plans (FERPs)

TABLE OF CONTENTS

1. PURPOSE

Human and animal food emergency response planning is a key element of all-hazards preparedness. This chapter identifies best practices and tools to help agencies better develop multi-agency response plans.

2. SCOPE

This chapter focuses on food emergency response plans (FERPs), referencing the National Association of State Departments of Agriculture (NASDA) Food Emergency Response Template. This chapter also clarifies the complementary roles of high-level plans such as FERPs and more operational documents such as job aids.

The key planning considerations, steps, templates, examples, and resources identified in this chapter will most directly apply to state agencies and US Food and Drug Administration (FDA) District/Program Division Offices developing FERPs for responding to complex and/or multi-jurisdictional emergencies. However, these are neither comprehensive nor specific to unique situations. State, local, and federal agencies seeking to improve multi-agency food emergency responses (e.g., States, FDA field offices) may utilize this chapter to assess and improve their response capabilities. Agencies with varying responsibilities (e.g., regulatory, public health, feed/animal health, law enforcement, laboratory) and target response capability levels may differ in how they customize and apply these best practices.

3. RESPONSIBILITY

3.1. RRT (or investigatory team, in states without an RRT) Leadership

RRT Leadership is responsible for ensuring that their respective response partners are aware of existing human and animal food emergency response plans, policies and procedures and are offered the opportunity to provide input as appropriate when plans are updated.

3.2. RRT Members

RRT Members are responsible for ensuring that they are familiar with their agency's emergency response plans, policies, and Standard Operating Procedures (SOPs) and that they can fulfill their assigned roles during multi-agency responses.

4. DEFINITIONS

The following terms are used frequently in this chapter: Food Emergency Response Plan (FERP).

See "Glossary of Key Terms" for definitions.

5. BACKGROUND

The National Response Framework and the National Preparedness Guidelines consider human and animal food emergency response planning to be an essential element of all-hazards preparedness.

In general, a standardized written framework for response consists of:

- High level plans (e.g., the FERP) which clarify agency roles and responsibilities regarding the "who," "what," and "when" of human and animal food emergency responses.
- More detailed operational procedures for specific subject matter tasks, which identify the "how" of specific aspects of the response.

6. SAFETY

General safety considerations should be addressed in agency policies and procedures and fleshed out in specific response plans.

7. EQUIPMENT/MATERIALS

N/A

8. PROCESS DESCRIPTION

8.1. General Approach

Development of both a high-level FERP and more specific response documents (e.g., procedures) requires a high degree of coordination among all the partners involved in food emergency response. It is very important to review and apply the "Working with Other Agencies" Chapter of this manual, which addresses the roles

and activities of the different agencies involved in a response, as the foundation for development of an effective FERP.

8.2. Recommendations for Developing a High-Level FERP

8.2.1. Primary Tool: The NASDA FERP Template

1. **Background:** The NASDA FERP template was developed jointly among federal partners (e.g., US Department of Agriculture Food Safety Inspection Service (USDA FSIS), FDA, Department of Homeland Security (DHS)), state partners (e.g., agriculture, health) and other associations (e.g., Association of Food and Drug Officials). This template is designed to assist states with development of a plan for conducting coordinated responses to food-related emergencies, either as a stand-alone plan or an addendum to an existing state emergency response plan. The template, developed beginning in 2005, was based on the information and response plans collected from states. This template document also identifies how states would integrate within the National Response Framework.
2. **How to use the template:** The template provides background (e.g., "Appendix A - Planning Considerations"), references, and a guide for developing a food emergency response plan. *(Attachment A of this chapter summarizes the recommended FERP elements identified in the NASDA template.)* Examples of state FERPs are included in the supplement to the NASDA template as a tool to customize, complete, and/or improve a state-specific plan.

8.2.2. Additional Tools

1. **Consider other state plans.** If interested in reviewing additional tools and examples, contact OP at OP.Feedback@fda.hhs.gov.
2. **Evaluate how FERP fits into all-hazards preparedness.** There are many frameworks and tools related to building preparedness and response. One example is the Food and Agriculture Readiness Measurement (FARM) Toolkit, which is a tool to examine program all-hazards preparedness. More information on this tool is available at: https://www.foodshield.org/projects/benchmarking.cfm.

8.3. Recommendations for Developing More Detailed Response Documents

8.3.1. Background: Detailed response documents may include documents such as Standard Operating Procedures (SOPs), checklists, and job aids. These complement and provide specifics to the concepts described in the higher-level FERP. These should be consistent with national standards whenever possible.

8.3.2. How to begin developing these documents: Attachment B ("Example Areas to Develop Detailed Response Documents") identifies an example of areas covered in a State's compendium of RRT SOPs. This set of topics,

while not comprehensive, provides an example of some common/important areas for which specific SOPs and other specific tools need to be developed to effectively execute the strategy described in the FERP.

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

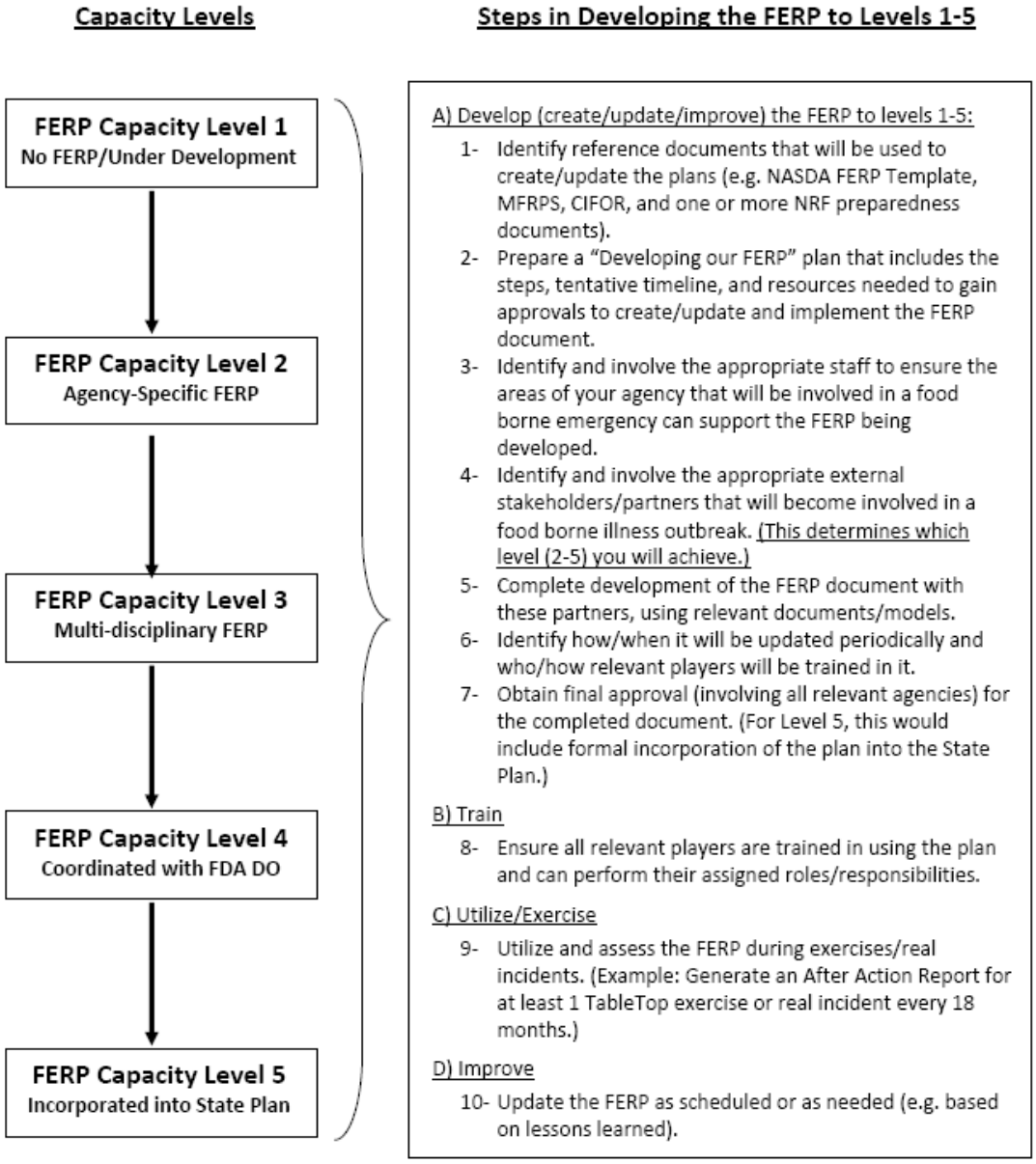
9.1. Achievement Levels

The levels below illustrate a progression that agencies can pursue to incrementally develop a capacity, with each level building on the previous one.

Level	Description
1	The agency does not have a FERP. (If "no," is one currently under development?)
2	The agency has an agency-specific FERP addressing its responsibility.
3	The state has a multidiciplinary FERP that has been coordinated with appropriate state agencies to ensure that food regulatory, laboratory, epidemiology, and law enforcement responsibilities are addressed.
4	The FERP has been coordinated with the appropriate FDA District/Program Division Office.
5	The agency plan is incorporated into, or otherwise linked with, the state all hazards response plan. (Should be exercised, at a minimum, every 18 months.)

9.2. Process Overview

Achievement of each of Capacity Levels 2-5 requires that agencies conduct the steps identified in sections A-D (Steps 1-10), see figure. The combination of partners engaged during Step 4 will determine which final Capacity Level is achieved.



10. RELATED DOCUMENTS

(Full citations are in the References Section, "List of Reference Documents," listed by author.)

10.1. National Response Framework (https://www.fema.gov/national-response-framework)

10.2. Multistate Foodborne Outbreak Investigations: Guidelines for Improving Coordination and Communication, National Food Safety System Project, Outbreak Coordination and Investigation Workgroup, February 2001 (http://www.cifor.us/clearinghouse/tooldetail.cfm?id=212)

10.3. National Preparedness Guidelines (https://www.dhs.gov/national-preparedness-guidelines)

10.3.1. Target Capabilities – Epidemiological Surveillance and Investigation, Food and Agricultural Safety and Defense, Public Health Laboratory Testing, and Environmental Health
10.3.2. Universal Task List

11. REFERENCES AND OTHER RESOURCES

(Full citations are in the References Section, "List of Reference Documents," listed by author.) Note: These documents are summarized in Attachment C.

11.1. National Association of State Departments of Agriculture (NASDA) FERP Template Version 4.0 (http://www.nasda.org/File.aspx?id=4065)
11.2. Manufactured Foods Regulatory Program Standards (MFRPS, 2010) – Standard 5 (https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf)
11.3. Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines for Foodborne Disease Outbreak Response (http://www.cifor.us/CIFORGuidelinesProjectMore.cfm)

12. ATTACHMENTS

12.1. Attachment A – FERP Elements in the NASDA FERP Template
12.2. Attachment B – Example "Table of Contents" for a State's Response Operations Manual
12.3. Attachment C – Summary of the following references: MFRPS, NASDA, and CIFOR

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	9/26/2011	RRT FERP Working Group (TX**, MI, WA, FL, OP**)
1.1	R	2/1/2012	ORA/OP
1.2	R	1/24/2013	ORA/OP
1.3	R	5/26/2017	ORA/OP

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)
**Workgroup Lead

Change History

1.1 – Editorial revisions made by ORA for document clearance.
1.2 – Minor editorial revisions made to Attachment A for clarification purposes.
1.3 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.

Attachment A – FERP Elements in the NASDA FERP Template (v 4.0)

Version 4.0 available at: http://www.nasda.org/File.aspx?id=4065.

The "FERP Supplement v 4.0" outlines planning considerations and examples to assist initial development of a plan. This is available at: http://www.nasda.org/File.aspx?id=12006.

FERP Table of Contents:

1. Introduction
2. Purpose
3. Scope
4. Situations
5. Assumptions
6. Concept of Operations
    a. Incident Identification
    b. Incident Management
    c. Defining Response Actions
    d. Communication and Coordination
    e. Assessment, Control, and Containment
        - Food Emergency Response Teams
        - Food Safety Surveillance
        - Foodborne Contamination or Adulteration Surveillance & Investigation
        - Laboratory Services
        - Recovery
7. Principal Parties (State, Federal, Tribal, Local, Private Sector)
8. Actions
9. Organizations and Assignment of Responsibilities
10. Direction, Control, and Coordination
11. Information Collection and Resources
12. Communications
13. Administration
14. Plan Development and Maintenance
15. Authorities and References

Attachment B – Example "Table of Contents" for a State's Response Operations Manual

Below is an example of a "Table of Contents" of a State's RRT Procedures/Field Operations Manual. This is not comprehensive, but identifies some areas for which a program would need to develop specific procedures and job aids to effectively carry out activities associated with an emergency response.

EXAMPLE: State X Rapid Response Team Standard Operating Procedures

A. Overarching Concepts

- Rapid Response Team Organization…….
- Incident Command System (ICS) principles…….
- Safety……
- Training…….

B. Communication and Partners

- Communication…….
- Epidemiology ……
- Laboratory……

C. Investigational/Follow-Up Activities

- Traceback (Investigational and Regulatory)…….
- Field Team Organization and Operations……..
- Coordination of Joint Investigations…….
- Sampling……
  - Food……
  - Environmental ……
- Environmental Assessments…….
- Recalls……
- Commodity-Specific Investigational Procedures……..
- Final Report Writing, Editing and Distribution……

D. Important References

- Standard Definitions…….
- Acronyms……

Attachment C – Summary of References: MFRPS, NASDA, & the CIFOR Guidelines

- **The Manufactured Food Regulatory Program Standards (MFRPS)** were developed by a committee of FDA and State officials responsible for the regulation and inspection of food manufacturing facilities. The first version was published in 2007 and this was updated in 2010, 2013, and 2016. **Standard 5** identifies a number of written procedures and guidance documents that state food regulatory programs should have in the area of food emergency response.
    - Purpose: The MFRPS are a set of ten standards that establish the critical elements of a regulatory program designed to protect the public from foodborne illness and injury.
    - Perspective: Mid-level guidance to identify key capabilities needed in the food protection program to facilitate effective emergency responses.
    - Scope: Focuses on general capabilities but requires documentation of resources and procedures.

  Website: https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf

- **The National Association of State Departments of Agriculture (NASDA) developed the Food Emergency Response Plan Template** as part of a cooperative agreement with USDA's Food Safety Inspection Service (FSIS), the Food and Drug Administration (FDA), and the Department of Homeland Security (DHS). The original template (2006) was revised in 2011 to be consistent with various developments in national frameworks (e.g., National Response Framework (NRF), Comprehensive Preparedness Guide (CPG) 101). In addition, this revised template has been reviewed and approved by federal, state and private sector subject matter experts.
    - Purpose: This template is designed to assist states with developing a food emergency response plan. This identifies best practices and guidelines for state and local groups involved in protecting the nation's food and agricultural sector.
    - Perspective: High-level guidance to assist states to integrate within the National Response Framework (incorporation DHS and emergency management concepts).
    - Scope: Focuses on preparing for larger scale incidents of national significance rather than procedures for specific food emergency response tasks.

  Website: http://www.nasda.org/File.aspx?id=4065

- **The Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines** are a set of recommendations developed through the collaboration of public health and food safety officials from local, state, and federal agencies over the course of three years.
    - Purpose: To aid agencies responsible for preventing and managing foodborne diseases by describing the overarching functions and related activities that are common to most outbreak investigations.
    - Perspective: Addresses the reality that multi-state food emergency responses are multi-agency (local, state, federal) and multidiciplinary (epidemiology, laboratory, and environmental health/food regulatory as core disciplines).
    - Scope: Strategic more than operational and does not include procedures for specific food emergency response tasks. Note that the CIFOR Toolkit is an additional resource that helps to identify areas for development of specific procedures, etc. for implementation of the recommendations outlined in the Guidelines. (http://www.cifor.us/toolkit.cfm)

  Website: http://www.cifor.us/CIFORGuidelinesProjectMore.cfm

Chapter 7. Building and Enhancing Communication SOPs for Incident Response

TABLE OF CONTENTS

1. PURPOSE

Effective communications among partners is critical for a multiagency, multi-jurisdictional incident response. This chapter provides RRTs with a mechanism to evaluate and improve existing communication Standard Operating Procedures (SOPs) to be used during incident responses. It will also provide information to assist non-RRT states in building or evaluating their communication plans. The chapter provides examples of best practices for communication plans, which includes developing joint communication SOPs and multiagency communication.

2. SCOPE

This chapter provides the basic central components of an effective communication SOP, including assessment criteria, worksheets, guidelines, and examples to assist in developing or improving communication SOPs.

The information in this chapter focuses on developing multiagency and multidisciplinary communication plans. The Working with Other Agencies (WWOA) chapter of this manual provides additional information on communication activities prior to and outside of emergency situations. This chapter complements policies and procedures described in the FDA-State Communication Field Management Directive 50: http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm056669.htm.

Because each State and RRT can vary in structure, it is important to remember that this chapter cannot be comprehensive enough to be all-inclusive nor specific enough to cover every type of situation. State, Federal, and Local agencies may use this chapter to assess and improve their incident response communication procedures, and agencies with varying responsibilities (e.g., regulatory, public health, law enforcement, laboratory, and other) may differ in how they apply these best practices.

3. RESPONSIBILITY

3.1. RRT Leadership (e.g., RRT Steering Committee or equivalent)

General note: this chapter uses broad terms to refer to various roles within a RRT or agency, such as "RRT Leadership", to allow each RRT to apply these best practices within their specific organizational structure or system. "RRT Leadership," as it pertains to the best practices within this chapter, should include members from each applicable RRT member agency/partner, and may exist as one of many different forms, depending on the individual RRT (such as a Steering Committee or a Joint Management Team, etc.).

3.1.1. SOP Development

Leadership will develop or identify personnel responsible for development of a communication SOP.

3.1.2. SOP Familiarization/training

Leadership will ensure that personnel assigned to respond to human or animal food incidents have proper training to complete their assigned tasks in accordance with the communication SOP.

3.1.3. SOP Maintenance

Leadership will identify personnel responsible for ongoing updates and maintenance of the SOP. The SOP should be updated on a regular schedule (e.g., annually) and after exercises or responses as necessary (e.g., deficiencies noted in after action reviews and reports). Implementing a document control system helps to ensure that SOPs are adequately reviewed, updated, approved and distributed to all appropriate team members. If the RRT chooses to maintain

communication SOPs at the individual RRT member agency level instead of developing joint procedures, the revision process should occur in a collaborative manner among applicable RRT member agencies (e.g., the State program(s) and the FDA District/Program Division Office) to ensure that all SOPs and documents are updated in a coordinated fashion.

3.2. RRT Members (investigatory team)

3.2.1. SOP Familiarization/training

Team members must be familiar with these SOPs (e.g., through orientation, training, exercises, etc.) and how they are to be implemented.

3.2.2. Skills Maintenance

Team members are each responsible for playing an active role in maintaining both their subject matter expertise and ability to work effectively in multidisciplinary and multiagency response teams.

4. DEFINITIONS

See Manual Section IV Reference Part B "Glossary of Key Terms" for definitions

4.1. **Business Process Review** – An evaluation or review of a RRT or organization's current practices, accomplished via a thorough analysis of the applicable people, processes, technologies, etc., involved in said practices. The main purpose is to assist organizations in becoming more efficient and effective as part of continuous process improvement. Examples include Kaizen[1] and Lean Process Improvement[2].

4.2. **External Communication** – Communication that extends beyond one agency, to partnering agencies, public, industry, academia, the press, etc.

4.3. **FDA Coordination Groups** – Coordinated Outbreak Response and Evaluation Network (CORE) Signals or Response Teams, Office of Crisis Management (OCM)/Office of Emergency Operations (OEO), Food Defense Emergency Response Coordination Staff (FDECS), Center for Veterinary Medicine (CVM).

4.4. **Federal Coordination Groups** – Federal Partners responsible for coordinating the Federal Agency's response with State and Local partners (FSIS, CDC, EPA, also see "FDA Coordination Groups").

4.5. **Internal Communication** – Communication within a single agency; for the state, can involve regulatory, epidemiology, public health, and lab team members involved in an incident response depending on state structure.

4.6. **Response Team** – The personnel assigned to conduct specific investigation activities and coordinate the RRT's response to an incident. These personnel will be selected from the subset of RRT member agencies or partners that will assume responsibility for the RRT response or activation. This response team may be in the form of an Incident Management Team (IMT) stood up under Incident

[1] https://www.kaizen.com/about-us/definition-of-kaizen.html
[2] http://gamep.org/services/lean-process-improvement/

Command System (ICS)/Unified Command, constituting a RRT activation, or could operate under a non-ICS structure that would constitute a RRT Response.

4.7. **RRT Activation** – Agency Executives or designees approve activation of RRT (e.g., stand up of an IMT). Actual definition and triggers for activation are determined by each RRT individually and must be properly documented in SOPs or other RRT agreements/plans. Triggers which may be considered prior to a potential RRT activation could include the number of ill persons or deaths, possibility of incident escalation, severity of the health hazard, etc.

4.8. **RRT Auxiliary Member Agencies/Partners** – Other regulatory programs within the state (retail/restaurant inspections, raw molluscan shellfish, grade A dairy, etc.), local health departments. This will vary and is defined by each RRT. See Chapter 1 of this RRT Manual (WWOA) for additional details.

4.9. **RRT Core Member Agencies/Partners** – FDA District/Program Division, state food regulatory program, state feed regulatory program, state epidemiologist, and state laboratory. May include others, as defined by the RRT. See Chapter 1 of this RRT Manual (WWOA) for additional details.

4.10. **RRT Response** – RRT response activities, other than RRT Activations, to incidents with increased potential public health risk. These do not include routinely scheduled regulatory activities and may involve a broad range of incidents, including but not limited to: human illness clusters and outbreaks, human or animal food contamination incidents with no human illnesses, requests for emergency assistance from another agency, large planned events, severe weather events, and other human or animal food emergencies. RRT Responses are those requiring enhanced coordination, communication, and subject matter expertise, and technical skills that RRT members have developed.

5. BACKGROUND

Effective communication is necessary for an effective response. Post-response evaluations (e.g., after action reports) frequently identify interagency and interpersonal communication challenges as a cause of inefficiencies in the actual response and may have significant detrimental public health consequences. These challenges may prolong the time between initial notification of a human or animal food problem and implementation of effective control measures.

Communication's central role in incident response necessitates a pre-established communication plan to optimize use of operational resources. This chapter was developed to facilitate development and/or improvement of Communication SOPs utilized in response to human or animal food incidents. Execution of the communications model set forth in this chapter provides a coordinated, cohesive approach to communication during an incident response.

6. SAFETY

N/A

7. EQUIPMENT/MATERIALS

A communication system is made up of a variety of communication devices. When compiling your communication equipment consider including (or securing access to) a variety of communication methods:

7.1. Telephones, smartphones, satellite phones, speaker microphones, portable or mobile radios

7.2. Portable computers, mobile devices (for email and internet), fax machine, scanner

7.3. Distribution lists, electronic alert networks, contact lists

7.4. Document sharing sites like FoodSHIELD or SharePoint

7.5. Secure webinar rooms and conference lines (approved for use by the specific agency/organization, and not publically available; e.g., requiring use of a passcode or log in to access). Examples include: WebEx, FoodSHIELD Adobe Connect.

7.6. Internet connection via hotspot, local area network, etc.

8. PROCESS DESCRIPTION

8.1. Assess to Achievement Level 1

To meet achievement level 1, your SOP should address the following basic criteria for intra-agency (internal) communication needs. It is recognized that each RRT may take a different approach to developing the SOP, and that the best practices are suggestions to allow for flexibility in the State Agency or District/Program Division Office's plan.

Achievement Level 1: Internal Communication SOP	
Criteria	**Best Practices, suggestions, considerations**
Approval	• Obtain approval and authority for developing communication procedures • Routinely (e.g., annually) review and update of SOP • Identify responsible individual(s) for reviewing and updating SOP • Obtain approval of final document (e.g., leadership signature(s)) • Obtain approval for providing training on updated procedures
Collaboration	• Work with internal staff to ensure communication needs are addressed • Include a variety of managers, field, lab, PIO, office, and etc. as appropriate
Document Review	• Obtain and review relevant documents to ensure consistency with agency and national standards • For example, consider routine communication procedures, RRT Best Practices Manual, CIFOR, Emergency Response Plans, NIMS/ICS sources
Format	• Use a format (or outline) to develop a comprehensive SOP • Consider a Quality Management System format
General Techniques	• Address general communication techniques and expectations • Consider the need for group communication methods (e.g., routine conference calls, regular RRT meetings, divisional meetings) • Secure conference lines, webinar sites, document storage sites (like FoodSHIELD) • Consider possible communication challenges during off-hours (evenings, weekends, Holidays, etc.) • See attachments A, B, E, J for more information

Achievement Level 1: Internal Communication SOP	
Criteria	**Best Practices, suggestions, considerations**
Legal Issues	• Ensure your SOP addresses how to store, share and protect confidential information (e.g., FOIA, HIPAA, or other protected information) • See Attachment C for more information

Notifications (Updates)	• Determine when each RRT member should be notified
	• Consider the triggers for notifications or escalated communications
	  ◦ Some RRTs have chosen to operate in a centralized manner and prefer to notify all core RRT members for all issues
	  ◦ Keeping key response partners informed on emerging issues can reduce "catch-up" time when a member becomes formally involved
	• Determine the preferred method of notification (e.g., teleconferences, phone calls, email) based on the issue or response mode
	• See Attachments D and E

Notifications (or Updates) Content	• Identify basic information or documents to be included in notifications/updates • Share available information while still complying with information sharing restrictions • Consider a high level notification without sensitive information, followed up by an additional notification to appropriate RRT members (that can receive confidential information) • Include explanation if necessary (e.g., cannot rule out lab results are not confirmed and no action is required at this time) • List the next action steps, responsible entities, and timeframes • Highlight required follow-up action • Clearly identify new information • See Attachments F, G, I
Timelines	• Establish reasonable timelines for notifications, updates, and responses ◦ Suggested: Responses within 24 hours of notification, respond to emails/calls within one business day, etc. • The originating RRT member will notify applicable RRT members or other agency personnel of any events that could escalate as soon as possible
Contact Lists	• Maintain contact lists that encompass core members and other agency officials • Include business and after hour contact information • Review, update, and disseminate routinely (e.g., annually) • Ensure that lists are accessible and that other internal partners know where to find them • Consider using an online platform (e.g., FoodSHIELD, SharePoint, or Outlook) for storing, updating, managing, and sharing • See Attachment H
Post-Response	• Identify procedures for conducting after action reviews and disseminating final after action reports (AARs) ◦ After action reviews should be scheduled and conducted with response team members to summarize the incident. The RRT Manual AAR Chapter suggests that the AAR be completed within 45 days of the response. See the AAR Chapter for additional best practices on conducting after action reviews and writing AARs.

8.2. Assess to Achievement Level 2

To reach achievement Level 2, the criteria from Level 1 should be met for intra-agency (internal) communication needs, plus additional criteria and/or best practices below for addressing inter-agency (external) communication procedures.

Achievement Level 2: External Communication SOP	
Criteria	**Best Practices, suggestions, considerations**
Level 1 Criteria	• Meet Level 1 criteria to address all internal communication needs.
Approval	• Same as Level 1
Collaboration	• Same as Level 1
Document Review	• Same as Level 1
Identification of Partners	• Identify external agencies that your agency interacts with during responses • Include epidemiology and laboratory partners (if not in the same agency) • Include other regulatory partners (e.g., Local, State, and Federal) • Include non-regulatory partners like industry, academia, trade groups, etc. • Consider situations where you may need to reach out to another state • Consider grouping like agencies and communicate in a similar manner • Identify agency leads to communicate with partners • Establish channels of communication and use them consistently • Utilize pre-established relationships; or; develop or strengthen relationships between partners through interactions such as ongoing working groups (e.g., food safety task force), or in-person trainings or workshops
Format	• Same as Level 1
General Techniques	• Same as Level 1, plus • Secure conference lines, webinar sites, document storage sites (like FoodSHIELD), group email boxes, video conferencing, etc. • See attachments A, B, E, J, K for more information
Legal Issues	• Same as Level 1, plus: • Address sharing of confidential information from your agency to external partners (may include FDA information sharing agreements, see 'Legal Issues' under Achievement Level 3), or other agency-specific legal parameters.
Notifications (Updates)	• Same as Level 1, plus • Schedule routine meetings or conference calls involving State and District/Program Division RRT members
Notifications (or Updates) Content	• Same as Level 1
Timelines	• Same as Level 1 • The originating RRT member will notify applicable RRT member agencies/partners as soon as possible of any events that could escalate
Contact Lists	• Same as Level 1 • Maintain contact lists that encompass core members, partners, agencies, auxiliary member or agencies, subject matter expert (SME) agencies or partners • Include notations for numbers that cannot be further disseminated • For reaching out to other states, include information on accessing the AFDO DSLO, RRT contact lists; including a courtesy notification to the FDA District Emergency Response Coordinator for awareness • See Attachment H

Achievement Level 2: External Communication SOP	
Criteria	**Best Practices, suggestions, considerations**
Alert Systems	• Identify who needs to be notified and when • Create and maintain standardized alert systems or distribution lists (e.g., Local health departments, commodity groups, trade organizations, etc.) • Sites like FoodSHIELD allow for creation of groups and automatic email/SMS texts to its members • See Attachment K
Post-Response	• Same as Level 1, plus • Consider additional reporting requirements (for example): • Foodborne illness outbreak response findings entered should be entered into NORS and Environmental Assessment (EA) findings should be entered into NEARS

Public Message	• Notify appropriate partners in advance of issuing public messages for situational awareness (e.g., internal agency partners, external agency partners [State/Local], Federal partners [e.g., public messages related to a multi-state outbreak])
	• Work with the Agency Public Information Officer (PIO), Public Affairs/Media Office or equivalent to review existing protocols and address the following:
	  • Establish standard channels of communication with media (i.e., website, telephone, etc.)
	  • Identify the steps needed to ensure timely release of information to the press or public, consider using templates
	  • Consider having an agency approved translation system
	  • Utilize pre-established relationships with consumer and community groups
	  • Create templates for press releases or fact sheets

8.3. Assess to Achievement Level 3

To obtain achievement Level 3, the RRT should work to ensure their Communication SOP is coordinated between the State and the FDA District/Program Division (a similar process should be done for other RRT member agencies/partners as well). Once the RRT has a comprehensive SOP that covers internal and external communication needs, then the State and FDA District/Program Division should complete the following criteria jointly.

Achievement Level 3: RRT Joint Communication SOP	
Criteria	**Best Practices, suggestions, considerations**
Level 1 and 2 Criteria	• Meet Level 1 and 2 criteria to address all internal and external communication needs
Approval	• Same as Level 1 and 2, plus • Obtain permission and identify a responsible person from each agency to collaborate on joint or coordinated communication SOP
Collaboration	• Same as Level 1 and 2, plus • Collaborate between agencies to ensure all communication needs will be addressed • Consider working through some recent incidents or plan an exercise to stimulate discussion regarding communication needs • Identify improvement areas to be addressed in the joint/coordinated SOP
Document Review	• Same as Level 1 and 2, plus • Each agency can provide a list of applicable agency documents that specifically address requirements for inter-agency communication (e.g., FDA FMD-50)
Identification of Partners	• Same as Level 2, plus • Identify specific divisions or groups within each agency that might be involved

Achievement Level 3: RRT Joint Communication SOP	
Criteria	**Best Practices, suggestions, considerations**
Format	• Same as Level 1 and 2, plus • Decide whether your team prefers one joint set of SOPs or separate but coordinated SOPs
General Techniques	• Same as Level 1 and 2, plus • Secure conference lines, webinar sites, document storage sites (like FoodSHIELD), group email boxes, video conferencing, etc. • See attachments A, B, E, J, K for more information
Legal Issues	• Same as Level 1 and 2, plus • Address sharing of confidential information from FDA to State agencies (Commissioning and Credentialing, 20.88 agreements) • Set schedules for maintaining, sharing, and reconciling credentialed and/or commissioned staff lists • Address confidentiality concerns and information sharing procedures relevant to other Federal agencies, such as FSIS Notice 45-16 'Sharing Information with State or Local Agencies, Foreign Government Officials ,and International Organizations' • See Attachment C for more information
Notifications (Updates)	• Same as Level 1 and 2, plus • Establish routine communication (e.g., monthly conference calls between State and District/Program Division, quarterly Face-to Face meetings), notification methods, response communication methods, and post-response methods • Leverage routine conference calls between core RRT member agencies/ partners (or pre-determined subset) by adding standing agenda items for emerging issues • Identify a list of triggers that will require each agency to notify the other (i.e., RFR, presumptive/confirmed sample results, complaints, recall, etc.) • Use the worksheet Attachment D • Convene a special conference call with other RRT member agencies/partners to brief them on an emerging incident

Information Flow	• Identify appropriate communication chain, for example:
	  • State → District/Program Division → Headquarters (e.g., CORE or other FDA Coordination Group) → District/Program Division → State
	• Communications to and from FDA Coordination Groups and/or FDA representatives outside the RRT are typically made by the FDA District Emergency Response Coordinator
	  • Other Federal agencies may have similar policies in place (i.e., , dedicated liaisons who serve as primary points of contact with State and Local agencies for a specific purpose) – these should be discussed in advance

Notifications (or Updates) Content	• Same as Level 1 and 2, plus • Identify when each Agency will need actual copies (e.g., sample reports, lab methodologies, attachment B, and other) instead of just a summary of them • Identify when and how to alert Federal agencies (e.g., FDA, CDC, FSIS) of RRT involvement in an incident (e.g., to alert FDA CORE about a potential multi-state outbreak investigation) for awareness and tracking purposes
Timelines	• Same as Level 1 and 2, • The originating RRT member will notify applicable RRT member, agencies, or partners as soon as possible of any events that could escalate • Discuss response rates and limiting factors (e.g., how long does it usually take to get a response from one of Centers, or how long will it take to mobilize), to ensure reasonable expectations • Document these expectations in each agency's SOP
Contact Lists	• Same as Level 1 and 2, • See Attachment H

Achievement Level 3: RRT Joint Communication SOP	
Criteria	**Best Practices, suggestions, considerations**
Alert Systems	• Same as Level 2 • See Attachment K
Post-Response	• Same as Level 1 and 2, plus • Provide procedures for conducting joint after action reviews and disseminating final after action reports • Identify which agency will take the lead for conducting after action reviews and disseminating final after action reports
Public Message	• Same as Level 1 and 2, plus • Agencies should work towards common or coordinated press recalls (and other public messaging) to release consistent general safety messaging, participants, response details, etc., when appropriate • Consider what is necessary for joint press releases or statements. Consider messaging requirements for each agency involved • Identify agency leads to communicate with the media and serve as Public Information Officer • Consider setting up a joint information center to streamline external communication • Consider making representatives from each of the pertinent RRT agencies available to media at designated times rather than answering media inquiries individually to ease spokesperson burdens

8.4. Assess to Achievement Level 4

Once the RRT has a joint (or collaborated) set of procedures, now the RRT members must receive training and the SOPs must be utilized. This can also be completed jointly by the applicable RRT member agencies/partners (e.g., State and FDA District/Program Division).

Achievement Level 4: Training and Utilization	
Criteria	**Best Practices, suggestions, considerations**
Training	• Identify RRT members who will require training • Develop role appropriate training materials to provide to team members • Hold refresher training as needed or as new members join the team • Consider holding an exercise to reinforce the training material
Utilization	• The RRT should utilize the joint procedures during each investigation involving the RRT • An After Action Report should be conducted in accordance with the SOP • The SOP should be updated based on AAR findings (if necessary)

8.5. Assess to Achievement Level 5

Achievement Level 5 will ensure efficiency and continuous improvement.

Achievement Level 5: Process Improvement	
Criteria	**Best Practices, suggestions, considerations**
Review	• Review the SOP and compare it to applicable portions of National Standards (e.g., MFRPS, AFRPS and Retail Standard 5) and Best Practices (e.g., RRT Manual, CIFOR, and others) • Conduct a Business Process Review to map the current process, identify inefficiencies, and identify possible improvements
Update	• Update as necessary based on the findings

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

The tool below is provided to help identify the status of communication SOP development and use along with its corresponding achievement level.

Do you have a Communication SOP that …				
Achievement Level 1	**Achievement Level 2**	**Achievement Level 3**	**Achievement Level 4**	**Achievement Level 5**
Is written to address internal communication needs?	Is written to address external communication needs?	Is a written collaboration or coordination with partner agencies (minimum: FDA District/Program Division & State)?	Is utilized in incidents or exercises regularly?	Has gone through a business process review?
___Yes or ___No	___Yes or ___No	___Yes or ___No	___Yes or ___No	___Yes or ___No

Achievement Level: Identify the status of your communication SOP. If you are able to check yes, then your Communication SOP is at the associated Achievement level. If you've checked "No", then that's where you can begin the improvement process as detailed in the following section. Further instruction, information, and criteria for each level are provided in section 8 of this chapter.

9.2. Process Overview

Use the criteria and best practice described in section 8 of this chapter and the attachments to assess and improve your RRT communication procedures. The RRT should identify each individual that may be involved in the response, what triggers would likely lead to notification of each person, and how each person will be notified. The RRTs should also select modes of communication best suited to the desired frequency and type of communication.

10. RELATED DOCUMENTS

Full citations are in the References Section, "List of Reference Documents," listed by author.

10.1. Other RRT Manual Chapters: Related to most other chapters (Food Emergency Response Plan, Joint Investigations, Traceback, etc.)

11. REFERENCES AND OTHER RESOURCES

(Full citations are in the References Section, "List of Reference Documents," listed by author.)

11.1. Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines for Foodborne Disease Outbreak Response (http://www.cifor.us/CIFORGuidelinesProjectMore.cfm)
11.2. FDA Field Management Directive (FMD) 50 (https://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm056669.htm)
11.3. FDA Investigations Operations Manual (IOM) (http://www.fda.gov/ICECI/Inspections/IOM/default.htm)
11.4. Federal Emergency Management Agency (FEMA) NIMS/ICS Courses (e.g., 100, 200, 300, 400, 700, 800) https://training.fema.gov/nims/
11.5. FSIS Notice 45-16 'Sharing Information with State or Local Agencies, Foreign Government Officials ,and International Organizations' (https://www.fsis.usda.gov/wps/wcm/connect/9968da35-84c2-463b-813e-7f60682f21d9/45-16.pdf?MOD=AJPERES)
11.6. FSIS Webpage "Information Helpful to FSIS During Foodborne Illness Investigations" (https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/audience-public-health/info-for-fsis-investigations)
11.7. FSIS Webpage "Resources for Public Health Partners: Foodborne Illness Investigation" (https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/audience-public-health/resources-for)
11.8. International Association for Food Protection (IAFP) "Procedures to Investigate Foodborne Illness – 6th Edition" (http://www.foodprotection.org/publications/other-publications/)
11.9. Multistate Foodborne Outbreak Investigations Guidelines for Improving Coordination and Communications (http://www.cifor.us/clearinghouse/tooldetail.cfm?id=212)
11.10. National Emergency Communications Plan (2014) (https://www.dhs.gov/national-emergency-communications-plan)
11.11. Regulatory Procedures Manual (RPM): Chapter 8 (http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179133.htm)

12. ATTACHMENTS

12.1. Attachment A – Information Sharing Best Practices
12.2. Attachment B – Meeting Etiquette and Best Practices
12.3. Attachment C – Sharing Confidential Information Best Practices
12.4. Attachment D – Notification Worksheet
12.5. Attachment E – Response Modes and Associated Communication Best Practices
12.6. Attachment F – Team Member Communication Roles
12.7. Attachment G – Activities Conducted/Coordinated During a Response
12.8. Attachment H – Contact List Example
12.9. Attachment I – Early Notification Form
12.10. Attachment J – FoodSHIELD Best Practices for States/Locals/FDA during Incidents (PFP surveillance, Response, and Post Response Workgroup)
12.11. Attachment K – Alert Systems/System Testing

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	9/26/2011	RRT Traceback WG (MI**, Minneapolis District**, MN, CA, Pacific Region, Los Angeles District, Florida District)
1.1	R	2/1/2012	ORA/OP
1.2	R	1/24/2013	ORA/OP
2.0	R	5/26/2017	MI**, IA**, ORA/OP

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)
**Workgroup Lead

Change History

1.1 – Editorial revisions made by ORA for document clearance.
1.2 – Revisions to achievement levels (Section 3) based on recommendations from the RRT 2012 Face to Face Meeting (November, 2012).
2.0 – Revised for the 2017 Edition of the RRT Manual. Revisions to the chapter based on recommendations from RRTs.

Attachment A – Information Sharing Best Practices

Communication is most effective when a mutual understanding of expectations is identified during routine communications, prior to the occurrence of an incident. Below are some best practices for communication and sharing confidential information.

General Communication:

- Establish a point of contact and preferred communication method
- Use common language, including Incident Command System (ICS) terminology, and consider your audience before using acronyms to avoid frustration, especially in multi-agency communications
- Distinguish between formal and informal communication needs (e.g., written versus verbal, any communications or documents requiring a signature, etc.)
- Respond to emails, calls, and other notifications in a timely manner
- Ensure that communications reach all appropriate parties (e.g., include field level if they've been involved, include upper management as requested, etc.)

Conference calls: Conference calls are extremely helpful during investigations to ensure that accurate, up to date information is shared among all agencies that need to know.

- Often initiated by a local, state or federal agency, usually hosted by CDC, FDA or a state.
- Several calls may occur on any given day (traceback group, epidemiology group, etc.) to discuss various factors affecting or guiding the response.
- Conference call best practices include:
    - Remind participants of any confidentiality requirements, as needed.
    - Provide call in information to participants early enough to ensure they can attend and the meeting can start on time
    - Provide an agenda so participants can be prepared
    - Announce who you are before speaking (e.g., name, organization)
    - Mute phones to cut down on background noise
    - Leader or facilitator takes charge, explains the purpose of the call, reviews ground rules
    - Get everyone involved (call on those not speaking up)
    - Focus on the call and avoid distractions
    - Avoid longer-than-necessary calls
    - Provide time for questions and answers (usually 5 minutes at the end will suffice)
    - End the call, thank participants, provide information for the next meeting
    - Follow up phone call conversation with a summary email (e.g., incorporate conference call information into the next Situation Report (SitRep) to ensure awareness among appropriate response partners)

Effective Email: Provide a concise written summary of an emerging or existing incident to other RRT member(s).

- Establish Distribution List (groups)
- Include a meaningful and consistent subject line (include the incident name, organism name, or other identifying information).
- Keep the message focused and identify the purpose of the email to provide situational awareness (e.g., FYI vs. Action required).
- Identify the importance or level of urgency (flag email)

- Include a summary, don't just forward a long email chain to a new recipient
- Proofread and keep it simple
- Don't assume privacy, protect confidential information

Incident Communication:

- Set up a routine for communication within an incident so participants, leaders, press, and others know what and when to expect messaging and updates (e.g., tactics or planning meetings taking place at the same time each day). This is important to facilitate greater participation from agency leaders with decision-making authority.

Attachment B – Meeting Etiquette and Best Practices

Below are some details on factors to consider for conference calls. In general, it is best to ensure ground rules are clearly established (in writing when possible) among all those who may be participating in joint meetings.

A. General Approach

1) Ensure all participants are aware of meeting plans and receive all relevant call-in information ahead of time.
2) Provide an agenda in advance.
3) Notify all relevant parties of their possible involvement as soon as possible to allow time for preparation.
4) Identify who will provide a brief summary of key points (e.g., investigational directions) or details (e.g., sample results) for the meeting and ensure all come away with the same understanding.
5) Ensure all participants are aware of what to expect and what is expected of them on the call (e.g., listening only, provide reports).

B. Meeting Order

1) Have a pre-identified moderator.
2) Follow established agenda. New topics raised may be added to the end of the agenda.
3) Generally, 3-5 minutes per speaker.
4) Limit time spent on roll call.

C. Discussion Etiquette

1) Don't interrupt speakers.
2) Determine if information is pertinent to the group before speaking.
3) If the meeting turns into a discussion between a few participants centered on details that the rest of the participants do not need to hear, the moderator should quickly suggest they move their discussion offline to prevent taking up too much time on the agenda.

Attachment C – Sharing Confidential Information Best Practices

This attachment addresses information sharing as described in the FDA-State Communication Directive http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm056669.htm), but can be adapted for sharing between other agencies. RRTs must be cognizant of information sharing regulations at the federal, state, and local levels and identify effective ways to work with the needs and restrictions of your partners. The following webpage provides details on information sharing under FDA commissioning and information sharing agreements: https://www.fda.gov/ForFederalStateandLocalOfficials/CommunicationsOutreach/default.htm.

- Information Sharing Agreements: RRTs must have the appropriate information sharing agreements (See federal regulations 21 CFR 20.88 and 20.91) in place prior to an incident, for example:
    - Memo of Understanding
    - Credentialing
    - Commissioning
    - Long term single-signature information sharing agreements (20.88s)
        - An emergency 20.88 (one time use) is obtained during an event and the proposed recipient of the information does not have the proper information sharing agreements in place (reach out to Infoshare-ORA@fda.hhs.gov, and the FDA District/Program Division Office may be able to assist in facilitating this process).
        - Templates for long term and emergency 20.88s can be found here: https://www.fda.gov/ForFederalStateandLocalOfficials/ResourcesforRegulatoryPartners/default.htm#comms.

- Maintain Lists: Identify local and state level individuals and/or jurisdictions with information sharing agreements so FDA District/Program Division Office will know with whom they can share information.
    - Routinely reconcile the State list with the FDA list to ensure correct identification of those with commissioning, credentialing, or 20.88.
    - A database of agencies with current long term single signature 20.88s is publically available: https://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=singlesignaturefood.
    - The FDA District/Program Division Office has access to a real time database of commissioned officials and agencies under a 20.88 agreement (note: this is an internal FDA website and non-FDA personnel will not be able to open/access it): http://intranetappslb.fda.gov/scripts/SDA/sdNavigation.cfm?sd=commissionedpersonnel

- Disseminating Information:
    - Non-public information shared with State agency personnel under a 20.88 or FDA commission cannot be further disclosed without written permission from FDA (https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ResourcesforRegulatoryPartners/UCM509883.pdf).
        - This should be taken into consideration during inter-RRT information sharing events (even if both state agencies have a 20.88 agreement in place).
- Questions:
    - Questions about commissioning: FDA ORA Office of Partnerships (OP.Feedback@fda.hhs.gov)
    - Questions about 20.88s: FDA ORA Office of Policy and Risk Management (OPRM) Infoshare-ORA@fda.hhs.gov

Attachment D – Notification Worksheet

Each RRT should jointly complete this worksheet to help determine when each participant should be notified during each situation.

Whom to Engage/Notify (for Situational Awareness, Coordination of Response Activities, etc.)				
Situation (use these examples below or add your own)	**RRT Core Member** (District/Program Division, Food Program, Feed Program, epi, lab)	**RRT Auxiliary Member**	**FDA Coord. Groups** (CORE, OCM/OEO, FDECS, CVM); **Other Federal partners** (FSIS, CDC, EPA)	**Law Enforcement** (State or FBI)
Example: Local cluster(s) of suspected foodborne/waterborne illness detected	*(A) P N*	*A (P) N*	*A P (N)*	*A P (N)*
Local cluster(s) of suspected foodborne/waterborne illness detected	A P N	A P N	A P N	A P N
Clusters across multiple counties, cases dispersed throughout state, or cases with matching serotype/subtype/PFGE/WGS; Human or animal food product or water suspected or implicated	A P N	A P N	A P N	A P N
Clusters detected in multiple states; Human or animal food product or water suspected or implicated	A P N	A P N	A P N	A P N
An outbreak occurs on an international or interstate airplane, bus, train, or vessel	A P N	A P N	A P N	A P N
Emerging/unusual consumer complaint trends/investigations that may escalate	A P N	A P N	A P N	A P N
A pathogen, chemical, or pesticide is detected in a human or animal food product (especially if imported, previously implicated in multi-state outbreak, unusual/virulent contaminant, prepackaged, interstate commerce, regulated by RRT core or auxiliary member agency/partner)	A P N	A P N	A P N	A P N
Microbiological/Chemical/Other human or animal food testing by regulatory agency prompts recall	A P N	A P N	A P N	A P N
Illness or positive sample prompts major recalls requiring significant resources to effectuate	A P N	A P N	A P N	A P N
Intentional contamination of human or animal food item is suspected or implicated	A P N	A P N	A P N	A P N
Circle: **A**: for always notify; **P:** Possible notification based on likely involvement; **N:** Not for this situation.				

Attachment E – Response Modes and Associated Communication Best Practices

Each RRT may vary slightly and should decide jointly how heightened communication will best serve the team. Below are some best practices and suggestions.

Leadership deliberation for RRT response/activation:

- Determine involvement based on your RRT structure
- Convene heightened communications and information sharing to ascertain more information/monitor the situation
- Be transparent and engage lead representatives from core RRT member agencies/partners

Leadership decides to activate (or not):

- Hold a conference call (or meeting) for RRT leaders to determine whether RRT response is warranted
    - Use standard/dedicated conference call numbers. Send an Outlook invite, e-mail, or other notification of the meeting as soon as possible
    - Focus on discussing/assessing factors directly aligned with the RRT's triggers for response or activation
- Determine structure/form of response, based upon established triggers
- Assign RRT member agencies/partners responsibility for leading the RRT response/activation
    - Assess available resources and the scope of the response activities to determine the leadership and format of the response (e.g., full activation, joint response/non-ICS, or one RRT member agency/partner leading with assistance from other(s)

RRT Response/Activation is warranted (follows ICS chapter):

- RRT members (core and auxiliary) are notified of:
    - Impending response
    - Persons filling ICS Command and General Staff positions, if activated
    - How to obtain updates
    - Changes to the response status
    - Critical meetings/conferences
    - The need to continue normal operations with readiness for immediate response
    - The need to be prepared for travel, if needed
- RRT will provide information to the responsible FDA Coordination Group (through the District Emergency Response Coordinator), or other Federal agency, as applicable

Response or Activation Mode:

- Conduct a conference call to review: documented firm inspection history; nature of problem; summary of laboratory and/or epidemiological findings, source of information; and facility registration checks; and other information as applicable/available
- Provide a mechanism for centralized storage/sharing of documents and other communications among response team members (e.g., a FoodSHIELD Workgroup). See Attachment J (PFP FoodSHIELD Best Practices)
- Provide updates and share summaries of accomplishments with all relevant players on a routine, pre-established schedule throughout the response
    - If activated, follow the ICS "Planning P" for all operational periods
    - Ensure key staff from RRT member agencies (especially those not actively/directly involved in the incident response team) are aware of RRT activities and know where to direct any questions they may receive regarding the incident. Keeping key response partners informed can reduce "catch-up" time when a member becomes formally involved

Demobilization and Post Response:

- After demobilization, the team will return to normal communication
- RRT will conduct hotwash/debrief/after action review and finalize after action reports or other final reports

Attachment F – Team Member Communication Roles

This attachment briefly describes the roles and responsibilities of various team members as it pertains to communication. Communication with each team member is essential to any multi-agency response.

- Epidemiologists:
    - Included when human illnesses are involved
    - Epidemiology ("Epi") variables: clinical specimen collection, food history, illness onset date/time, symptoms, incubation period, illness duration, epidemiologic data analysis
    - When applicable, designate an epi liaison to improve the efficiency and accuracy of communication, and to:
        - Coordinate collection of clinical specimens to be transported to the laboratory
        - Coordinate epi data collection and perform data analysis/interpretation
        - Disseminate epi data conclusions to guide the investigation and further sampling
        - Act as consultant for epi data collection and analysis procedures
- State Veterinarian:
    - Included when animal illnesses are involved
    - Responsible for conducting animal illness investigations
    - Veterinary variables: animal specimen collection, necropsy results, feed and environmental sample collection, illness onset date/time, clinical signs, incubation period, illness duration, knowledge of potential exposures and husbandry practices, epi data analysis
    - When applicable, designate a veterinary liaison to improve efficiency and accuracy of communication, and to:
        - Coordinate collection of specimens/samples to be transported to appropriate lab
        - Coordinate collection of data and lab results and perform analysis/interpretation
        - Disseminate conclusions as appropriate to guide the investigation
        - Act as consultant for specimen/sample collection and analysis procedures
- Laboratorians:
    - Included when laboratory testing is or may be required to respond to the incident; note that different laboratories may be required for different testing needs, depending on the capabilities and capacity of the laboratories within your State
    - Laboratory ("Lab") variables: lab capacity, type of analyses to be performed, timeframe (when to expect sample results), sample scheduling, and expertise
    - When applicable, designate a lab liaison (especially when the field investigatory team is working with multiple labs) to ensure effective communication of lab information to overall operations, and to:
        - Coordinate transport to the laboratory and receipt of samples upon arrival
        - Ensure that all laboratories have adequate resources to perform analyses
        - Act as consultant for sampling procedures
        - Interpret findings and/or testing results to guide the investigation and further sampling
- Liaison Officer: Centralize and streamline communications with agency representatives who require updates on response activities and assist in coordinating resource needs with the participating agencies.
    - Task a response team member with these duties in RRT Responses (short of IMT stand-up)
    - Note: The District Emergency Response Coordinator must serve as the liaison officer or equivalent for communications between FDA Coordination Groups and the response team.

Attachment G – Activities Conducted/Coordinated During a Response

Below are examples of investigation and response activities. Communication SOPs should address sharing findings and outcomes from these activities (e.g., to whom, when, and how are updates shared).

Regulatory	Epidemiology (Animal and Human Health)	Laboratory (public health or regulatory)
POTENTIAL HUMAN OR ANIMAL FOOD INVESTIGATION ACTIVITIES ~Provide incident reports/updates (within RRT and externally)		
• Conduct joint inspection, investigations, or environmental assessment ~Share significant findings • Conduct food, feed and Env. Sampling ~Notify whether incoming samples are associated with an outbreak/incident, routine, or part of a special-project ~Share results of presumptive positive (cannot rule out) or confirmed positive samples tested at local, state, or federal labs. • Provide situational awareness to law enforcement officials • Conduct traceback/traceforward (informational or regulatory) ~Share notable progress. • Conduct Criminal investigation	• Detect clusters of notable epi interest indicating common human or animal food vehicle • Create case definition • Conduct Patient interviews ~Share specifics of the human or animal food vehicle: product info, purchase dates, consumption date, purchase locations, sell-by/best if used by dates. • Conduct data analysis & analytical studies as needed ~Share results of epi analysis • Coordinate clinical specimen collection ~Notify lab of incoming outbreak-assoc. specimens. • Contribute to or assist with criminal investigation	• Conduct Clinical sampling ~Share serotype, subtype, WGS or PFGE clusters (either in-state or matching in other states) • Conduct Food, Feed, Env. Sampling ~Share recommendations (e.g., volume, types) ~Share sample results (e.g., microbiological and PFGE/WGS or other subtyping, chemical, necropsy, tissue residue, other) • Contribute to/assist with criminal investigation
POTENTIAL CONTAINMENT AND CONTROL ACTIVITIES ~Provide incident reports/updates (within RRT and externally)		
~Provide public notification • Continue Food, Feed, Environmental Sampling • Recall products ~Provide product information for possible press release • Recall effectiveness assessment ~Share effectiveness determination of the recall • Seizure, embargo, withdrawal, stop sale • Issue Import alert • Close/limit facility • Conduct enforcement actions (other) • Enforce public health law/regulations • Control secondary spread	~Public notification • Issue prophylaxis • Conduct ongoing surveillance and investigation of cases ~Share potential for ongoing exposure • Control secondary spread	• Continue Food, Feed, and Env. Sampling ~Share sample results

POTENTIAL DISPOSAL AND DECONTAMINATION ACTIVITIES ~Provide incident reports/updates (within RRT and externally)		
• Conduct Hazard assessment • Characterize waste • Select Disposal method • Conduct Environmental sampling ~Public notification (as appropriate)	~Public notification (as appropriate)	• Conduct Environmental sampling • Conduct Finished product sampling
~ Represents specific opportunities for information sharing between disciplines (regulatory, epi, lab)		

Attachment H – Contact List Example

It is vital to maintain a contact list for notification to staff in state, federal, and local agencies. It is important to keep this list updated so that it is accurate when needed. This information should be reviewed on a semi-annual basis by the State RRT Coordinator and the FDA District Emergency Response Coordinator, with updated contact information disseminated to recipients of the RRT's Communications SOP.

An excel file template of such a contact list is available upon request to FDA Office of Partnerships (OP.Feedback@fda.hhs.gov) and is posted in the RRT Workgroup in FoodSHIELD[3]. A screenshot of each tab of the excel file is provided within this attachment. As not all States are structured the same way, modification of this template is likely needed to meet the needs of individual RRTs.

RRT Communications SOP Contact List Example -- Introduction

It is important to maintain a current list of contact information for notification to staff in state, federal, and local agencies. This is an example template for identifying and maintaining that information. However, a spreadsheet or document list may not be the sole or best way to store and updated this information. For example, several agencies publish their staff directories on web sites. Using these directory web site URLs may reduce redundant list creation.

Regardless of how the contact information is stored, this information should be reviewed on a semi-annual basis by the State RRT Coordinator and the FDA District Emergency Response Coordinator and updated contact information should be disseminated to recipients of the Communications SOP.

After Hours/Emergency Contact

Agency	Department	Emergency or 24/7 Phone	Notes/Instructions
State Agriculture	All		State Duty Officer
State Health			
FDA			
Local Health [City, County, etc.]			
FBI			

[3] Closed workgroup only accessible to RRTs: RRT Program Workgroup, Folder: Best Practices Manual, Subfolder: 2017 Edition FINAL, Subfolder: RRT BPM Supplemental Resources

	A	B	C	D	E	F	G
1	**State Agriculture**						
2	**Name**	**Title**	**Agency**	**Office Phone**	**Cell Phone**	**24/7 Contact**	**Email**
3		Rapid Response Team Supervisor					
4		Food Program Manager					
5		Food Supervisor					
6		Dairy Program Manager					
7		Meat, Poultry, & Eggs Program Manager					
8		Feed Program Manager					
9		Compliance Supervisor					
10		Communications/Public Information Officer					
11		Emergency Planning Director					
12		Legal Advisor					
13		IT Staff					
14		Outreach/Community Relations Coordinator					

	A	B	C	D	E	F	
1	**State Health**						
2	**Name**	**Title**	**Agency**	**Office Phone**	**Cell Phone**	**24/7 Contact**	**Email**
3		Epidemiology Supervisor					
4		Environmental Health Supervisor					
5		Communications/Public Information Officer					
6		Legal Advisor					
7		IT Staff					
8		Outreach/Community Relations Coordinator					

	A	B	C	D	E	F	G
1	**Laboratory**						
2	**Name**	**Title**	**Agency**	**Office Phone**	**Cell Phone**	**24/7 Contact**	**Email**
3		Food Laboratory Supervisor					
4		Clinical Laboratory Supervisor					
5		Laboratory Receiving					

	A	B	C	D	E	F	
1	**FDA**						
2	**Name**	**Title**	**Agency**	**Office Phone**	**Cell Phone**	**24/7 Contact**	**Email**
3		FDA District Director					
4		FDA District Director of Investigations					
5		FDA Special Assistant to the District Director					
6		FDA District Emergency Response Coordinator					
7		FDA District Director of Compliance					
8		FDA District Recall Coordinator					
9		FDA District State Program Coordinator					
10		FDA Regional Office					
11		FDA HQ CFSAN					
12		FDA HQ DFSR					
13		FDA HQ Office of Emergency Management					

	A	B	C	D	E	F	
1	**USDA**						
2	**Name**	**Title**	**Agency**	**Office Phone**	**Cell Phone**	**24/7 Contact**	**Email**
3		FSIS District Manager					
4		FSIS Public Health & Epi Liaison (AES)					
5		FSIS OIEA Investigator					
6		APHIS					
7		AMS (grading)					

	A	B	C	D	E	F	
1	**FBI & Law Enforcement**						
2	**Name**	**Title**	**Agency**	**Office Phone**	**Cell Phone**	**24/7 Contact**	**Email**
3		FBI Regional Director					
4			State Highway Patrol				
5			[County/City] Law Enforcement				

	A	B	C	D	E	F	
1	**Local Health**						
2	**Name**	**Title**	**Agency**	**Office Phone**	**Cell Phone**	**24/7 Contact**	**Email**
3			[County, City, Tribal] Public Health Dept.				

	A	B	C	D	E	F	
1	**Industry or Firm Contacts**						
2	**Name**	**Title**	**Company**	**Office Phone**	**Cell Phone**	**24/7 Contact**	**Email**
3							
4							

	A	B	C	D	E	F	G	
1	**Subject Matter Experts**							
2	**Subject**	**Name**	**Title**	**Agency**	**Office Phone**	**Cell Phone**	**24/7 Contact**	**Email**
3	Dairy							
4	Dry Milk Processing							
5	Feed							
6	RTE Food							
7	Nuts							
8	Toxicology/Environmental Chemistry							
9	Environmental Sampling							
10	Meat and Poultry							
11	Eggs (in-shell, processed)							

	A	B	C	D	E	F	G	
1	**Commodity-Specific List for Information Sharing**							
2	**Subject**	**Name**	**Title**	**Agency**	**Office Phone**	**Cell Phone**	**24/7 Contact**	**Email**
3	**Dairy**		Division Director					
4			Dairy Association Contact	ADADC (Midwest)				
5			USDA-FSIS Contact					
6								
7	**Feed**		Feed Inspections Manager	Animal Health				
8			State Veterinarian					
9								
10	**etc…**							

Note some other useful directories:

1. Association of Food and Drug Officials Directory of State and Local Officials - Public directory of state and local regulatory officials involved with food, animal feed, animal health, and food defense functions. http://dslo.afdo.org/
2. FoodSHIELD Contacts Directory (under “Apps”) – Secure directory (for FoodSHIELD account holders) of FoodSHIELD membership. http://www.foodshield.org

Attachment I – Early Notification Form

Consider using the template below or develop your own as an RRT to ensure consistent communication that meets the entire team's needs.

<table>
<tr><td colspan="4">State of _____
Multi-jurisdictional Illness Outbreak
Early Notification Fax/Email Template (DRAFT)</td></tr>
<tr><td rowspan="3">Date:</td><td colspan="2">To:</td><td>Fax:</td></tr>
<tr><td colspan="2">cc:</td><td>Fax:</td></tr>
<tr><td colspan="2">cc:</td><td>Fax:</td></tr>
<tr><td>Date LHD first notified:</td><td colspan="3" rowspan="2">State notifications sent to:
☐ Food & Dairy Division, FOODBORNE CONTACT Fax: XXX-XXX-XXXX
☐ Communicable Disease Division FOODBORNE CONTACT Fax: XXX-XXX-XXXX
☐ Other</td></tr>
<tr><td>County of Exposure:</td></tr>
<tr><td></td><td colspan="2">From:</td><td>Phone:</td></tr>
<tr><td colspan="4">This is an early warning/notification on an investigation we are conducting. The information contained in this notice should be considered preliminary and confidential. This information should not be shared or distributed without permission from the sender. If you have similar cases, please notify us and other appropriate agencies immediately.
The _____ Health Department is currently investigating an outbreak that is suspected to be
☐ Foodborne
☐ Waterborne
☐ Of unknown source/vehicle</td></tr>
<tr><td colspan="2">Number of cases: _____</td><td colspan="2">Number of clusters: _____</td></tr>
<tr><td colspan="2">Earliest onset time/date, if known: _____</td><td colspan="2">Latest onset time/date, if known: _____</td></tr>
<tr><td colspan="4">Incubation : _____ ☐ Hours ☐ Days</td></tr>
<tr><td>Main symptoms:</td><td>Pathogen/Agent:</td><td colspan="2">☐ suspected
☐ confirmed</td></tr>
<tr><td>Food/Water Product(s):
☐ Suspected
☐ Confirmed</td><td>Suspected Place(s) of Exposure:</td><td colspan="2">Date(s) of Exposure:</td></tr>
<tr><td colspan="4">Details:</td></tr>
</table>

Attachment J – Foodshield Best Practices for States/Locals/FDA during Incidents (PFP Surveillance, Response, and Post Response Workgroup).

RRTs should jointly review this attachment to ensure that each RRT member understands proper communication procedures when FDA CORE is involved.
http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM451642.pdf

Attachment K – Alert Systems/System Testing

1. Alert Systems
   1.1. General
      1.1.1. Purpose: Establishing an alert system (electronic, phone tree, etc.) ahead of time ensures that needed information is shared to all appropriate parties as quickly as possible.
      1.1.2. Communication elements to consider:
         - Modes of communication: telephone (text or voice; landline, cell phone, satellite, etc.); fax; email (email in Outlook/other, email to a secure machine); web-based (instant message, websites, web portals), etc.
         - Distribution process: call center, agency staff (management, field operators, etc.), volunteer program, and electronic system.
         - Distribution list: Core/leadership, RRT staff, agency staff, partner agencies, community, and media.
         - Timing: Simultaneous blast or tiered/serial notification. (Need to determine frequency of notification.)
         - Content: Process for the development of the notification and clearance processes.
   1.2. Examples
      1.2.1. Health Alert Network (HAN):
         - The Health Alert Network (HAN) is a nationwide information and communication system that is available to any state or territory. The HAN is a platform for the distribution of health alerts and prevention guidelines, distance learning, national disease surveillance and electronic laboratory reporting, and other initiatives to strengthen state and local preparedness. (Contact your state HAN coordinator to access the HAN user guide for the state.)
      1.2.2. Local Area Networks:
         - These are computer networks with limited access (e.g., only state agencies) that can be used during an incident when a certain response (e.g., state emergency operations center (EOC)) is activated. It is a secure system for email communication and helps facilitate activities such as submitting daily reports to the EOC.
2. Systems Testing:
   2.1. Agencies should conduct periodic tests (e.g., quarterly) of the electronic system to:
      - Check for any technical glitches.
      - Test language development/approval process.
      - Test clearance process.
      - Ensure contact lists are updated.
      - Document results of the tests and implement corrective measures, as appropriate.

Chapter 8. Incident Command System Concepts in RRTs

TABLE OF CONTENTS

1. PURPOSE

This chapter defines RRT Best Practices in forming unified federal-state incident management structures using the Incident Command System (ICS). Implementation of these principles facilitates improved interagency communication, coordination, and documentation of response activities. This may also serve as an important element of federal and state emergency response plans.

2. SCOPE

ICS is a modular management system that can support the emergency response needs of a single organization or multiple organizations working under a unified (i.e., shared) command. ICS is a component of The National Incident Management System (NIMS), which is the management system, mandated for all emergency response agencies throughout the United States (US).

This chapter complements but does not replace the detailed guidance provided by the National Response Framework (NRF) for “all-hazards” response. This chapter also does not supplant ICS resources developed by the Federal Emergency Management Agency (FEMA). Moreover, it is recommended this chapter is used in conjunction with ICS

classroom training and/or ICS-related response experience (see Chapter 8 of the Best Practices Manual (BPM) for more information regarding response team training).

The best practices described in this chapter identify key areas and elements of ICS, but are neither comprehensive nor specific to unique situations. State, local, and federal agencies seeking to improve human and animal food incident responses (e.g., states, FDA field offices) may utilize this chapter to assess and improve their response capabilities. Agencies with varying responsibilities (e.g., regulatory, public health, feed/animal health, law enforcement) and capacities may differ in how they customize and apply these best practices.

Outlined in this chapter are various factors for states and FDA Districts/Program Divisions to consider when implementing ICS principles identified in general ICS classroom training (see Related Documents, below). This chapter also identifies how ICS forms (e.g., ICS 209 for situational reports) are useful for identifying strategies and providing updates to agency leadership during incident responses.

3. RESPONSIBILITY

3.1. RRT (or investigatory team, in states without an RRT) Leadership

RRT Leadership (state and District/Program Division) is responsible for working cooperatively with other agencies to effectively institute ICS concepts for the command, control, and coordination of responses. Leadership commitment to and implementation of these concepts is critical for effective implementation of a Unified Command Structure. RRT leadership is also responsible for ensuring that internally, participating team members are properly trained prior to a response. Additionally, Command and General Staff positions are pre-identified using the standard definitions found in Part IV.

3.2. RRT Members

RRT Members are responsible for ensuring that they are: a) familiar with the concepts, forms, policies, and Standard Operating Procedures (SOPs) for implementing ICS; and b) can fulfill their assigned roles in an ICS structure.

4. DEFINITIONS

A glossary of ICS terms and definitions, including definition of ICS command and general staff roles and responsibilities can be found at:
https://training.fema.gov/emiweb/is/icsresource/glossary.htm

See BPM “Glossary of Key Terms” for definitions of additional terms used throughout various BPM Chapters, including this one.

5. BACKGROUND

The U.S. food supply consists of many highly complex and interconnected systems. Incidents impacting the U.S. food supply (referred to as human or animal food incidents in this chapter) may require management through a unified command structure. These incidents can be distinguished by at least one of the following characteristics:

- Multi-Jurisdictional Incidents routinely involve agencies of different regulatory responsibilities (e.g., federal, state, local).
- Geographicaly Dispersed- Incidents are spread throughout defined geographical areas.
- Extended Duration - Incidents routinely involve multiple operational periods.
- Continuity of Routine Operations - Within smaller incidents, responders continue to perform at least some of their day-to-day responsibilities.

Incidents meeting the characteristics listed above, often require participating organizations to shift resources to adequately respond, and a unified command structure may help ensure availability of adequate response-specific resources.

Table 1: Incident Typing Examples and Potential Triggers (Human and animal food emergency responses). This table uses a progressive investigation to help identify escalation triggers and response activities between agencies.

NRF Incident Type	Example Incident	Example of Incident Response	Possible Response Structure	Potential Escalation Factor
5-Local Response	**Food:** *Listeria monocytogenes* (*LM)* isolated from patients in local hospital.	• Epi: Identify chicken salad as common exposure among case patients. • EH: Visit hosp. kitchen, review food prep; learn chicken salad is made onsite, sample chicken salad and ingredients (incl. celery), collect records of origin of ingredients. • Lab: Isolate LM from chicken salad, celery tests positive for LM.	Local-level response possibly involving clinical and food labs, epi and EH (either state or local). Designated State RRT Point of Contact (POC) notified by Local Partners. ***RRT Posture**: **State Lead w/Situational Awareness.**	EH determines celery is purchased from a local wholesale food distributor.
	Feed: Vet reports single ill dairy cow possibly associated w/on-farm custom feed mix.	• Animal Health/State Vet: Visit farm, investigate illness, obtain feed samples. • State Chemist: Analyzes samples for chemical and biological contaminants.	Coordinated response between local/state feed partners and animal health. ***RRT Posture**: **State Lead w/Situational Awareness.**	Illness seems particularly debilitating and/or lethal. Farm sent mix to a dairy in neighboring county.

NRF Incident Type	Example Incident	Example of Incident Response	Possible Response Structure	Potential Escalation Factor
4- State & Local Response	**Food**: State reviews purchase invoices and distribution records at the wholesaler that distributed celery to the hospital.	• Epi: Cont. case investigations, coord. use of suppl. questionnaires re: celery exposures. • EH: Conduct traceback (TB) investigation to determine source of celery. • Lab: Conduct PFGE analysis on clinical and commodity samples.	Local-level response possibly involving clinical and food labs, epi and EH (either state or local). State RRT POC notifies FDA ERC. ***RRT Posture**: **State Lead w/Situational Awareness.**	Records collected indicate celery is processed/packed in-state with interstate distribution. Additional PFGE match *LM* cases reported across state.
	Feed: More livestock illnesses reported in close proximity to each other; traceforward (TF) indicates limited distrib. to farms in small geo. area.	• Animal Health/State Vet: Visit additional farms with illnesses to determine cause. • State Chemist: Conduct TF to determine were product was sent. Continue to analyze samples to determine contaminant.	Coordinated response between local/ state feed partners and animal health, communicate with federal partners. ***RRT Posture**: **State Lead w/ Situational Awareness.**	Feed was further distributed to or shared with secondary accounts through an informal process.
3- Multiple Regions in State	**Food:** State reviews produce records at celery processor/ packer and collects invoices showing distribution in commerce during timeframe of interest.	• Epi: Coordinate with CDC and other states to determine potential multi-state clusters. • EH: Continues TB investigation to determine source of celery. • Lab: Characterizes positive specimens using PFGE and WGS and uploads data into PulseNet.	Local-level response possibly involving clinical and food labs, epi and EH (either state or local level). Designated State RRT POC notifies FDA ERC of interstate movement of product. ***RRT Posture: State Lead w/Assistance.**	Purchase invoices collected at the celery packer indicate the celery was purchased from a wholesaler in another state/country.
	Feed: TF indicates feed associated with livestock illnesses was distributed to dairy farms within the state.	• Animal Health/State Vet: Prepare press notice; outreach to farms w/in the state. • State Chemist: Continue TF to determine were product was sent. Keep analyzing samples to determine contaminant.	Coord. response between local/state feed partners and animal health. Communicate with federal partners. ***RRT Posture: State Lead with Assistance.**	Feed product distribution is larger than expected. A farmer purchased a load of feed for a friend and delivered it to him (in a nearby state).
2- State & Federal Response	**Food:** Invoices from the celery packer show it was obtained from an out of state wholesaler.	• Epi: States notify CDC that product is in interstate commerce. Coordinates surveillance with CDC • EH: Cont. TB/TF, notify Fed partners, schedule activation meeting. • Lab: Cont. clinical/commodity characterization.	RRT activated w/a unified ICS structure (+ local involvement) for recalls. ***RRT Posture**: **Joint RRT Response or Activation.**	PulseNet reports outbreak PFGE matches outbreak strains in multiple states.

NRF Incident Type	Example Incident	Example of Incident Response	Possible Response Structure	Potential Escalation Factor
2-State & Federal Response	**Feed:** Investigation of feed formulation shows an ingredient has bone meal and mammalian meat not for ruminants.	• Animal Health/State Vet: Place hold on feed and animal movement on affected farms . • State Chemist: Analysis confirms ingredient contains mammalian meat and bone meal not for consumption by ruminants.	Unified Command w/State Ag, Animal Health, FDA, and USDA. ***RRT Posture: Joint RRT Response or Activation.**	Investigation reveals that feed containing prohibited material was distributed to dairy farms in multiple states.
1-State & Federal Response (Nation-wide)	**Food:** RRT conducts TB, participates in Multi-state FDA Coordinated Outbreak Response and Evaluation Network (CORE) calls, environmental assessment.	• Epi: CDC coordinates Multi-state epi investigation. • EH: TB continues to identify source, TF continues, Recall Audit Checks start. • Lab: Coord. w/CDC or FDA lab for verification. • Feds: CORE activated, coordinates TB/TF efforts.	FDA and Multi-state UCS implemented in multiple states or FDA/multi-state UCS Implemented. ***RRT Posture**: **RRT Activation.**	Recall, audit checks, and response could expand if celery was used as an ingredient in additional food products.
	Feed: Microbiological/ microscopic analysis of ruminant tissue in feed reveals possible Bovine Spongiform Encephalitis (BSE).	• Animal Health/State Vet: BSE Response Plans activated at federal and state levels. • State Chemist: Coordinate with USDA/FDA labs on analysis of additional product as well as animal tissues.	FDA and Multi-State UCS implemented in multiple states or FDA/multi-state UCS implemented. USDA Office of Inspector General, Law Enforcement notified. ***RRT Posture: RRT Activation.**	Investigation reveals that contamination of feed with BSE positive meat and bone meal was intentional and wide-spread.
** These are possible RRT postures. Actual posture will depend on State regulatory and epidemiology structure and Standard Operating Practices within the RRT.*				

6. SAFETY

Preventing or minimizing the loss of life is the primary objective during any incident response. Human and animal food related incidents can pose a number of potential threats to response personnel including biological, chemical, and potentially physical threats, even to those accustomed to food/feed environments. The ultimate responsibility for the safe conduct of incident management operations rests with the Incident Commander and Safety Officer (SO).

The Safety Officer (SO) is also responsible for the set of systems and procedures necessary to ensure all on-going safety efforts. For example, the Safety Officer might work with any State or FDA District/Program Division Office to determine any safety alerts or issues related to a firm that might be inspected. The SO has authority to stop and/or prevent unsafe acts during incident operations, and may coordinate and execute "just-in-time" safety training as necessary for specific hazards identified for an incident.

7. EQUIPMENT/MATERIALS

Personnel, facilities, equipment and materials under a command structure are often referred to as resources. Resources can be specific teams, items, or a single person (i.e., Subject Matter Expert). During an incident, RRTs will need to be able to quickly identify personnel resources that may serve on an Incident Management Team (IMT). Although resources for each State and FDA District/Program Division Office RRT will vary based on food/feed industry type and incident type, size, and complexity, it is recommended that the following types of resources be discussed and acquired as part of a response teams preparedness measures before an incident occurs:

- A team roster with position "back-ups" if possible
- A pre-filled Delegation of Authority citing specific expectations, authorities, and the charge of the team (see attachment B for example templates)
- Personal protective equipment (PPE)
- Sample collection supplies
- Previously agreed upon forms (hardcopy and digital) (i.e., Inspection Forms, ICS Forms, Standard Operation Procedures) (See Section X. Related Documents, for links to ICS Forms)
- Incident Management Handbooks and other Incident Management reference materials (i.e., FDA's Incident Management Handbook (see Related Documents section within this chapter), FEMA's Field Operations Guide, U.S. Coast Guard Incident management Handbook)
- Predetermined, redundant communications (i.e., team contact info, audio conference lines, video-conference lines, web-conference accounts, data sharing sites such as FoodShield)
- Base of Operations (i.e., Physical or Virtual Incident Command Post)

It is important that resource items be stored in a readily-accessible location or locations throughout a given state or District/Program Division. An individual should be assigned to monitor the equipment inventory so that consumed/damaged/expired items are replaced in a timely manner.

Maintaining a roster that specifies each ICS position with a listing of all RRT members that are capable of filling each role is ideal as a preparedness-measure. This list can also be used to help ensure that each agency has depth for each position, current contact information, and properly documented training. RRTs should have a method for requesting and notifying personnel of participation in an ICS response.

Documentation is a critical aspect of any response, especially an ICS response. Therefore, it is crucial that the RRT initially agrees on the set of forms and references that will be utilized during an incident to create the Incident Action Plan and appropriately document the response (see Chapter 4 in FDA IMH in Related Documents section within this chapter).

Hard-copy references and electronic forms should be provided to RRT members for use in exercises and responses, and to enable preparation of unified reports during incident responses.

8. PROCESS DESCRIPTION

8.1. Preparedness

It is recommended each member of the RRT completes ICS training prior to participating in an actual response. Active roles in the IMT will be determined based on each member's level of training and experience. FEMA courses are recommended to help establish an educational foundation in ICS for individuals on the response roster who will serve within the command and general staff positions: http://training.fema.gov/is/nims.aspx**.**

Note: Several variations of ICS classroom training are also available and strongly recommended, for example:

- ICS 300 - Intermediate ICS for Expanding Incidents
- ICS 400 - Advanced ICS: Command and General Staff – Complex Incidents

Note: See the Training Chapter within the RRT Best Practices Manual for more information regarding response team training.

8.2. Proposed RRT Unified ICS Structure and Flow

During an ICS response, the agency with direct responsibility for any current or subsequent regulatory action, must have direct participation in the decision making process for any information and evidence that will be collected as part of the team's response objectives. Entities within a state without direct tactical field responsibilities (i.e., epidemiology, laboratories, etc.) can occupy specific sections in either the Command or General Staff of the ICS structure (e.g., epidemiology or laboratory personnel could serve as part of a Technical Specialist under the Operations or Planning Sections or engage by communicating directly with the Liaison Officer within the Command Staff).

Incident communications during an ICS response are dependent on the back and forth flow of information among all the Command and General Staff (or those under Unified Command) members.

When responding jointly with the FDA, State or Local IMT members must be FDA commissioned or operating under an active 20.88 agreement so information collected by FDA can be freely shared and discussed among all responders in the IMT**.**

When other Federal Agencies are involved (e.g., USDA FSIS), a similar check should be done to ensure that appropriate information sharing agreements (e.g., MOUs,

etc.) are in place among all agencies represented in the Unified Command and IMT.

A formal written Delegation of Authority template should be part of any RRTs preparedness goals and/or activation process (see Attachment B). Ideally, the Delegation of Authority, should reference:

- The lead agency (or agencies if "unified") involved
- Incident Commander (or Commanders, if unified)
- Incident timeframe
- Response priorities per agency leadership
- Resources assigned/committed
- Financial allotments per operational period
- Signature and date of authorizing official(s)

RRTs have found that when an incident escalates to involve more than one agency, it is best to develop a unified command structure. The diagram in Attachment A (Proposed RRT Unified ICS Structure and Flow) is a functional, generic template of a unified command structure that can be used for various types of multi-agency response and coordination. In this model, incident information continually flows up and down the structure. Additional information-sharing (e.g., investigational, laboratory) is expected at all levels within the ICS chain of command (e.g., laboratories communicating to ensure the same methods/worksheetsare being utilized).

Although example structures are shown in Attachment A, the use and exact structure of ICS will ultimately be the decision of the RRT state agency or agencies and the cooperating FDA District/Program Division Office.

This proposed structure can be developed into the following two uniquely different models during a response, depending on the needs of the agencies involved:

1. Use of a **unified command structure** (Attachment A-1) allows for the preservation of each regulatory entity's jurisdiction and independence.

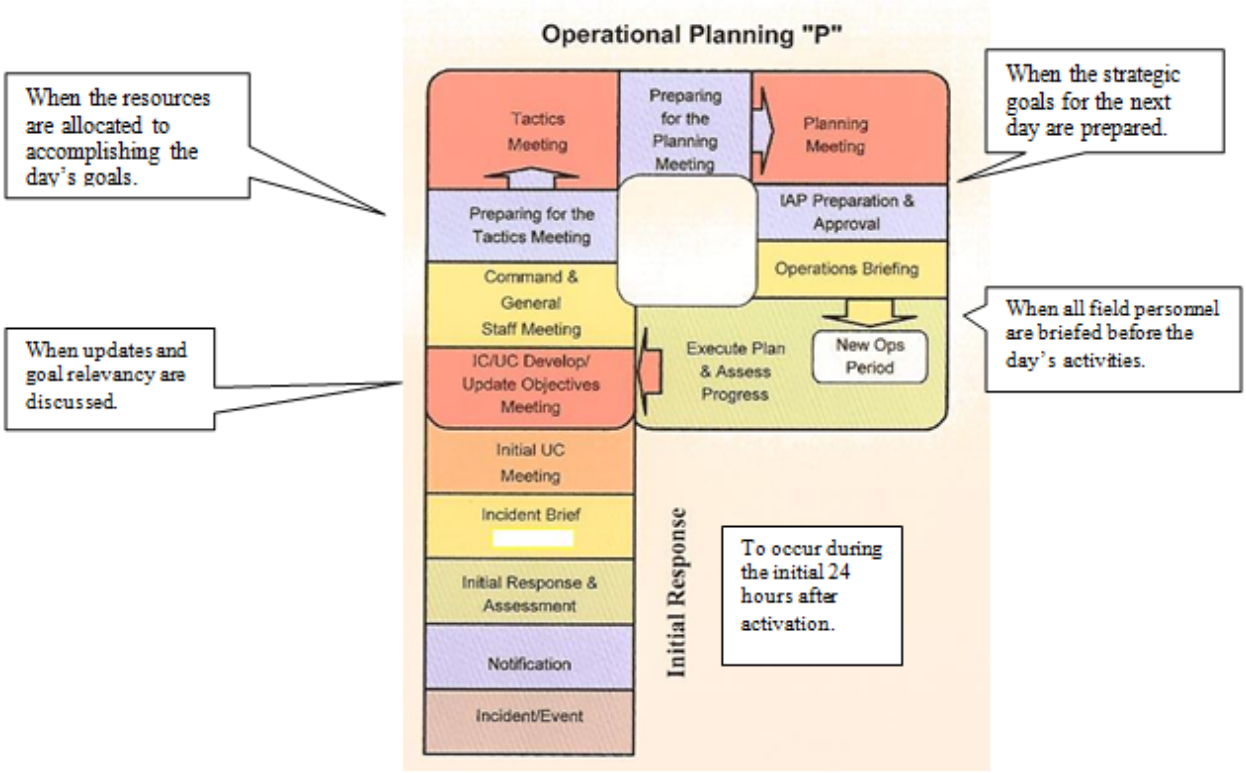
2. Use of an **integrated command structure** (Attachment A-2), in which the agency providing the majority of resources or with lead jurisdictional authority staffs the Section Chief positions while the other agency provides deputies to ensure their responsibilities are fulfilled.

It is important to emphasize that, within the incident command structure, roles can be occupied by any qualified individual regardless of the day-to-day title (e.g., a Branch Director under ICS is not necessarily equal to a branch director within a

regulatory agency). Each agency is responsible for ensuring that personnel designated to staff positions (e.g., Section Chief) in the ICS structure are qualified (i.e., properly trained) to fulfill those responsibilities.

The ICS basic command structure will coordinate the response and should expand or contract as determined by the size and complexity of the incident and the availability of resources. Effective communication throughout this response framework is necessary for an effective response. Post-response evaluations (e.g., After Action Reports) frequently identify interagency and interpersonal communication challenges as a cause of inefficiencies in the actual response.

The central role of communication in emergency response necessitates a pre-established plan to optimize use of operational resources. For example, building briefings and planning meetings into the ICS structured response through the "Planning P" (depicted below) establishes a foundation for regular communication.



Execution of this model provides a coordinated, cohesive approach to communications during a response to an incident.

8.3. Incident Action Plans (IAPs) and Other ICS Forms

An IAP is a collection of forms that the IMT completes during the planning process (see Chapter 4 in FDA IMH in Related Documents section within this chapter) to communicate the work objectives and tactics for each operational period. A new IAP is generated prior to each operational period for the duration of the incident.

A typical IAP includes ICS forms 202, 203, 204, 205, and 206 and additional supporting documents as such as detailed maps of the incident area, weather forecast, etc. (See the Related Documents section for a link to any pertinent ICS Forms). It is important to emphasize that an IAP is dynamic, so the forms necessary and amount of information included may vary throughout an incident as the scope changes and between incidents. In addition to the IAP forms, the IMT may also use other ICS forms such as 215 (Operational Planning) and 215A (Incident Safety Analysis), to support decision-making and record-keeping of incident related events, and Form 209 (Incident Status Summary), to share updates among agency administrators.

RRTs should use the references, forms, and templates as previously agreed upon, to appropriately document the incident response and create the IAP.

The ICS forms listed in the *Related Documents* section are solely for reference within this chapter. Prior to the incident as well as during a response, a digital and dynamic IAP should always be used to provide computerized record entry and storage.

RRTs should jointly participate in an after action review and create an After Action Report once the incident response comes to a close. More information can be found in the After Action Reviews Chapter of the BPM.

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

The ICS structure outlined in this chapter represents a best practice. This involves fully trained personnel staffing each of the positions within an incident management team (i.e., incident commander with command and general staff) and effective communication among jurisdictions operating under one incident action plan (IAP).

Level	Description
1	Novice – Responders identified and initial FEMA training completed.
2	Intermediate – Use of ICS in response is exercised and after action reports completed.
3	Advanced – More advanced/complex exercises, training, and responses completed.

9.2. Process Overview

9.2.1. Level 1: Novice – Responders identified and initial FEMA training completed

1. Identify individuals within an agency/department that will occupy a position on, or provide support to, an incident management team.
2. Take FEMA's ICS 100, 200, 700 and 800 online.
3. State and federal partners should take ICS 300 and 400 as face-to-face courses together when possible.

9.2.2. Level 2: Intermediate – Use of ICS in response is exercised and after action reports completed

1. Exercise (discussion, workshop, or tabletop format) an incident with trained staff.
2. Conduct an after action report to identify strengths and weaknesses and assign a corrective action report.
3. Enhance training of incident management team command and general staff with FEMA's position-specific courses.

9.2.3. Level 3: Advanced – More advanced/complex exercises, training, and responses completed

1. Conduct an exercise (e.g., functional, full-scale) , or actual response with fully trained Federal/State incident management team to generate an IAP.
2. Conduct an after-action report to identify strengths and weaknesses and assign a corrective action report.
3. Enhance training of incident management teams with FEMA's course for the development of incident management teams/position-specific training.
4. Seek additional position-specific shadowing opportunities on major incidents.

10. RELATED DOCUMENTS

As a preparedness measure, it is important for RRTs to have mutually agreed on which references and documents each team will utilize during an emergency response. This should be determined prior to an actual emergency situation, e.g., as part of a table top exercise or strategy meeting. Below are both FEMA and FDA links for dynamic ICS forms for use in creating an Incident Action Plan (IAP):

- Federal Emergency Management Agency Incident Command System documents http://www.training.fema.gov/emiweb/is/icsresource/icsforms.htm for fillable Microsoft (MS) Word forms from FEMA).
- http://www.fda.gov/EmergencyPreparedness/NIMS/ucm268797.htm for MS Word and Adobe PDF forms from FDA

- FDA's Incident Management Handbook: https://www.foodshield.org/member/workgroups/docs.cfm?dir=1087 (FoodSHIELD pathway: RRT Program Workgroup; folder: examples and sharing, subfolder: ICS)

11. REFERENCES AND OTHER RESOURCES

11.1. Homeland Security Presidential Directive (HSPD) 5: http://www.dhs.gov/publication/homeland-security-presidential-directive-5

11.2. Presidential Policy Directive (PPD) 8: http://www.dhs.gov/presidential-policy-directive-8-national-preparedness

11.3. ICS Review Materials: ICS History and Features: https://training.fema.gov/emiweb/is/icsresource/assets/reviewmaterials.pdf

11.4. The National Response Framework: https://www.fema.gov/media-library/assets/documents/32230

11.5. FDA Commissioning and Credentialing: https://www.fda.gov/ForFederalStateandLocalOfficials/CommunicationsOutreach/ucm472941.htm

11.6. FDA Information Sharing and the 20.88 Agreement: https://www.fda.gov/ForFederalStateandLocalOfficials/CommunicationsOutreach/ucm472936.htm

11.7. FDA Information Sharing Templates and Guidance Documents: https://www.fda.gov/ForFederalStateandLocalOfficials/ResourcesforRegulatoryPartners/default.htm#comms

11.8. FDA 20.88 Single Signature Agreements Database: http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=singlesignaturefood

12. ATTACHMENTS

12.1. Attachment A (1-2) – Proposed RRT Unified ICS Structure and Flow

12.2. Attachment B (1-4) – Examples of Delegation of Authority

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	9/26/2011	RRT ICS WG (New England District**, MI(**), MA, Florida District)
1.1	R	2/1/2012	ORA/OP
1.2	R	1/24/2013	ORA/OP
2.0	R	5/26/2017	RRT ICS Ch. Revision WG (MI, TX, WA, BLT-DO, DAL-DO, DET-DO, SEA-DO, FDA CORE, CVM, MD**, NER**)

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)

**Workgroup Lead

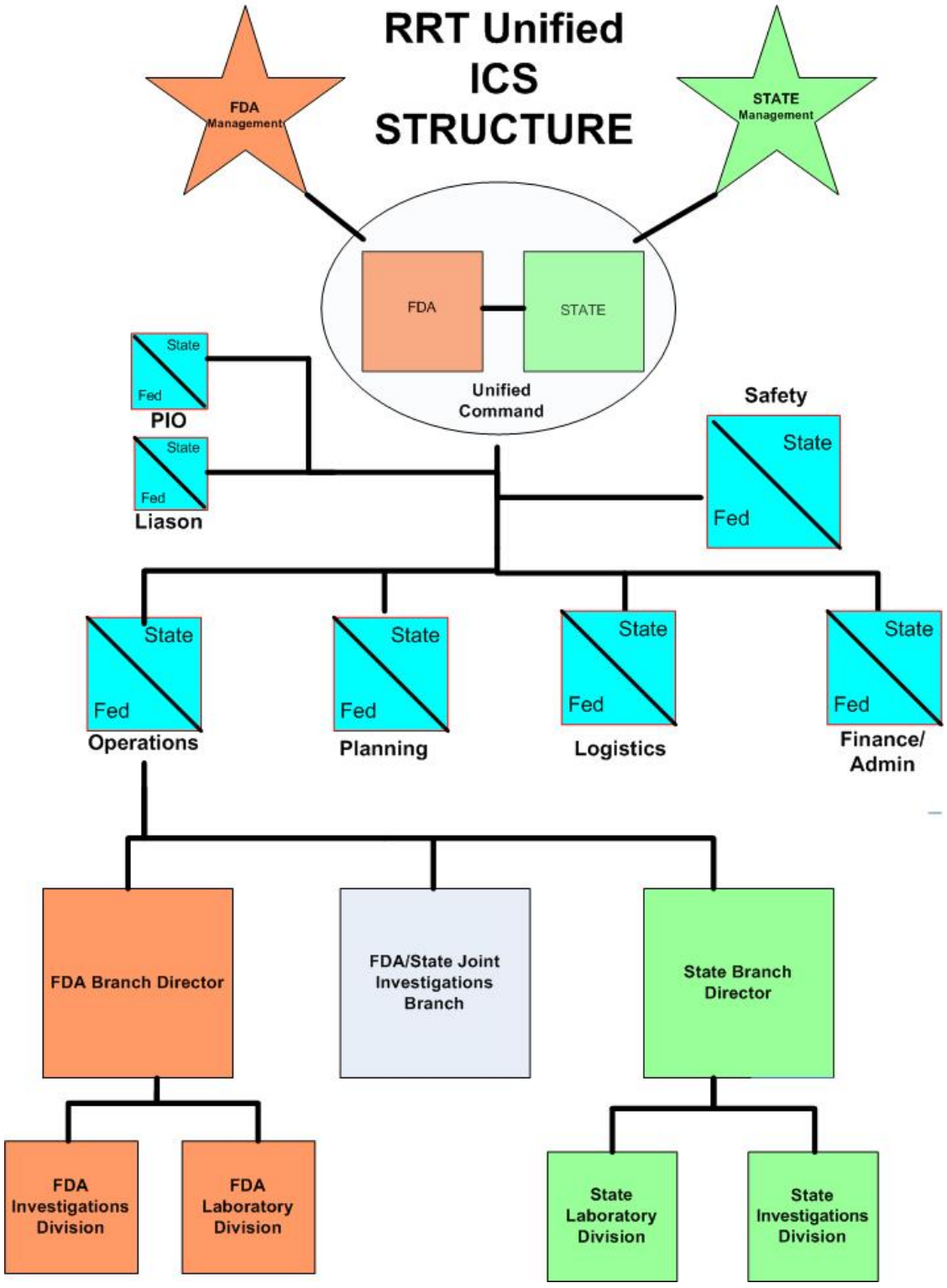
Change History

1.1 – Editorial revisions made by ORA for document clearance.

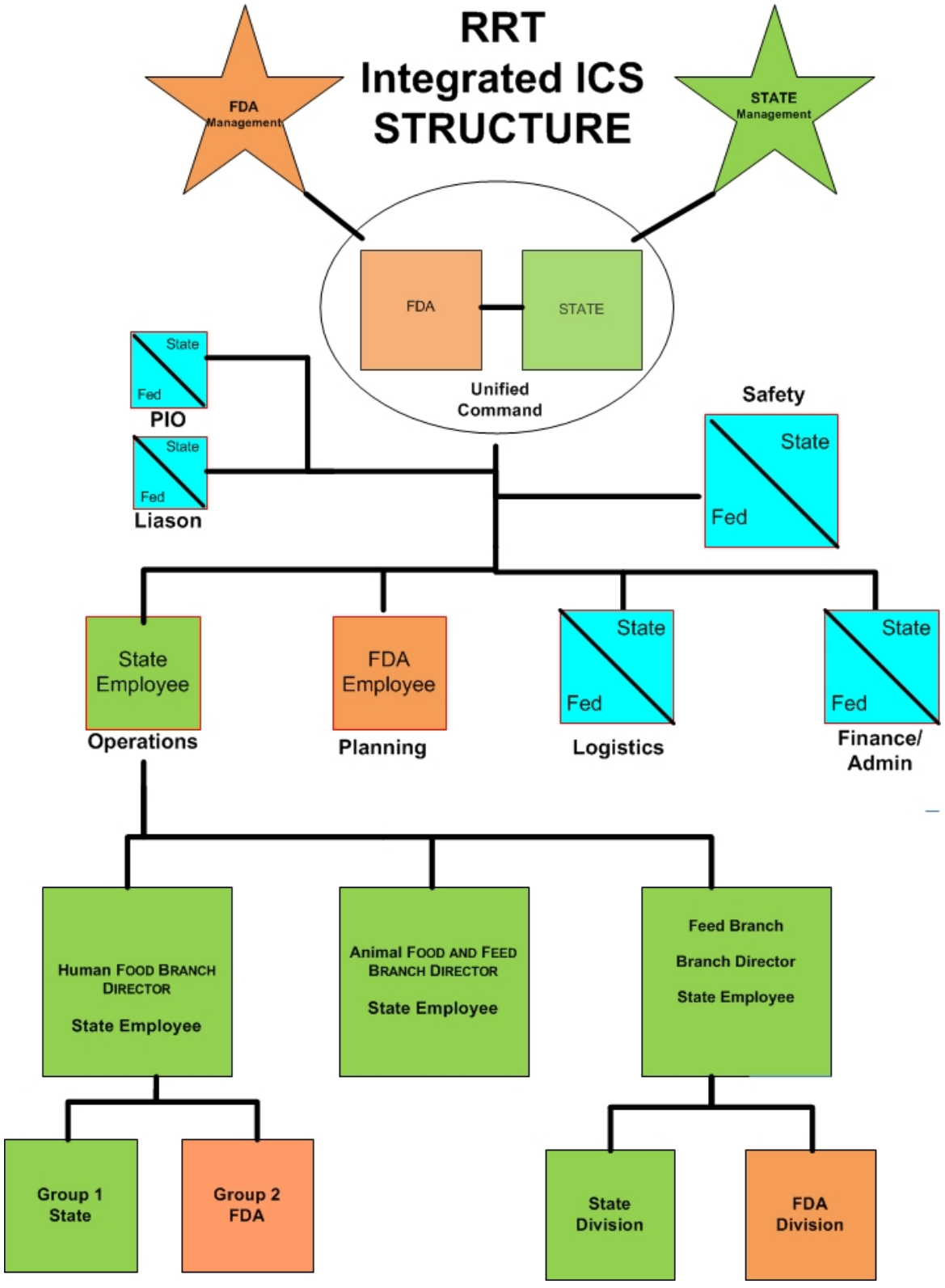
1.2 – Revision to achievement levels for clarification purposes based on RRT recommendations.

2.0 – Revised for the 2017 Edition of the RRT Manual by the RRT ICS Chapter Revision Workgroup

Attachment A-1 – Proposed RRT Unified ICS Structure and Flow (Example using FDA & State Unified Command)



Attachment A-2 – Proposed RRT Intergrated ICS Structure and Flow (Example using FDA & State Unified Command)



Attachment B – Examples of Delegation of Authority

Iowa RRT

Delegation of Authority

Memorandum

Date [Click **here** and type Date]

From [Click **here** and type From name]

Subject Delegation of Authority, _____ (Name of Incident)

To _____, Incident Commander

I hereby delegate authority for the management of _____ (Name of Incident) to you as Incident Commander..

This incident is currently under the jurisdiction of _____. You will report to me daily as well as the appropriate headquarters staff on the incident and any updates.

Your team will assume full command of the incident as of _____ and I expect your team to comply with all applicable policies and guidance.

I have designated _____ as my representative in my absence. I or my representative will be available for daily review/consultation throughout this incident.

Effective management of costs commensurate with resource values to be protected is critical and property accountability should demonstrate adherence to departmental protocols. Your fund allocation is a maximum of $_____ per day.

Resources committed to the incident are _____. All resources assigned to this response will report to you until further notice.

Media relations will be coordinated with _____ in partnership with your agency's Public Information Officer _____.

I request that personnel assigned be sensitive to all issues related to this incident.

You can reach me and/or my representative at _____ (List contact information for both).

Texas RRT:

All Hazards Emergency Response
Delegation of Authority for
(*Incident name***)**

_____(*Name of Incident Commander*)_____is assigned as an Incident Commander for the unified Command of (*incident name*). While the Incident Commander listed here has full authority to act, due to the nature of the Incident *(Name*), the EAB has assigned _(*Name of Lead Incident Commander*)_____ as the lead Incident Commander.

(*Name of Incident Commander*) _____has full authority and responsibility for managing all incident management activities within the frame work of the law, agency policy, and direction. The primary responsibility of the Incident Commander is to organize and direct resources for efficient and effective management of the incident.

Incident Commander(s) are accountable to the Agency Representatives for the agencies responding to the incident. The Incident Commander and Command staff will provide updates for each operational period to all Agency Representatives and EAB as listed on the Incident Specific TRRT Organizational Chart.

Specific directions for management and environmental concerns follow:

Mission tasks:

_____

_____

_____

Resource limitations

The IC shall conduct all operations in a cost effective and efficient manner. Specifically, the following shall apply to this incident:

The IC has the authority to mobilize TRRT resources (mobilized and reserve) as specified below for each participating agency. Agency Specific Logistic Section Representatives will identify TRRT staff with appropriate skills through Agency supervisory channels and notify mobilized personnel:

FDA # of personnel _____
DSHS # of personnel _____
OTSC # of personnel _____

The IC has the authority to request emergency supplies within the scope of the event such as lab supplies, sampling supplies, sampling gear, etc.

The maximum amount of initial expenditures on supplies shall not exceed:
FDA _____
DSHS _____
OTSC _____

The maximum number of initial laboratory samples is specified below. It is assumed that if a sample is reported positive a PFGE will be run:
FDA (Food/Feed) _____
DSHS (Clinical)_____
DSHS (Food)_____
OTSC (Food/Feed) _____

The IC has the authority to authorize travel of staff to response locations. When possible the logistics section should utilize staff in the area of the incident to control travel expenses. Approval for travel remains with the Agency. All travel orders for staff should be handled through the Agency specific Logistic Chiefs to ensure proper protocols are followed.

If overtime is required for staff in order to meet the incident objectives, the IC must contact the Agency Representatives.

Due to the differing travel and purchase requirements of each responding agency, a Logistics Chief (and if needed a Finance Chief) will be assigned from both federal and state level agencies.

The IC must contact the Agency Representatives when the resource needs are beyond the initial TRRT resource limitations identified for the *(incident name)*.Public Information Management

A PIO will be established for each responding agency. The PIO conducts media relations and public information management according to *Appendix C – Communications SOP*. Expiration of delegation _____.

The Incident Commander shall take over management of the incident on or before _____.
The agency representative as shown below for Department of State Health Services (DSHS) will be available and the contact information will be maintained on ICS Form 204.

_____
Name Agency Representative

_____
Agency

_____
Signature

_____

Date

The Incident Commander shall take over management of the incident on or before _____.

The agency representative as shown below for the Office of the Texas State Chemist (OTSC) will be available and the contact information will be maintained on ICS Form 204.

_____
Name Agency Representative

_____
Agency

_____
Signature

_____
Date

The Incident Commander shall take over management of the incident on or before _____.

The agency representative as shown below for the Food and Drug Administration (FDA) will be available and the contact information will be maintained on ICS Form 204.

_____
Name Agency Representative

_____
Agency

_____
Signature

_____
Date

Michigan RRT

Date:
Subject: Request for Incident Management Team Activation,
_____ Incident
To: _____, Incident Commander

I hereby authorize activation of the Michigan Department of Agriculture (MDA) Incident Management Team for the _____ Incident. This incident is located in region ___ in the city of _____ in _____County.

You will report to the _____ Incident Command Post following the Agency Administrator's briefing on _____ at _____ am/pm in the _____ room at Constitution Hall in Lansing, MI. Your team will assume full command of the incident effective _____ am/pm on _____.

I expect all Incident Management Team efforts will be conducted in accordance with the selected strategy identified by the MDA Division Directors for the _____ Incident.

The following priorities have been identified:

1.
2.
3.

Resources committed by MDA to this incident include: ____.

The following emergency management plans are being provided:

Incident information and media relations will be coordinated through _____.

I or my representative(s) will be available for the daily review of the incident summary reports throughout this incident. I have designated _____ as my representative in my absence.

_____ _____
(MDA Director) (E.M. Coordinator)

Washington RRT

Washington Rapid Response Team (RRT)
Multi-Agency Letter of Expectation

Date: [Date]

Re: [NAME OF RRT INCIDENT/RESPONSE]

To: [NAME], Incident Commander, Washington State Dept. of Agriculture Food Safety and Consumer Services (WSDA FS&CS)
[NAME], Incident Commander, Food and Drug Administration Human and Animal Food Program Division 6 West (HAF6W)/Seattle District Office (FDA SEA-DO)

From: [NAME] Assistant Director, WSDA FS&CS
[NAME] Program Division Director FDA HAF6W, District Director FDA SEA-DO

Incident Commander(s) [LAST NAME(S)],

Effective [INSERT MILITARY TIME] hours on [MONTH] [DAY], 20[##] you are hereby delegated authority to manage the Washington RRT response stated above occurring in/at [GENERAL LOCATION]. Abiding by your professional skills and abilities along with those of your Incident Management Team members, you are responsible for the management of resources and costs directly associated with this incident/response.

The participating agencies have established the following general priorities for this incident:

- Ensure life safety of all RRT responders and associated personnel.
- [INSERT PRIORITY #2]
- [INSERT PRIORITY #3]
- [INSERT PRIORITY #4]
- [INSERT PRIORITY #5, ETC.]

The response must be accomplished within the following parameters:

[*Note: The following list is highly customizable and is expected to change based on the response-specific needs/desires of the agencies/stakeholders.]*

- You will work with [STAKEHOLDER ENTITIES] and will enter into a Unified Command with [SELECTED STAKEHOLDER ENTITIES].

- You will establish your Incident Command Post (ICP) at [LOCATION].
- The FDA HAF6W/SEA-DO representative and your point of contact for daily response operations will be [NAME]. This individual hereby has full authority to make decisions on behalf of the FDA HAF6W/SEA-DO Program Division Director/District Director.
- The WSDA FS&CS representative and your point of contact for daily response operations will be [NAME]. This individual hereby has full authority to make decisions on behalf of the WSDA FS&CS Assistant Director.
- Any requested changes to this letter must be submitted to the FDA HAF6W/SEA-DO and WSDA FS&CS representatives stated above for approval.
- You are authorized up to [NUMBER] days of operation. Additional days, if needed, will require authorization from the appropriate Agency Executive.
- You are authorized up to [NUMBER] staff members, including Food Safety Officers/Consumer Safety Officers and management personnel.
- You are authorized up to [NUMBER] work hours per day for all response personnel. Additional hours for selected personnel, if warranted, will require authorization from the appropriate Agency Executive.
- Overtime-time exempt WSDA employees who are participating in the RRT response may accrue Exchange Time, hour-for-hour, to a maximum amount of eighty (80) hours. During special circumstances such as authorized extended operations, the eighty (80) hour maximum may be increased for specific personnel pending approval from myself or my representative and the Unified Command.
- If warranted, FDA HAF6W/SEA-DO employees who are participating in the RRT response may request approval for overtime through the FDA SEA-DO representative of the Unified Command.
- You are authorized to use vehicles assigned to WSDA Food Safety field staff and those available through Washington State and GSA Motor Pools. Additional rental vehicles [ARE/ARE NOT] authorized.
- All personnel living farther than fifty (50) miles from the ICP or their temporary duty station are authorized per diem and travel status. Personnel living within 50 miles of the ICP or their temporary duty station are authorized per diem and travel status, if necessary for their health and safety or to facilitate the RRT response (according to state travel policy 10.30.30b).
- [DETAIL INSTRUCTIONS ON FDA TRAVEL ORDERS, IF NECESSARY].
- [DETAIL CONTENTS AND FREQUENCY OF REQUIRED FINANCIAL REPORTS, IF ANY].
- Public information releases will be coordinated through the WSDA/FDA HAF6W/SEA-DO Joint Information Center (JIC). Public information releases [NEED/DO NOT NEED] to be reviewed and approved by each agency prior to distribution.

The Unified Command will work within all legal statutes and current policy of the responsible agencies, the focus provided in this Letter of Expectation, and the broad direction provided at the initial incident briefing. If you are replacing another Incident Commander, ensure that the transfer of command is appropriately documented according to Washington RRT procedure.

All documentation related to the RRT response will be archived in accordance with Washington RRT policy. Freedom of Information Act (FOIA) requests will be addressed in accordance with the policies and procedures of the agency receiving the request.

Please forward any questions to your appropriate Agency Executive or their designated representative as they may arise. We wish you a safe and successful RRT response.

/s/
Assistant Director, WSDA FS&CS

[PHONE]

Date

/s/
Program Division Director, FDA HAF6W
District Director, FDA SEA-DO
[PHONE]

Date

/s/
[NAME]
Incident Commander, WSDA
[###-###-####]

Date

/s/
[NAME]
Incident Commander, FDA HAF6W/SEA-DO
[###-###-####]

Date

Enclosures:

List of Agency Contacts

Role	Agency	Name	Cell Number Office Number
Agency Rep	WSDA		Cell: Office:
Agency Rep	FDA HAF6W SEA-DO		Cell: Office:
Incident Commander	WSDA		Cell: Office:
Incident Commander	FDA HAF6W SEA-DO		Cell: Office:
Finance/Admin. Advisor	WSDA		Cell: Office:
Finance/Admin. Advisor	FDA HAF6W SEA-DO		Cell: Office:
PIO	WSDA		Cell: Office:
PIO	WSDA		Cell: Office:
PIO	FDA HAF6W SEA-DO		Cell: Office:

Chapter 9. Rapid Response Team (RRT) Training

TABLE OF CONTENTS

1. PURPOSE

Training is essential to provide a strong regulatory and scientific foundation for the investigative work conducted by state and federal regulatory officials. This chapter describes a basic training framework for state and FDA RRT staff assigned to respond to and investigate human or animal food related illness outbreaks or contamination, which can be used by groups to build the capabilities needed for an effective RRT.

2. SCOPE

This chapter identifies key training, including a general training program, for field staff that respond to intentional and unintentional human or animal food incidents. This aligns with Standard 2, Training, of the Manufactured Food Regulatory Program Standards (MFRPS) and the Animal Feed Regulatory Program Standards (AFRPS). The best practices described in this chapter identify key areas and elements for training, but are neither comprehensive nor specific to unique situations. State, local, and federal agencies seeking to improve multi-agency food emergency responses (e.g., States, FDA field offices) may utilize this chapter to assess and improve their response capabilities. Agencies with varying responsibilities (e.g., regulatory, public health, feed/animal health, law enforcement, laboratory) and target response capability levels may differ in how they customize and apply these best practices.

3. RESPONSIBILITY

3.1. RRT (or investigatory team, in states without an RRT) Leadership

Program managers and supervisors overseeing RRT activities are responsible for ensuring that personnel assigned to respond to human or animal food emergencies have been provided with the basic training curriculum that is necessary for them to successfully complete the tasks they are assigned.

3.2. RRT Members

RRT members are each responsible for playing an active role in maintaining both their subject matter expertise and ability to work effectively in multidiciplinary and multi-agency response teams.

4. DEFINITIONS

The following terms are used frequently in this Chapter: Rapid Response Team (RRT), Incident, and Incident Command System (ICS).

See "Glossary of Key Terms" for definitions.

5. BACKGROUND

Training is essential to provide a strong regulatory and scientific foundation for the investigative work conducted by state and federal regulatory officials. Each agency should develop a training program to ensure that all field staff receive appropriate classroom and field training to conduct thorough and effective inspections and investigations. This RRT Manual Chapter addresses key training for RRT field response personnel. Supervisors and Managers of these personnel should also receive response related training in addition to supervisory and leadership training commensurate with their positions.

RRT managers should review and be familiar with appropriate state and federal emergency preparedness guidance and utilize existing training programs (e.g., Incident Command System (ICS)-100) where appropriate. RRT training and capacity development should occur within a comprehensive approach to emergency preparedness that includes coordinated activities in planning, equipping, training, and testing capabilities through periodic exercises.

The Guidelines for Foodborne Disease Outbreak Response published by the Council to Improve Foodborne Outbreak Response (CIFOR) identifies three core disciplines that are typically involved in multi-agency responses:

- Environmental health/food regulatory;
- Epidemiology; and
- Laboratory.

This set of best practices is intended to address the training needs of the regulatory team members; however, opportunities for cross training with other disciplines should always be encouraged.

Other disciplines such as law enforcement and emergency responders become involved as needed. RRT staff training should address the need for both subject matter expertise and effective skills in working in multi-agency/multidiciplinary response teams.

Standard 2 of the FDA MFRPS and AFRPS identifies the basic elements of a training program for manufactured food and animal feed regulators and can be used to guide the development of a state or agency specific training program.

Effective training programs include elements of basic training, advanced training and continuing education to ensure staff are fully prepared to respond to any assignment.

6. SAFETY

Safety concerns and practices related to specific activities should be addressed within each training course. Examples of such courses may include, but not be limited to:

- Respiratory Protection,
- Confined Spaces, and
- Driver Safety.

7. EQUIPMENT/MATERIALS

7.1. Training program materials (e.g., written training materials, internet, training facilities, computer, projector).

7.2. Training documentation system (electronic or hard copy).

7.3. Individualized or position-specific training plans. These can be based on a generic model, as appropriate.

8. PROCESS DESCRIPTION

8.1. Training Program Principles

It is important for food safety programs responsible for regulation and investigation of food establishments to establish a training program to ensure appropriate classroom and field training for all field staff responding to emergencies. These staff should have the training to conduct thorough and effective inspections and investigations based on the role(s) and tasks they may be assigned.

Each program should assign a Training Coordinator to oversee the administration of the basic, advanced, and continuing education components of the training program. Coordinators should leverage federally funded or subsidized training when available. Examples include training provided by the FDA Office of Training

and Educational Development (OTED)/Office of Regulatory Affairs' University (ORAU), the Federal Emergency Management Agency (FEMA) Emergency Management Institute, the International Food Protection and Training Institute (IFPTI), and the National Center for Biomedical Research and Training (NCBRT). Coordinators from agencies that often work together should meet regularly to take advantage of possible joint training opportunities.

Training can be achieved through a combination of distance learning (internet based courses such as ORA-U and/or other web based courses), classroom training, and field training. Agencies should take advantage of joint training opportunities with other key agencies to improve staff understanding of their respective roles and responsibilities.

All human food program field investigative staff should receive the equivalent of Level I - FDA MFRPS Basic Training before being assigned to rapid response activities. (See Attachment A for additional details). The FDA MFRPS identifies minimum training requirements, training frequency, and documentation maintenance requirements for state food programs. Compliance with the requirements of MFRPS Standard 2 will serve as a strong foundation from which to further develop staff for response to emergencies and outbreaks. New employees who have not completed this basic training may still perform supporting activities in an RRT response if they are operating under the oversight of an experienced team member.

All animal food program field investigative staff should receive the equivalent of Level I - FDA AFRPS Basic Training before being assigned to rapid response activities. (See Attachment C for additional details). The FDA AFRPS identifies minimum training requirements, training frequency, and documentation maintenance requirements for state animal food programs. Compliance with the requirements of AFRPS Standard 2 will serve as a strong foundation from which to further develop staff for response to emergencies and outbreaks. New employees who have not completed this basic training may still perform supporting activities in an RRT response if they are operating under the oversight of an experienced team member.

8.2. Team-Oriented Training

In addition to online or distance learning, classroom, and field training, an effective RRT training program includes the following informal sessions to inform RRT members about their roles and build working relationships:

8.2.1. Initial orientations for new staff that identify the RRT structure and individual roles.

8.2.2. Meetings with public and private sector response partners to: (1) introduce new RRT staff, (2) clarify roles and responsibilities, (3) identify points of contact and notification procedures, and (4) begin the process of establishing effective working networks.

8.2.3. Regularly scheduled workgroup meetings with other RRT members and response partners. These can be effective training tools for building multidiciplinary team skills, updating subject matter knowledge, and focusing and aligning on-the-job training efforts.

8.3. Example of a Generic RRT Training Program

Field staff assigned to respond to human or animal food incidents should receive additional training specific to the roles to which they will be assigned. Each jurisdiction should determine the specific coursework and commodity-specific training that is relevant to its jurisdiction. The following list of training courses is a generic example of the types of training each RRT program may want to consider:

8.3.1. Pre-requisite Training

1. Level I MFRPS or AFRPS Training Requirements.
2. Aseptic Sampling Techniques: environmental and food samples
3. ICS/National Incident Management System (NIMS) 100 & 200, including prerequisite courses.
4. Role-appropriate introduction to agency emergency response plans and procedures.
5. Foodborne Illness Investigation or Epi-Ready Training.
6. (Optional) LSU/NCBRT: A Coordinated Response to Food Emergencies: Practice and Execution (http://www.ncbrt.lsu.edu/catalog/performance/foodresponse.aspx).
7. Traceback Training.
8. Specialized inspection training as required by the type of environment/commodity (e.g., manufacturing process).

8.3.2. Within Six Months of Assignment to Emergency Response Activities

1. Additional role-appropriate training in agency emergency response plans and related procedures.
2. Advanced First Aid or First Responder training.
3. Team Building Training (Choose an Appropriate Course for your Agency).

8.3.3. Within 12 Months of Assignment

1. Commodity-specific training appropriate for the incidents the RRT may need to respond to, such as Produce Farm Investigations.
2. Communication Skills for Regulators or Tactical Communication.

3. ICS 300 & 400 (for Field Team Leads and Unified Command), including prerequisite courses.
4. ICS 402 – ICS for Executives for staff in managerial and supervisory capacity (for selected members).
5. Advanced Sampling Techniques.
6. Joint training with law enforcement on evidence preservation and other key components of investigation for intentional acts.

8.3.4. Intermediate Training (For Specific Personnel)

1. Water Systems: Agricultural water (well, district, reservoir, aqueducts, open water ways)/municipal water/waste water systems (septic, farm waste water).
2. Table Top Exercise of Foodborne Outbreak Investigation Scenarios.
3. Mock Traceback Exercise.
4. Post Harvest Investigations (e.g., coolers, packing sheds, harvesters, processing facilities).
5. ICS Position Specific Training (Incident Command, Logistics, Planning, Operations) for selected staff.

8.3.5. Advanced Training (For Specific Personnel)

1. Industry standards for processing commodities (sprouts, spinach, lettuce, tomatoes, nuts, etc.).
2. Wildlife training (i.e., identifying animal prints at fields).

8.3.6. Continuing Education

MFRPS and AFRPS establish a requirement of 20 contact hours of continuing education training for each human or animal food regulatory employee every 36 months. It is critically important that members of an RRT receive ongoing training to maintain expertise in the response activities for which they may be assigned to participate. Training may take the form of internet-based training, classroom training, or on the job field training, and it should address both programmatic/technical and teamwork skills needed to accomplish the response activities assigned. Continuing education training should address changes in technology utilized by the regulated industry, cover disaster response and recovery, and include exercises designed to reinforce knowledge and skill sets utilized during response activities. Continuing education should address lessons learned, best practices, etc. which have been identified during previous investigations (e.g., as identified in After Action Reports).

8.3.7. Documentation

Organizations should establish training files for each staff member and maintain documentation of required training in a centralized location. Electronic databases are a valuable tool for tracking completed training courses, conducting periodic queries to identify missing or overdue training curriculum, and querying specific skills or expertise to assemble an investigation team for an incident.

8.3.8. Specific practices related to documentation

1. Maintain Individual Training Records. See Manufactured Foods Regulatory Program Standards Appendix 2.3 (Attachment B).
2. Document the following information for each training course: complete course description, course category, name, number (if applicable), dates, instructor(s), sponsor (if applicable), location, Clock/CE credit hours, expiration of licensure (if applicable), and agenda/curriculum.
3. Document any related training received prior to joining RRT and training received in member's area of expertise.
4. Document regular reviews of course curriculum to determine if updates to a course are warranted. Document any updates and decisions to re-train previous attendees to ensure proficiency.

8.3.9. Verification of Effectiveness

RRT training programs and documentation should be reviewed annually to verify the program's effectiveness and to determine if training plans and objectives continue to address identified needs (e.g., response technologies and protocols). Identified deficiencies or improvements should be addressed promptly to ensure the training program is as effective as possible.

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

Level	Description
1	The agency has, within the past 12 months, updated written Training Procedures, updated their assessment of their training program against the MFRPS or AFRPS, and developed an improvement plan to prioritize future training activities that will move the program towards full compliance.
2	Agency personnel have completed MFRPS or AFRPS Level I training within the prescribed timeline established in the Training Procedures and is on track to develop and maintain either intermediate or advanced capacities.

Level	Description
3	Agency personnel assigned to RRT activities have completed core response training identified in their Training Procedures consistent with recognized national/multi-jurisdictional best practices (example: RRT Manual). The agency has reassessed their training program, including an assessment of their needs and gaps, within the last 12 months and developed an improvement plan to address any deficiencies identified.
4	Agency personnel assigned to RRT activities have completed the necessary intermediate response training identified in their Training Procedures consistent with recognized national/multi-jurisdictional best practices (example: RRT Manual).
5	Agency personnel assigned to RRT activities have completed the necessary advanced response training identified in their Training Procedures consistent with recognized national/multi-jurisdictional best practices (example: RRT Manual). The agency has reassessed their training program, including an assessment of their needs and gaps, within the last 12 months and developed an improvement plan to address any deficiencies identified.

10. RELATED DOCUMENTS

(Full citations are in the References Section, "List of Reference Documents," listed by author.)

Note: Some of the documents identified in this section are maintained on secure websites (e.g., the Homeland Security Information Network (HSIN)). Homeland Security or Agricultural Security personnel within each jurisdiction may have information on how to gain access to this information.

10.1. National Response Framework (https://www.fema.gov/national-response-framework)

10.2. National Preparedness Guidelines (https://www.dhs.gov/national-preparedness-guidelines)

- **10.2.1.** Target Capabilities – Epidemiological Surveillance and Investigation, Food and Agricultural Safety and Defense, Public Health Laboratory Testing, and Environmental Health
- **10.2.2.** Universal Task List

10.3. Food and Agriculture Sector Specific Plan: An Annex to the National Infrastructure Protection Plan, 2015 (https://www.dhs.gov/sites/default/files/publications/nipp-ssp-food-ag-2015-508.pdf)

10.4. Manufactured Foods Regulatory Program Standards (2016) Level I Training Curriculum (https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf)

11. REFERENCES AND OTHER RESOURCES

(Full citations are in the References Section, "List of Reference Documents," listed by author.)

11.1. Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines for Foodborne Disease Outbreak Response (3.2.3.4 Training for the Team) (http://www.cifor.us/CIFORGuidelinesProjectMore.cfm).

11.2. Manufactured Foods Regulatory Program Standards – Standard 2 (https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf)

12. ATTACHMENTS

12.1. Attachment A – MFRPS Appendix 2.4 Curriculum Example Basic Food Inspector Training

12.2. Attachment B – MFRPS - Appendix 2.3 Inspector Training Record

12.3. Attachment C – AFRPS Appendix 2.2 Inspector Training Record

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	9/26/2011	RRT Training WG (CA** MI, FL, VA)
1.1	R	2/1/2012	ORA/OP
1.2	R	1/24/13	ORA/OP
1.3	R	5/26/17	ORA/OP

**Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)*

***Workgroup Lead*

Change History

1.1 – Editorial revisions made by ORA for document clearance.

1.2 – Minor editorial revisions to achievement levels for clarification purposes and addition of optional pre-requisite training within generic RRT Training Program.

1.3 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.

Attachment A – MFRPS Appendix 2.4 Curriculum Example Basic Food Inspector Training (https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf)

Appendix 2.4: Curriculum Example Basic Food Inspector Training

Standard 2 requires a State program to have a documented training plan that ensures all inspectors receive training to adequately perform their work assignments. Additionally, Standard 2 identifies thirteen coursework areas for basic food inspection training and allows for coursework to be obtained from distance learning, for example satellite downlinks or web-based training such as those available from FDA Office of Regulatory Affairs University (ORAU).

The list below is an example of the basic food inspection training coursework that could be used to meet section 2.3.2 Basic Food Inspection Training coursework requirements. Unless indicated below, the majority of FDA courses are available through http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm119016.htm

PREVAILING STATUTES, REGULATIONS, ORDINANCES

1. Basic Food Law for State Regulators (60) FDA35
2. Basics of Inspection: Beginning an Inspection (90) FDA38
3. Basics of Inspection: Issues & Observations (90) FDA39
4. An Introduction to Food Security Awareness (60) FD251 (ORA U internet site)
5. Food & Drug Law: FDA Jurisdictions, FDA01
6. Food & Drug Law: Prohibited Actions, FDA02
7. Food & Drug Law: Judicial Actions, FDA03
8. Food & Drug Law: Criminal Actions Violations, FDA04
9. Food & Drug Law: Imports & Exports, FDA05
10. Recalls of FDA Regulated Products, FDA24

NOTE: Specific state/local laws & regulations to be addressed by each jurisdiction

PUBLIC HEALTH PRINCIPLES

1. Public Health Principles (90) FDA36

EMERGENCY MANAGEMENT

FEMA – Incident Command System and National Incident Management System: Course available from FEMA web link. – http://training.fema.gov/IS/NIMS.asp

1. IS-100.a, Introduction to Incident Command System, (180) ICS-100 or IS-100 for FDA
2. IS-200.a, ICS for Single Resources and Initial Action, Incidents, (180) ICS-200
3. IS-700.a, NIMS an Introduction, (180) ICS 700
4. IS-800.b, National Response Framework – An Introduction, ICS 800

COMMUNICATION SKILLS

1. Communication Skills for Regulators (Course can be accessed through https://ifpti.absorbtraining.com/#/purchase/category/49067)

FOOD MICROBIOLOGICAL CONTROL (SERIES):

1. Overview of Microbiology (60) MIC01
2. Gram-Negative Rods (60) MIC02
3. Gram-Positive Rods & Cocci (90) MIC03
4. Foodborne Viruses (60) MIC04
5. Foodborne Parasites (90) MIC05
6. Mid-Series Exam (30) MIC16
7. Controlling Growth Factors (90) MIC06
8. Control by Refrigeration & Freezing (60) MIC07
9. Control by Thermal Processing (90) MIC08
10. Control by Pasteurization (90) MIC09
11. Control by Retorting (90) MIC10
12. Technology-Based Food Processes (120) MIC11
13. Natural Toxins (90) MIC12
14. Aseptic Sampling (90) MIC13
15. Cleaning & Sanitizing (90) MIC15

EPIDEMIOLOGY: Foodborne Illness Investigations (series):

1. Collecting Surveillance Data (90) FI01
2. Beginning the Investigation (90) FI02
3. Expanding the Investigation (90) FI03
4. Conducting a Food Hazard Review (90) FI04
5. Epidemiological Statistics (90) FI05
6. Final Report (30) FI06

HACCP: Basics of HACCP (series):

1. Overview of HACCP (60) FDA16
2. Prerequisite Programs & Preliminary Steps (60) FDA17
3. The Principles (60) FDA18

ALLERGEN MANAGEMENT

Food Allergens (60) FD252

BASIC LABELING

Food Labeling (60) FDA45 (Course can be accessed through https://ifpti.absorbtraining.com/#/purchase/category/49067)

FOOD DEFENSE

ALERT: Food Defense Awareness Training

SAMPLING TECHNIQUE

Aseptic Sampling (90) MIC13

Attachment B – MFRPS Appendix 2.3 Individual Training Record (https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf)

Appendix 2.3: Inspector Training Record

State Agency _____

Name of Inspector _____ **Start Date** _____

Basic Food Inspection Curriculum Coursework		
Course *Please provide the course name and location for each subject area*	**Date completed**	**Course Documentation Available for Review (Y/N)**
Prevailing statutes, regulations, and ordinances		
Public health principles		
Emergency Management		
Communication skills		
Microbiology		
Epidemiology		
Basics of HACCP		
Allergen Management		
Basic food labeling		
Food defense awareness training		
Sampling Techniques and preparation		

Attachment B – MFRPS Appendix 2.3 Individual Training Record *(continued)*

Basic Food Inspection Curriculum Fieldwork				
JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS		**Date Completed**	**EVALUATION/AUDIT Acceptable (Y/N)**	**Documentation Available for Review (Y/N)**
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

Attachment B – MFRPS Appendix 2.3 Individual Training Record *(continued)*

Advanced Food Inspection Curriculum Coursework		
Course *Please provide the name and location of the course.*	**Completion Date**	**Course Documentation Available For Review (Y/N)**
Acidified food		
Low acid canned food		
Juice HACCP		
Seafood HACCP		
Traceback Investigations		
Foodborne Illness Investigations		

Attachment B – MFRPS Appendix 2.3 Individual Training Record *(continued)*

Instructions: Identify and record the type of specialized food inspection conducted for the JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS, such as acidified foods, low acid canned foods, juice HACCP, or seafood HACCP.

Advanced Food Inspection Curriculum Fieldwork			
Specialized food inspection			
JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS	**Completion Date**	**EVALUATION/AUDIT Acceptable (Y/N)**	**Documentation Available for Review (Y/N)**
Please provide the name of the food plant and identification number.			
1.			
2.			
3.			
Specialized food inspection			
JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS	**Completion Date**	**EVALUATION/AUDIT Acceptable (Y/N)**	**Documentation Available for Review (Y/N)**
Please provide the name of the food plant and identification number.			
1.			
2.			
3.			

Attachment B – MFRPS Appendix 2.3 Individual Training Record *(continued)*

CONTINUING EDUCATION COURSEWORK			
Activities in Program Element 2.3.4.4 *Maximum of 20 CONTACT HOURS*			
Type of Activity *(Provide Title and Brief Description*	**Date Completed**	**Documentation Available for**	**CONTACT HOURS Earned**
		Subtotal	
Presenting, Training, or Publishing (Program Element 2.3.4.5) *Maximum of 10 CONTACT HOURS*			
Type of Activity *(Provide Title and Brief Description*	**Date Completed**	**Documentation Available for**	**CONTACT HOURS Earned**
		Subtotal	
Reading Technical Publications (Program Element 2.3.4.6) *Maximum of 4 CONTACT HOURS*			
Type of Activity *(Provide Title and Brief Description*	**Date Completed**	**Documentation Available for**	**CONTACT HOURS Earned**
		Subtotal	
		Total CONTACT HOURS	

Attachment C – AFRPS Appendix 2.2 Inspector Training Record (https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM542302.pdf)

Appendix 2.2: Inspector Training Record

Inspector Name _____ Employement START DATE _____

A. Basic Feed Inspector Training

Instructions: If the inspector has greater than five years of experience and an evaluation of the inspector's previous performance and experience shows adequate training has been completed, mark the Name and Location of Training Column, with "Met via Evaluation."

Subject Areas	Name and Location of Training	Completion Date	Inspector Initials	Supervisor Initials	Documentation Verifying Completion (Y/N)
Animal and Public Health Principles					
Basic Animal Nutrition					
Basic Feed Ingredients, Processing, and Technology					
Basic National Incident Management System and Incident Command System					
Communication					
Current Statues, Regulations, and Policies					
Feed Defense					
Inspections, Compliance, and Enforcement					
Labeling					
Professionalism					
Risk Awareness					
Safety					
Sampling					

Attachment C – AFRPS Appendix 2.2 Inspector Training Record *(continued)*

Instructions: Record the name of the firm where the joint training inspection took place as well as the competencies covered.

Basic Field Training (Name and Location of Firm)	Competencies Covered	Completion Date	Inspectors Initials	Supervisor Initials	Mastered (Y/N)

Attachment C – AFRPS Appendix 2.2 Inspector Training Record *(continued)*

B. Advanced Feed Inspector Training

Instructions: If the inspector has greater than five years of experience and an evaluation of the inspector's previous performance and experience has found that no additional training for a subject area is needed, mark the Name and Location of Training Column, with "Met via Evaluation."

Subject Areas	Name and Location of Training	Completion Date	Inspector Initials	Supervisor Initials	Documentation Verifying Completion (Y/N)
Advanced Feed Ingredients, Processing, and Technology					
Advanced Labeling					
Animal Sickness and Death Investigation					
Current Statues, Regulations, and Policies					
Epidemiology					
Microbiological Pathogens					
Traceback and Traceforward Investigations					
Specialized Advanced					
Advanced National Incident Management System and Incident Command Systems					
BSE and Ruminant Feeding Ban					
Medicated Feed Good Manufacturing Practices Regulations					

Attachment C – AFRPS Appendix 2.2 Inspector Training Record *(continued)*

Instructions: Record the name of the firm where the joint training inspection took place as well as the competencies covered.

Advanced Field Training (Name and Location of Firm)	Competencies Covered	Completion Date	Inspectors Initials	Supervisor Initials	Mastered (Y/N)

C. Continuing Education

Instructions: Record the continuing education activity as well as the name and location of the activity.

Type of Activity	Name and Location of Activity	Completion Date	Inspectors Initials	Supervisor Initials	CONTACT HOURS Earned

Surveillance and Detection

To be developed

(complaint follow-up, sampling, etc.)

RRT Investigations

Chapter 10. Tracebacks

TABLE OF CONTENTS

1. PURPOSE

This chapter describes RRT best practices for regulatory and informational tracebacks, in alignment with existing traceback materials identified in the RRT Manual's References section. These best practices can help agencies achieve more consistent gathering and communication of core traceback information and improve overall traceback capabilities.

2. SCOPE

This chapter identifies basic components of multi-agency traceback investigations as they involve local, state, and federal agencies. This blends lessons learned from RRTs with existing traceback materials and job aids to describe common elements and unique considerations of both regulatory and informational tracebacks.

This chapter does not include details on other related human or animal food investigations, such as traceforward investigations and environmental assessments and investigations. This chapter also does not specifically address the important roles played by all environmental health and food regulatory agencies.

The best practices described in this chapter identify key areas and elements for traceback, but are neither comprehensive nor specific to unique situations. State, local, and federal agencies seeking to improve multi-agency food emergency responses (e.g., States, FDA field offices, FSIS) may utilize this chapter to assess and improve their response capabilities. Agencies with varying responsibilities (e.g., regulatory, public health, feed/animal health, law enforcement, and/or laboratory) and target response capability levels may differ in how they customize and apply these best practices.

3. RESPONSIBILITY

3.1. RRT (or investigatory team, in states without an RRT) Leadership

RRT leadership is responsible for ensuring that personnel assigned to conduct human or animal food traceback investigations have been provided with appropriate training. Examples of important training topics can be found in Chapter 8: Rapid Response Team Training.

3.2. RRT Members (State Partners, FDA District/Program Division Offices, etc.)

RRT members are each responsible for playing an active role in maintaining both their subject matter expertise and ability to work effectively in multidisciplinary and multi-agency response teams. For traceback investigations that are part of a multi-state outbreak involving FDA regulated product(s) (i.e., when FDA CORE is involved), FDA District/Program Division Offices are responsible for serving as the point of contact for the RRTs. In these cases, FDA District/Program Division Offices receive and distribute information, including records collected, meeting invites, and other documents, from FDA CORE to RRT members, in accordance with applicable confidentiality agreements. FDA District/Program Division Offices are

also responsible for submitting traceback investigation findings from the RRT to FDA CORE. FSIS RRT members are subject matter experts in traceback investigations involving meat, poultry, and processed egg products and serve as a point of contact for RRTs during traceback investigations involving FSIS regulated product(s).

3.3. FDA (Coordinated Outbreak Response and Evaluation (CORE) Network)
CORE serves as the coordinating body for traceback work completed on investigations requiring FDA involvement. CORE reviews traceback information collected by the RRTs, drafts traceback diagrams and timelines, and presents traceback findings to FDA headquarters staff. CORE coordinates with other federal agencies such as CDC.

3.4. FDA (Office of Regulatory Affairs)
The Office of Regulatory Affairs (ORA) is comprised of both headquarters and field staff nationwide. When it comes to making decisions about beginning a traceback, continuing a traceback, or ending a traceback, representatives from headquarters and the affected field staff will be a part of the decision-making process. The field will conduct the gathering of information through either an informational or regulatory traceback and will work with their RRTs as appropriate. If the field has any issues on resources or logistical issues, they will work through their management who will work with headquarters to help resolve these issues. ORA will work with CORE, the Centers, and others as appropriate during tracebacks.

4. DEFINITIONS

The following terms are used frequently in this chapter: traceback. See "Glossary of Key Terms" for definitions.

The following terms are used uniquely in this Chapter:

4.1. Cluster – Part of ongoing public health surveillance activities; used to described a larger number of people than expected with the same illness in a given time and space. "Clusters" of illness occur frequently and may not necessarily be related to a common food source.

4.2. Inventory Control Records – Records used by investigators to document and assess the degree to which an establishment can link incoming deliveries with outgoing shipments/sales. Examples include: Facility standard operating procedures (stock rotation, facility use of commercial codes such as Universal Product Codes (UPC), Stock Keeping Unit (SKU), Price Look Up (PLU) numbers, Global Trade Item Numbers (GTIN) and daily inventory records. These documents may exist in a paper or electronic format.

4.3. Informational Traceback – Human or animal food product investigations conducted to support epidemiological investigations by determining whether human or animal food items consumed by multiple case-patients in a cluster or outbreak have a common source or distribution point. This may sometimes be

referred to as an epidemiological traceback. Informational tracebacks can be helpful during an investigation and include gathering data about product distribution from companies involved in the suspected flow of product from its source to the point-of-sale. Information traceback data can help show product source and/or distribution patterns; however, it is often incomplete. Informational tracebacks lack complete, verified documentation including: shipping/receiving invoices, bills of ladings, and/or import documents. The chronological order of shipments at each point in the distribution chain or statements made by firms' management are unable to be verified without complete documentation. While informational tracebacks progress rapidly, results should be confirmed by regulatory traceback prior to use as regulatory evidence.

4.4. **Outbreak –** Part of ongoing public health surveillance activities; when an investigation shows that ill persons in a cluster have something in common to explain why they all got the same illness, the group of illnesses is called an outbreak. This could be attributed to a food, environmental exposure, animal contact, community event, or person-to-person contact starting from one ill person.

4.5. **Receiving Records –** Records documenting the source(s) of products or ingredients of interest during the time period of interest. Examples include purchase orders, bills of lading, invoices, and import documents, if applicable. These documents may exist in a paper or electronic format.

4.6. **Regulatory Traceback –** Food product investigations used to determine and officially document the complete distribution pathway of a contaminated food product, tracking it back to its origin or source. Sufficient shipping and receiving documentation is gathered to support regulatory actions, if needed, to ensure adulterated human or animal food is removed from commerce. This is the preferred traceback for regulatory officials and can sometimes be referred to as a formal traceback.

4.7. **Sales/Shipping Receipts –** Records documenting the distribution of products of interest after they leave the facility. Examples include shopper cards at retail level, and distribution records for processors and distributors. These documents may exist in a paper or electronic format.

4.8. **Subcluster –** A group of cases associated with a single establishment (e.g., restaurant, institution, or event) within a larger, more widely-dispersed cluster of illnesses due to the same pathogen.

4.9. **Traceback Flow Diagram –** A visual reference illustrating each level of the investigation as it branches from the point-of-service to its original source(s). Attachment B is a regulatory traceback example from an existing FDA document. Attachment C is an informational traceback example that combines both timeline and flow diagram elements into a single document.

4.10. **Traceback Timeframe –** For a traceback investigation, a timeframe of interest will be determined depending on the type of product, product shelf life, onset and length of any associated illness, product rotation practices, among other factors. If

it is an FDA traceback, FDA CORE will determine the timeframe with feedback from the FDA District/Program Division Offices and the CDC. CORE will issue these start-end dates in any related assignments and all documentation collected by the food safety inspectors for the investigation must include anything produced within the timeframe. While fewer records may be needed at the point of service (versus further in the supply chain), it is important to collect all information to identify patterns. The investigators are crucial for finding out if there is a "key" that may be needed to decode records.

4.11. Traceback Timeline – An easy visual reference that provides information on the volume and movement of product(s) of interest at various facilities over time. A timeline is a tool used to narrow down the most suspect shipments relative to time and exposure/purchase information. Specifically, for each facility and level of distribution of the product of interest, the timeline identifies information such as volume and lots of products in inventory and delivery receipt dates. Attachment A is a regulatory traceback example from an existing FDA document.

4.12. Traceforward – The determination of where an implicated food product was shipped, sold, or distributed from the location under investigation, starting with the source and tracing the product forward to the consumer through each point of service. This process is often used during a product recall and can be useful in outbreak investigations.

5. BACKGROUND

This RRT Manual chapter was developed by a work group of representatives from RRT state public health and agricultural agencies and FDA staff to describe best practices for regulatory and informational traceback.

Regulatory traceback investigations are conducted to determine the source of contaminated human or animal food that has been implicated by a foodborne illness investigation, laboratory analysis, or routine inspection.

Epidemiological and traceback investigations have historically been viewed as sequential activities, with tracebacks initiating once human or animal food is implicated. These regulatory tracebacks routinely involve on-site visits, interviews, inspections, and collection of records to verify the traceback information.

To reduce the time between outbreak detection and implementation of effective control measures, epidemiologists are increasingly requesting assistance from food regulatory partners during epidemiological investigations. Epidemiologists ask food regulatory officials to determine whether a food item consumed by multiple case-patients in a cluster or outbreak has a common source of distribution or a point of convergence linking multiple subclusters. Informational tracebacks are sometimes conducted; these are time-sensitive and exploratory in nature so they may not always include the collection of all records or on-site inspections typically conducted during regulatory tracebacks.

Sometimes, as informational tracebacks progress, increasingly convincing evidence is gathered regarding the source of a contaminated product. For example, all known cases may be linked to a single source or point in the distribution chain. In the past, this has meant that regulatory agencies have sometimes needed to rapidly retrace their steps to gather whatever additional formal documentation is needed to support regulatory enforcement activities.

It is important that each agency in the response team has a clear understanding of its sister agencies' legal authorities and the evidence (epidemiological, laboratory, and regulatory) these sister agencies require to trigger various responses under those authorities.

Epidemiologists and food regulatory officials continue to explore ways to gather informational traceback data in ways that are accurate, timely, and an efficient use of regulatory resources. This chapter shares some of the best practices that have emerged to date.

6. SAFETY

Agencies must ensure that personnel conducting tracebacks have the training necessary to safely complete their tasks.

7. EQUIPMENT/MATERIALS

Key individuals working on traceback investigations will require access to FoodSHIELD to receive updates on the investigation and share relevant information with other regulatory partners. Equipment and materials needed for specific activities (e.g., graphics software to generate flow diagrams and timelines) should be addressed within each agency's policies and procedures. In addition, portable printer/scanners may assist in collection of records.

8. PROCESS DESCRIPTION

8.1. Generic Traceback Process Flow

Traceback investigations are generally not needed when the origin of implicated or suspect foods is known (e.g., clearly labeled processed food with production lot and manufacturer information identified). Specific procedures for conducting traceback investigations are identified in the References and Other Resources section of this chapter. Attachment D is a flow diagram depicting the generic steps of both regulatory and informational tracebacks. For both regulatory and informational tracebacks, the basic investigational process (interviews, observations, and record collection) and types of information to be gathered are virtually identical. These two types of traceback differ in how investigators collect information to achieve the timeliness and accuracy requirements for their respective purposes.

8.2. Regulatory Traceback Investigation

This section provides an overview of regulatory tracebacks including triggers, sharing of epidemiologic summaries, coordination, and documentation.

8.2.1. Overview of Regulatory Traceback Investigations [1]

Tracebacks are an important component of an investigation. The purpose of a traceback is to determine and document the complete distribution and production chain for a product that has been implicated by any of the events listed in the table below. Each point along the farm-to-table continuum must then be examined for opportunities for introduction, survival, or growth of the identified agent.

8.2.2. Regulatory Traceback Triggers

There are various factors that may trigger a regulatory traceback and related regulatory agency actions. Table 1 outlines situations favoring the initiation of a traceback. In addition to the factors identified in Table 1, there are a number of conditions that, when some or all occur, indicate that a regulatory traceback may be performed:

1. Epidemiological subject matter experts designate a suspect food vehicle.
2. Cases are able to provide a purchase receipt or shopper card information, or at least a definitive date of purchase and purchase location.
3. Shipping/receiving documentation must be available from the POS.

8.2.3. Outbreak Epidemiology Summaries for Tracebacks

Before initiating a regulatory traceback for a foodborne illness outbreak, obtain a brief written summary of the epidemiological investigation from the lead epidemiology organization. The summary should include a description of the outbreak and cases (e.g., verified exposure dates, earliest and latest dates of onset, symptoms, laboratory testing, locations of cases, study design, study results, suspected food(s)). The summary should also include a line listing of all cases completed by the appropriate communicable disease control agency.

The regulatory agencies should review the epidemiologic information to determine if sufficient information exists to launch a traceback investigation. The

[1] Acknowledgement: The information in this section was from the California Department of Public Health/CalFERT Traceback Procedures (with some editing).

following table (Table 1) summarizes the kind of information that should be evaluated. Additional instructions for collection and evaluation of case information is available in the attached PFP Job Aid (Attachment F).

Communication with the RRT's epidemiological agency or other lead epidemiological agency (e.g., CDC) should be maintained throughout the traceback investigation, in case there is new information or any changes to older information. These changes could affect the relevancy or outcome of the traceback.

Table 1: Factors to Determine Appropriateness of a Traceback Investigation for an Outbreak

Factor	Examples Favoring Initiation of a Traceback
Has a potentially severe public health risk been identified with a human or animal food product suspected to be the vehicle of transmission?	Irreversible health state/conditions, life threatening illness, or death.
How strong is the evidence that the cases of illness may be related?	1. Epidemiological subject matter experts indicate the cluster/outbreak is significant and has identified a common food item that is most likely to be the vehicle for the outbreak or source of contamination. 2. Cases are laboratory confirmed with indistinguishable genetic fingerprint patterns (e.g., Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS) or Multi-Locus Variable-number tandem repeat Analysis (MLVA)).
Is there high confidence that the product or ingredient in question was consumed one or more times during the time period of interest?	Interviews of case-patients with good food history recall identify very few food items potentially associated with illnesses and no obvious non-food common exposure(s) that can explain the outbreak.
Is/are the consumption date(s) for cases known?	The following types of dates can serve as bases for tracebacks (most preferred type listed 1st): 1. Specific consumption dates 2. Illness onset dates 3. Isolation dates (when positive laboratory test results were reported).
Is an accurate food/product description available?	Availability of receipts, shopper card information, product labels or photos.
Is there accurate information regarding the place of exposure/purchase?	Receipts, shopper card information, credit card receipts, invoices.

8.2.4. Traceback Coordination

When coordinating traceback with multiple agencies please refer to the Communications Chapter and ICS Chapter within the RRT Manual.

8.2.5. Traceback Documentation

All traceback investigation documentation should include a summary of the information gathered from the observations, interviews, and records collected at every firm. This includes:

1. A summary of shipment dates and amounts of the implicated food item(s). Verification of record completeness by matching incoming shipments (e.g., volume, dates) with outgoing sales where possible.
2. A traceback diagram and/or timeline (hand-drawn or computer generated) detailing names, locations, amounts, and dates of receipt and shipment.
3. A completed questionnaire for each visit (if used).
4. Copies of invoices, bills of lading, daily inventories, HACCP plans, etc.
5. Photos of all relevant findings. Note: products on-site at the time of inspection may not be relevant to the time period of interest.

Copies of paperwork (i.e., invoices, shipping receipts, bills of lading, etc.) are required from each level of the distribution system and should be included in the report. Daily inventories of the product of interest, if available, will likely be useful. For distributor-level investigations, request documentation regarding any on-site processing, packing and/or repacking of the product of interest. These documents may be faxed and copied several times; therefore, please ensure that the photocopies are legible and complete (i.e., no missing corners/dates).

8.2.6. Specific Procedures

Note: The records, interview questions, and observation are not all inclusive lists provided in this section but are example to improve the consistency and effectiveness of traceback investigations.

This section highlights considerations for teams conducting regulatory traceback investigations. On-site record collection, interviews, and observations are key tools for gathering traceback information from food establishments.

Agencies should strongly consider use of standardized data collection worksheets or questionnaires to increase the consistency and completeness of information gathering. Attachment E is a generic worksheet that can be used to gather core information if more specific forms/worksheets/questionnaires have not been developed.

1. <u>Records Collection</u>
   a. Unless otherwise specified, for tracebacks at Point of Sale/Service (POS), consider collecting records beginning two weeks prior to

the earliest date of exposure or documented product contamination. Examples of records that typically need to be collected include but are not limited to:

i. Invoices
ii. Shipping and receiving records
iii. Bills of lading
iv. Inventory records
v. Identifying information for implicated product
vi. Label information
vii. Container type, size, description
viii. Grade
ix. Lot codes
x. Universal Product Codes (UPCs) or Global Trade Item Numbers (GTINs)
xi. Production dates, pull dates, "use by" and/or "sell by" dates
xii. Product origin
xiii. Raw ground beef grinding logs/records
xiv. Product shelf life
xv. Product turn over

b. Examination of the delivery frequency at the POS will help determine the timeframe for record collection at facilities further back in the distribution chain.
c. Verify label and product information with invoices and shipping receipts for the time period in question. Collect product information (labeling, lot codes, etc.) for the product that was used during the outbreak exposure time period.
d. Verify and document any handwritten comments and marks on the documents and their meaning and significance.

2. <u>Interviews and Observations</u>
   a. Determine product ordering practices:
      i. Identify how and when product is ordered.
      ii. Estimate average daily use.
      iii. Determine alternative sources of product if establishment runs out before another shipment is received (e.g., purchase from grocery store, request more from supplier, etc.).
      iv. Determine how deliveries and receipt dates are recorded.
      v. Compare the shipping dates to the dates received.
      vi. Determine suppliers during the time period of interest, including cash transactions.
      vii. Estimate the transportation time from supplier(s) to the establishment.

viii. Determine if the product (e.g., fresh produce) was re-packed during distribution.

b. Determine shipping and receiving practices, making note of exact receiving dates and times for each shipment (critical). **Do not make assumptions that the date on the invoice, bill of lading, etc., is the date of receipt**. This is often best determined via interviews with various levels of facility staff (management and front line employees).
c. Conduct interviews with more than one employee at multiple levels of the organization regarding the implicated product.
d. Observe and verify that the procedures described by employees are reflected in their work.

3. Storage, Handling, and Preparation Considerations
   a. Review the standard procedures for stock rotation and how the product is unloaded and added to existing inventory. Determine if first-in-first-out (FIFO) rotation policy is standard operating procedure and, if so, how closely the policy is followed.
   b. Determine if food product storage conditions are in accordance with the manufacturer's requirements (e.g., "keep refrigerated").
   c. Determine if implicated food item is used as an ingredient in the preparation or manufacture of another food item.
   d. Determine how stock inventory is recorded. Determine how partial cases/containers are accounted for, and how and if carryover is recorded. If an inventory record is available for this time period, understand how it is used, including its strengths and weaknesses, and determine what time of day the inventory is performed.

4. Analysis of Traceback Data
   a. Analyze and discuss the data from each level of the investigation (e.g., retail, distribution, production) before continuing the investigation to the next level.
   b. Determine which shipments received at the establishment could have been used to prepare the implicated food item.

5. Farm Traceback Procedures
   The purpose of a farm traceback investigation is to gather information and observe and document practices that may have led to the pathogen-specific contamination of produce, which could support regulatory action, if appropriate.

a. Investigation of produce-related outbreaks should follow the FDA's "Guide to Produce Farm Investigations" (http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074962.htm). FDA Form 3623 "Farm Investigation Questionnaire" may also be used as a guide (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072131.pdf). Documentation of the findings for each farm should accompany the final report.
b. Other tips to consider during farm tracebacks:
    i. The investigation team should focus on the time period and conditions that existed during the growing, harvesting, packing, and cooling of the product implicated in the outbreak or positive sample.
    ii. Evaluate sources of microbial contamination based on the pathogen of concern. If the pathogen's only reservoir is humans, then focus on disease prevalence in the community and farm workforce, worker hygiene, and contaminated water and sewage inputs. If the pathogen of concern has both a human and animal reservoir, then the investigation should be broadened to cover possible animal contamination sources.
    iii. Consider any cultural considerations and protocols that should be followed.
    iv. Consider printing off hard-copies of questionnaires for investigators to use during the investigation. Documentation of the traceback findings for each farm should accompany the final report.
c. In addition to the items listed under Farm Traceback Procedures, farm traceback investigations should include a map of the area(s) under investigation, specific to the implicated fields, surrounding area, and packing facility. Ask the firm to provide a map or diagram, of the farm, growing lots, and/or facility locations, including GPS coordinates, if available. Diagramming the farm layout and its surroundings will assist in identifying and assessing contamination sources. If the firm cannot supply a map or diagram, sketch one with the firm's assistance. It also helps to use mapping software or online resources to map out the area before your farm inspection and revise it after your inspection, if needed. Try to include:
    i. Potential sources of contamination (e.g., cattle feed lot).
    ii. Topography (direction of slope/drainage for run-off and barriers).
    iii. The process flow of the product from field to packing.

iv. Documented Global Positioning System (GPS) coordinates of each field visited, with notations of areas where samples were collected.
v. Locations of nearby bodies of water, farms with livestock, manure storage, possible animal harborages or composting areas.

d. Other aspects of the farm traceback investigation should include an evaluation of water quality and sources; manure and biosolids that may be used in soil preparation and as fertilizer; worker health and hygiene, including sanitary facilities; any food additives or pesticide use; cooling processes; and transportation leaving the farm.
e. If implicated shipments can be verified during the farm investigation, document the system and coding that allows the product to be traced from the field to packing facility through loading and distribution. Basic information should include crop, field identification, harvest date, harvest crew, lot identification or product code, shipment dates, and customers.

8.3. Informational Tracebacks[2]

Note: The best practices described in the section below may help to improve the consistency and effectiveness of informational tracebacks, recognizing that there may be legal or policy restrictions in some organizations that prevent full or partial implementation.

Tracing the source of food items or ingredients through distribution to source of production can be critical to confirming epidemiologic links among cases or ruling them out. For non-branded commodities, such as produce items, the convergence of multiple cases along a distribution pathway may identify the source of contamination. Conversely, failure to identify common suppliers may indicate that the food item in question is not the likely vehicle. Informational tracebacks need to be conducted quickly in order to support the epidemiologic studies (e.g., assist with hypothesis generation and data gathering). While the types of available information or evidence often vary, food regulatory agencies typically have broad investigative authorities that can support these activities.

[2] Abstracted from the whitepaper: *Product Tracing in Epidemiologic Investigations of Outbreaks due to Commercially Distributed Food Items – Application, Utility, and Considerations*, Smith, K., Miller, B., Williams, I, et al, 2015.

Regulatory agencies participating in informational tracebacks should carefully review their legal authorities and agency policies to ensure that appropriate administrative procedures are followed in case enforcement action is needed. Expedited information gathering efforts, including regulatory tracebacks, may be needed to more formally document the distribution of implicated products. The determination of appropriate regulatory response is made on a case-by-case basis and is often based on several factors, including but not limited to: the certainty of the evidence, the severity of the disease, the potential for ongoing exposure, and the availability of effective control measures that could prevent additional illnesses and/or deaths.

8.3.1. Epidemiological Investigations and Informational Tracebacks

1. Deciding when to initiate an Informational Traceback
   Whenever possible, informational tracebacks should be closely coordinated with partner agencies. In addition to the factors identified in Table 1, there are a number of conditions that, when some or all occur, indicate that an informational traceback may be warranted:
   a. Linked cases occur in multiple locations or jurisdictions (particularly if they occur in multiple states);
   b. A vehicle cannot be clearly implicated with traditional epidemiologic, laboratory, and environmental investigation methods alone; and
   c. More information is needed to determine if similar food items from different establishments/stores/firms can be linked to a distributor or processor.

   The decision to conduct an informational traceback should be based on input from both the public health and regulatory agencies.

2. Joint epidemiology and environmental health investigational data review
   a. Review and discuss epidemiology data
      If an epidemiologic investigation meets the above criteria to initiate an informational traceback, the appropriate regulatory agency(ies) should be contacted and provided with the following background information:

      i. A brief written summary describing the outbreak and cases, including the earliest and latest onsets and points of exposure, symptoms, geographic distribution of cases, etc.
      ii. De-identified case interview forms.
      iii. Results of preliminary case-control study (if conducted).

iv. Epidemiologic curve for state cases and multi-state cases (if applicable).
v. Information on any cases with product available for testing (with permission for regulatory agency to contact the individual and obtain samples).
vi. Product description: Type of food (as specific as possible), brand name, labeling, lot codes, and any other unique identifiers that might be available – UPC, PLU, etc.).
vii. Purchase date(s) linked to specific retail food locations (try to verify with actual receipts or shopper card information if available).
viii. Identification of all known menu item(s) that included the suspect food item (if purchased from a food service establishment/restaurant).
ix. Consumption date and menu for the week before illness if the food was eaten at an institution (e.g., long-term care facility, college cafeteria, prison) – to help identify food items/ingredients that may have been served on multiple days.
x. If necessary, a permission form signed by the consumer, allowing their shopper card history to be released by the store or chain to investigators – determine if the store or chain has its own form or will accept a generic form.

b. Investigation Plan and Objectives
Informational tracebacks are an unscheduled workload in addition to agency priorities with pre-existing deadlines such as high-risk inspections and investigations. Epidemiologic and food regulatory agencies should consider resource availability and agency operational constraints, without jeopardizing public health, when developing the investigation plan and objectives.

An investigation to reconstruct the distribution pathways of one or two food items from a single point may require a considerable amount of time depending on the types of information collected and the time taken to obtain information. In general, informational tracebacks do not take as much time as regulatory tracebacks to complete. If local or state jurisdictions cannot spare the resources to conduct timely data collection for a particular traceback investigation, a number of alternatives may be available. For example, State agencies (public health or regulatory) may be able to assist local health departments and/or

neighboring states. Federal partners may also be consulted to assist in data collection.

3. Identify and Document Distribution of Suspect Food(s)
   a. The informational product tracing process needs to be accomplished quickly if it is to be successful. Gathering information by telephone, fax, or e-mail is likely to be faster than sending inspectors to gather physical records from each establishment. The following practices are recommended when conducting a telephone (i.e., informational) traceback:
      i. Identify most senior food safety professional within the firm's organization (for example, the Vice President of Food Safety and Quality Control).
      ii. Be prepared to provide a de-identified summary of the current epidemiologic investigation, emphasizing that no specific food item has yet been identified as the source of the outbreak.
      iii. Be prepared to explain how cooperation with this investigation will assist in the identification of the source of the outbreak, or the ruling out of a product of interest.
      iv. Be prepared to cite and provide reference to statutory authority for obtaining records.
      v. State programs should consider confirming requests via email after telephone conversations have been concluded, so that the specific request is documented. Programs should also be prepared to submit requests on letterhead via fax, if necessary.
      vi. Set firm deadlines for receipt of requested information, requesting that documents be provided in hours, rather than days.
      vii. Be prepared to follow up with firms repeatedly via phone, email, fax, or in person, as needed.
      viii. Verify that records or documentation described over the phone or via email are provided (either hard copies or electronic copies).
   b. Establishing firm deadlines for information requests is critical to the timeliness of the investigation. It is important to convey the urgency of the request to parties who may be unfamiliar with expectations. This will help ensure that the necessary data is available from each point in the trace in a timely manner.
   c. On-site visits may still be necessary to confirm the accuracy/completeness of the information. Indicators that on-site

visits may be needed to ensure collection of accurate information include:

i. An entity in the supply chain is slow in providing information following multiple requests. It may be necessary to send a field investigator to the facility to collect the relevant documents.
ii. Inconsistent information is being gathered that requires clarification.
iii. Epidemiological or product distribution evidence suggests the possibility of on-site contamination of a particular product (e.g., on-site packing, repacking, processing).

The documents collected and processes observed during an on-site informational traceback should be identical to a regulatory traceback.

8.4. Typical Problems and Potential Solutions

Some typical problems and potential solutions are described in the Table 2 below.

Table 2: Troubleshooting Document Collection

Issue	Problem	Solutions
Firms are slow in providing requested documents	• The firm may not be convinced that the gathered evidence is credible. • The firm may be attempting to gather information that is not needed. • The firm may have limited first-hand experience with foodborne illness outbreaks and potential impacts on their business.	• Provide clear and concise summaries of available epidemiologic, laboratory, and environmental health evidence to firm decision-makers. • Clearly identify the specific information being requested – time period of interest, exact product description, types of records. • Share factual information from recent outbreaks illustrating the potential regulatory, economic, and civil consequences (i.e., class action lawsuits) of delaying identifying the source of the outbreak. • Assign staff to visit the facility, as their presence at the facility often can generate more responsiveness than a request made over the phone.
Inconsistent or incomplete records for some date(s) of interest	• Non-existing records. • Incomplete records. • Poor recordkeeping.	• Gather additional records from before and after the period of missing records (bracketing) to better define usual/typical patterns of receiving, inventory control, and shipping. • Take note of the firm's ordering pattern and confirm that no records are missing. • Request overlapping records (shipping documents to this firm, from their supplier at the same time that you request their supplier's receiving records).

Issue	Problem	Solutions
Voluminous paper-based records	• Firm provides requested records in paper-only format. • Firm is providing records that do not pertain to the request.	• Request that firm provide records in a ***searchable*** electronic format, if available. Sometimes firms won't provide records electronically unless directly requested. • If records are not available electronically, the agency should have the capacity to scan the records with Optical Character Recognition (OCR) so that they may be rapidly queried. • Request that the firm provide records for only the product(s) and dates that are requesting at this time, however your request may expand at a later time.
Agencies lack jurisdictional authority over all entities in the product(s) distribution chain(s)	• Local and state agency regulatory authorities vary significantly from state to state. • Information sharing sometimes requires legally binding agreements.	• Before the next outbreak, contact local, state, and tribal authorities to discuss strategies for collaboration during future outbreak responses. Consider becoming actively involved in your state's Food Safety Task Force and/or other networking mechanisms. • Consider formalizing agreements with an MOU or other written document, when needed.

8.5. Factors to Consider When Determining the Most Appropriate Method(s) for Gathering Informational Traceback Information

The following Table 3 describes situations where the use of a Telephone, Fax, or E-mail traceback may be most appropriate to gather information requested by epidemiological and/or environmental health investigators.

Table 3: Informational Traceback Factors

Information Type	Factors Suggesting Telephone, Fax, or E-mail May Be Appropriate
Product Identifying Information	Cases with exposure to common food occur in multiple locations or jurisdictions at the same time (particularly if they occur in multiple states). Firm may be able to provide a description of the product over the phone or photos via e-mail or fax.
Ordering, Receiving, and Shipping Practices	Firms with a proven record of maintaining accurate, reliable, readily-available records could provide information via telephone, fax, or email in a timely manner.
Handling and Storage Practices	Minimal potential for introduction of the contaminant of interest exists (e.g., no on-site packaging, repackaging, or processing of the product). If the product had a high potential for introduction of the contaminant, a regulatory traceback would be more appropriate. Otherwise, an on-site environmental assessment or investigation is often in order.
Stock rotation practices	Firms with a proven record of maintaining accurate and reliable inventory management systems and records indicate that they can provide reliable information via telephone, fax, or email in a timely manner. If the firm is unable to provide consistent information, then a regulatory traceback wouldon-site be more appropriate.

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

The following levels described assume that agencies with higher level capacities meet all the elements for lower level capacities.

Level	Description
1	The agency has processes or procedures for conducting tracebacks.
2	The agency has written traceback procedures and has reviewed the procedures within the past 12 months, including a review for equivalency to a national/multijurisdictional best practices document (e.g., the chapter).
3	The agency has a traceback procedure that is equivalent to a national/multijurisdictional best practices document (e.g., the chapter) that allows the program to complete both regulatory and informational tracebacks. A scheduled formal review of the document has been established and procedures are updated as necessary.
4	100% of relevant staff have been trained on traceback procedures (informational and regulatory). Staff receive training within 12 months of updates or revisions of the policy.
5	Within past 12 months, the program has documented the ability to conduct informational and regulatory tracebacks through audits, exercises, or real world experiences.

9.2. Process Overview

9.2.1. Review the steps identified in the RRT Food Emergency Response Plan (FERP) Chapter, which are appropriate for agencies interested in developing any RRT capacity.

9.2.2. Determine what traceback capacity level your agency needs to develop and maintain based on agency objectives, identified risks, past experiences, and the availability of resources.

9.2.3. Consider how to most effectively use staff training, supervision, jurisdictional authorities, and other resources to achieve desired traceback capacity level. It is often best to accomplish this through agency involvement in a comprehensive process improvement initiative (e.g., enrollment in the Manufactured Food Regulatory Program Standards (MFRPS)).

9.2.4. Use information from exercises and actual responses to assess the costs and benefits of developing a higher traceback capacity Level.

10. RELATED DOCUMENTS

Other RRT Manual Chapters: RRT Manual Chapters on Working with Other Agencies, Communication SOPs, Training, and Food Emergency Response Plans.

11. REFERENCES AND OTHER RESOURCES

Full citations are in the References Section, "List of Reference Documents," listed by author.

11.1. Product Tracing in Epidemiologic Investigations of Outbreak due to Commercially Distributed Food Items – Utility, Application, and Considerations - October 2015 (http://www.cifor.us/clearinghouse/uploads/Product%20Tracing%20in%20Epidemiologic%20Investigations.pdf?CFID=42475325&CFTOKEN=78980292&jsessionid=6BF72ED79E866E9079E8077EE94664B6.cfusion).

11.2. FDA: Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations - June 2006 (http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm075005.htm).

11.3. FDA: Guide to Produce Farm Investigations (http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074962.htm).

11.4. FDA Investigations Operations Manual, Subchapter 8.3 - INVESTIGATION OF FOODBORNE OUTBREAKS 8.3.5.5 - Tracebacks of Foods Implicated in Foodborne Outbreaks (https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123515.pdf).

11.5. Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines for Foodborne Disease Outbreak Response, 2nd Edition (Section 5.2.4.1.7 (http://www.cifor.us/documents/CIFOR%20Industry%20Guidelines/CIFOR-Industry-Guideline.pdf).

11.6. Procedures to Investigate Foodborne Illness, 6th Edition 2011, International Association for Food Protection (http://www.foodprotection.org/publications/other-publications/index.php).

11.7. Examples of state procedures, checklists, and guidance documents are available on FoodSHIELD (www.foodshield.org).

11.8. FDA: Office of Regulatory Affairs' on-line university (ORA U) online units, registration required (http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm119016.htm).

11.9. FDA "Guide to Investigation of Eggs and Farms Implicated in Foodborne Outbreaks of Salmonella Enteritidis." (Note: This internal FDA document is available upon request to FDA personnel and commissioned state officials.)

11.10. FDA Training modules

Title	Course Code	Class Type
Traceback Investigations 1: Introduction	TI01	ORA U
Traceback Investigations 2: Point-of-Service Investigations	TI02	ORA U
Traceback Investigations 3: Distributor Investigations	TI03	ORA U
Traceback Investigations 4: Traceback of Eggs and Other Commodities	TI04	ORA U
Traceback Investigations 5: Concluding the Investigation and Reporting the Results	TI05	ORA U
ER220: Traceback Investigations	ER220	Classroom

Title	Course Code	Class Type
ER321: Produce Farm Investigations	ER321	Classroom

12. ATTACHMENTS

12.1. Attachment A – Example Traceback Investigation Timeline from FDA's ER220 Traceback Investigations training course

12.2. Attachment B – Example Traceback Investigation Flow Diagram FDA's ER220 Traceback Investigations training course

12.3. Attachment C – Example Traceback Investigation Master Flow Diagram from FDA's ER220 Traceback Investigations training course

12.4. Attachment D – Generic Traceback Process Flow Diagram

12.5. Attachment E – Generic Traceback Information Gathering Worksheet

12.6. Attachment F – Partnership for Food Protection (PFP) Job Aid

12.7. Attachment G – FDA CORE: Routine Traceback Assignment Questions During Manufacturer Investigation (April 8, 2015 – Version 2.0)

12.8. Attachment H – FDA CORE: Routine Traceback Assignment Questions During Distributor/Supplier Investigation (July 7, 2015 – Version 3.0)

12.9. Attachment I – FDA CORE: Routine Traceback Assignment Questions During Point of Service Investigation (May 15, 2015 – Version 2.0)

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	9/26/2011	RRT Traceback WG (MI**, Minneapolis District**, MN, CA, Pacific Region, Los Angeles District, Florida District)
1.1	R	2/1/2012	ORA/OP
1.2	R	1/24/13	ORA/OP
2.0	R	5/26/17	RRT Traceback Ch. Revision WG (GA, MO, RI, SAN-DO, FDA CORE, FDA Office of Policy & Risk Management, MN**, MIN-DO**)

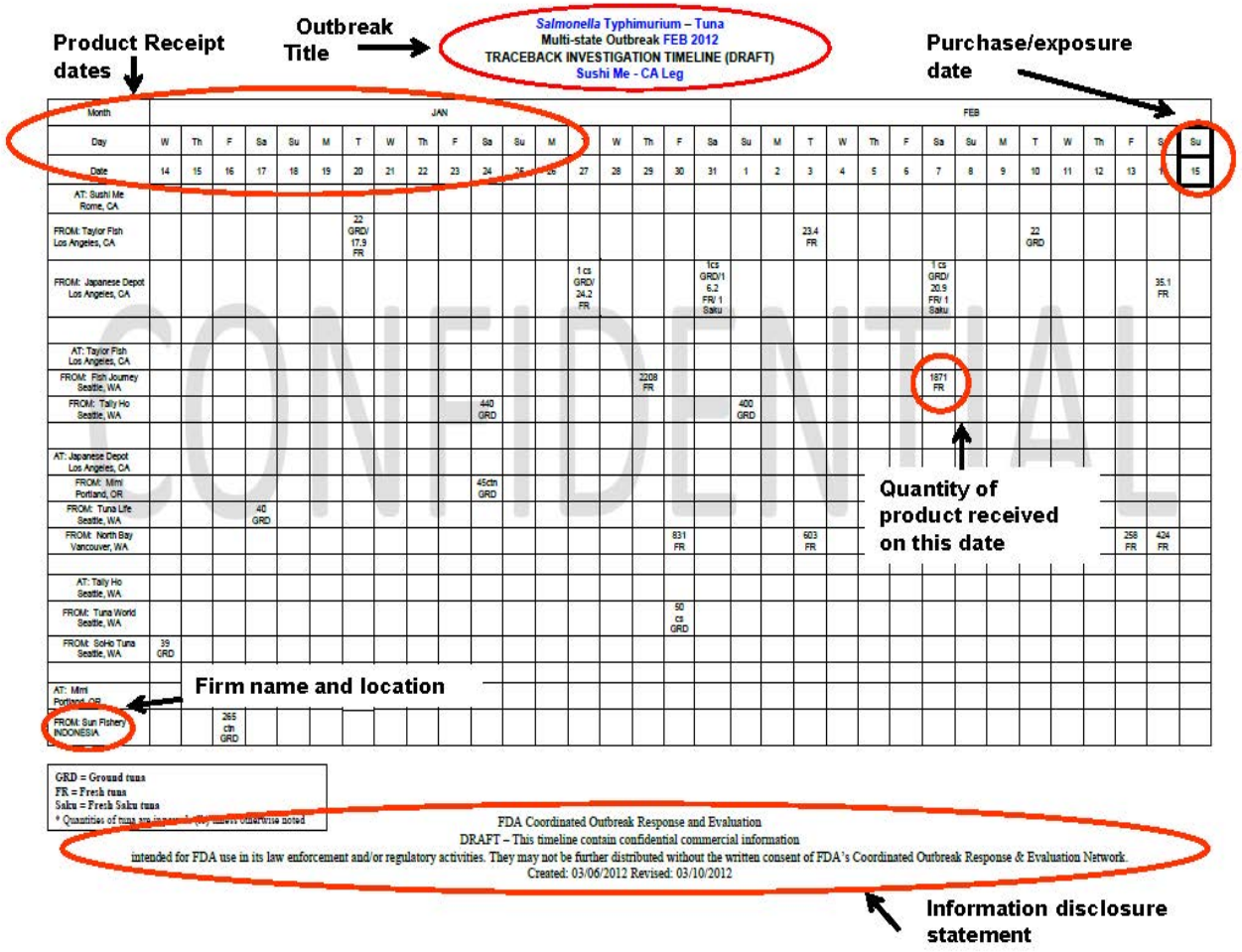
*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)
**Workgroup Lead

Change History

1.1 – Editorial revisions made by ORA for document clearance.
1.2 – Revisions to achievement levels (Section 3) based on recommendations from the RRT 2012 Face to Face Meeting (November, 2012).
2.0 – Revised for the 2017 Edition of the RRT Manual by the RRT Traceback Chapter Revision Workgroup

Attachment A – Example Traceback Investigation Timeline from FDA's ER220 Traceback Investigations training course

Note: Attachments A-C are examples of FDA documentation; header/footer information (e.g., agency disclosure statement) will depend on the agency drafting the timeline.

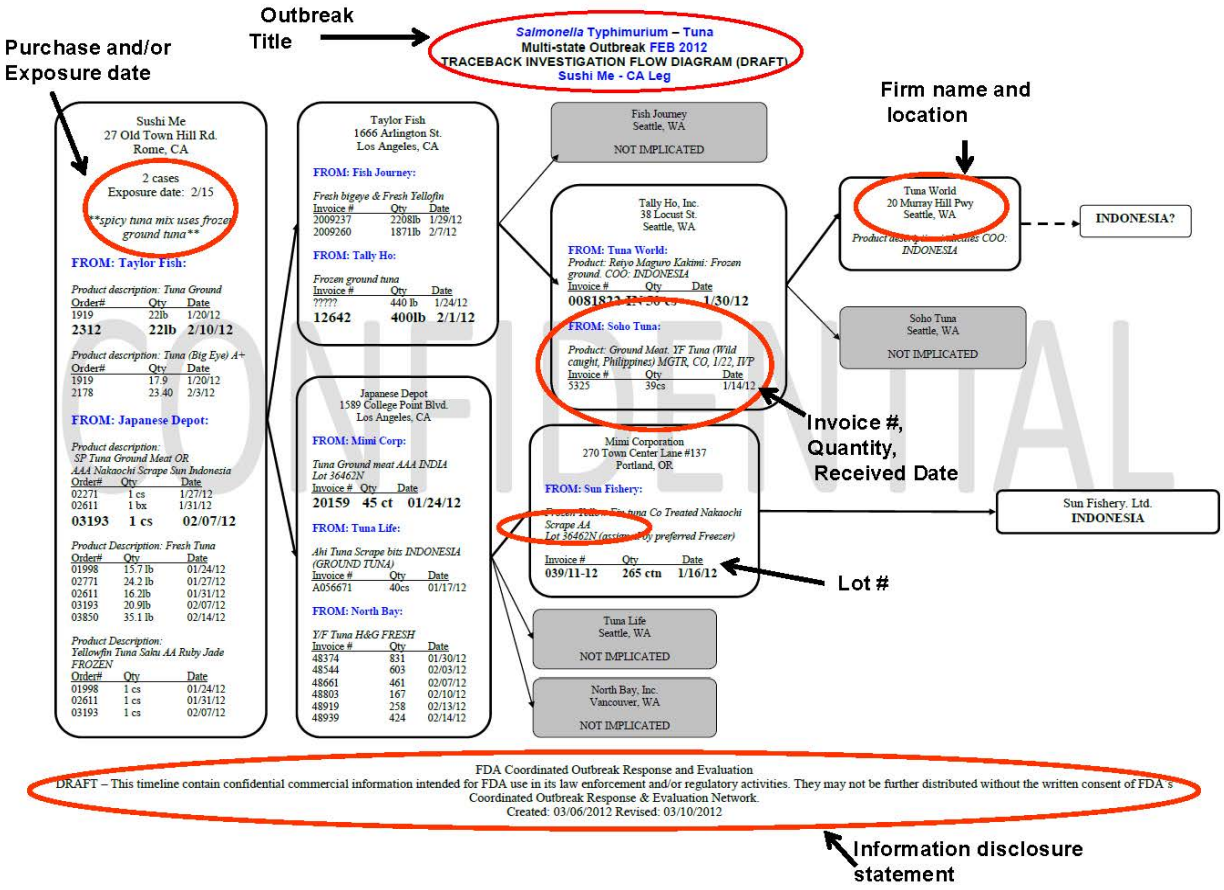


Directions for Completing or Interpreting This Type of Traceback Investigation Timeline:

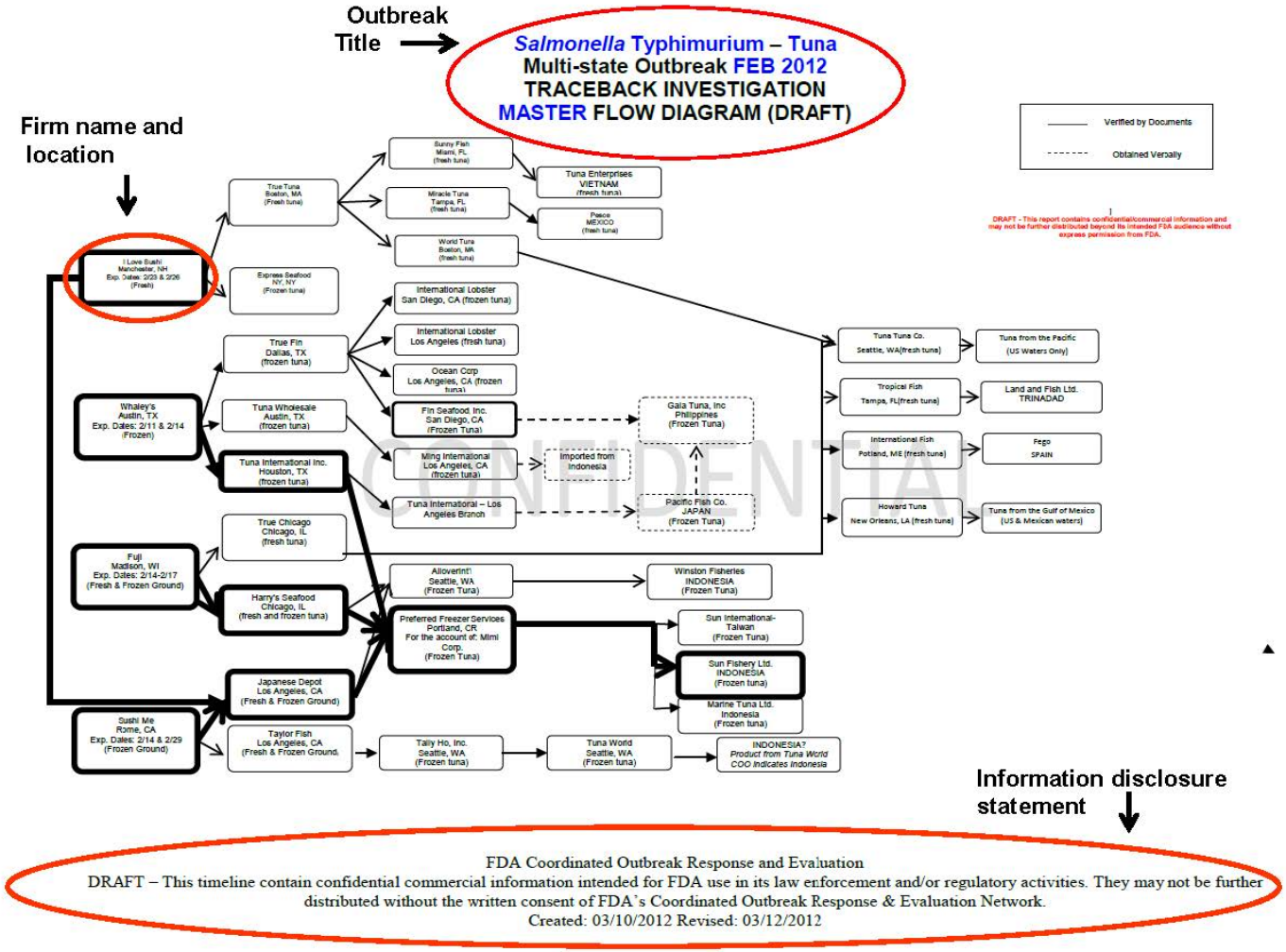
- Label with title of traceback, implicated product, traceback number, and date(s) of the outbreak(s) (*month and year)*.
- The last date of purchase/exposure should be the furthest, upper-right hand cell. The rest of the dates continue backwards to the left for the entire time frame covering the record collection dates.
- The first left cell on the line under "DATE" contains the POS name, preceded by the word "At." All suppliers to the POS are listed on a separate line below the POS name and are preceded with the word "From."
- If there were inventory records at POS, record the inventory under the corresponding dates on the same line as the POS. *Note at the bottom of the timeline if inventory was taken before or after that day's shipments were received*. If there were no inventory records (or if inventory was not taken on a given day), then line should remain blank (*do not use zero to represent blanks)*.
- Quantity of each shipment should be indicated on the date it was received at POS from the corresponding supplier.
- Implicated shipments will usually be bold, or have a bold border.

Attachment B – Example Traceback Investigation Flow Diagram from FDA's ER220 Traceback Investigations training course

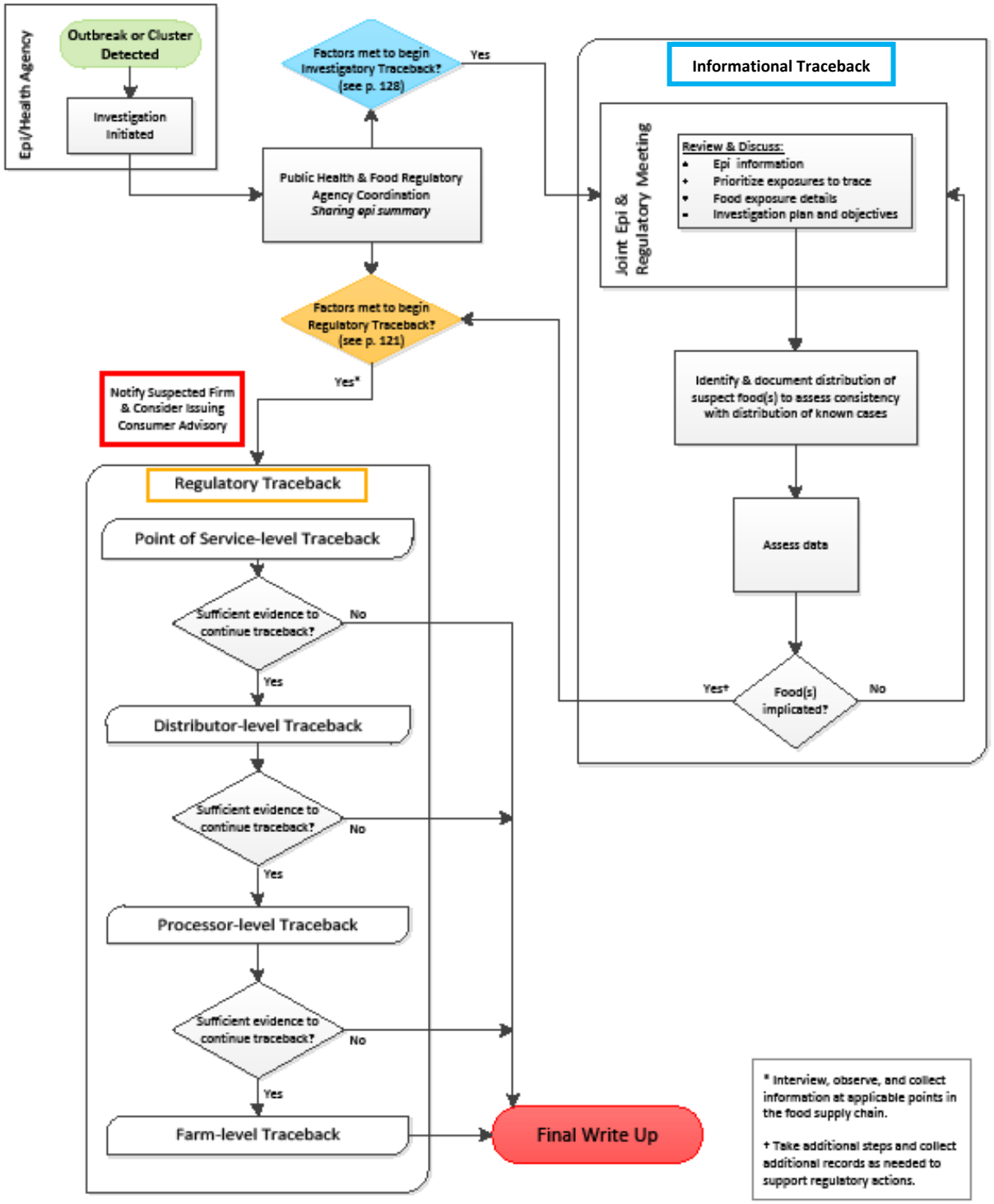
Most traceback investigations resemble a branching tree because of multiple suppliers throughout the distribution chain. An easy way to visualize the ongoing investigation and shipments of product is to draw a flow diagram illustrating each level of the investigation as it branches from the point of service to its original source(s). Prepare a flow diagram illustrating distribution of the product up through the distribution level currently under investigation. For each implicated distributor, include the following: name, city, state, invoice/purchase order number, date received, quantity, lot number, and Freight/AWB number and date. For non-implicated distributors list only the distributor name and location. If there are numerous shipments involved and the flow diagram would become too complex, just list date received, quantity, and invoice number on the flow diagram, and include other record information in a separate document.



Attachment C – Example Traceback Investigation Master Flow Diagram from FDA's ER220 Traceback Investigations training course



Attachment D – Generic Traceback Process Flow Diagram



Attachment E – Traceback Information Gathering Worksheet

A Microsoft Word file template of the Traceback Information Gathering Worksheet is available upon request to FDA Office of Partnerships (OP.Feedback@fda.hhs.gov) and is posted in the FDA RRT Workgroup in FoodSHIELD (closed workgroup only accessible to RRTs). A screenshot of the file is provided within this attachment.

Traceback Information Gathering Worksheet	
The purpose of these investigations is to identify and document the distribution of implicated foods or foods suspected of contamination. This involves reconstructing past production and distribution events during a specific time period through interviews, observations, and record collection.	
Establishment Name and Address:	
Epidemiological Investigational Information:	**Notes:**
Preliminary product description	
Time period of interest verified (Dates and times product of interest was prepared/served/distributed and consumed at point of service)	
Epi data (to share with industry as needed)–number of cases, association certainty	
Product Identifying Information:	
Product description (Brand, food type, size, container type)	
Include pertinent label information (collect copy or photo if available)	
Document product identifiers (i.e. Lot Codes, Universal Product Codes (UPC), Stock Keeping Unit (SKU), Price Look Up (PLU) numbers, Production/pull dates)	
Manufacturer name and production facility address	
Determine how product is received (i.e. frozen, fresh, shelf stable)	
Identify food items that may contain the product of interest	
Shipping and Receiving Practices (obtain copies of invoices, receipts, bills of lading, etc…):	
Document receiving dates, times, and amounts for each shipment (or transfer) in requested time period	
Determine whether firm wholesales and/or retails product of interest	
Indicate how the dates on the shipping records reflect the date the product was received	
Determine how supplier deliveries are documented or recorded	
Identify firm's suppliers during this time period (include cash transactions)	
Determine or estimate transportation time from supplier to point-of-service	
Handling and Storage Practices:	
Determine if there is any on-site packing, repacking, and/or processing that could have allowed introduction of contamination	
Determine if an environmental assessment/investigation is needed (i.e. to assess cross-contamination opportunities like repacking of fresh produce during distribution)	
Stock Rotation Practices:	
Review the standard operating procedure at the firm	
How is the product unloaded and added to inventory	
Determine if first-in-first-out (FIFO) rotation policy is standard operating procedure and how closely it's adhered to	
Stock Inventory (daily or otherwise):	
Review inventory record (logs) for time period of interest (how records are used by firm, identify record system strengths and weaknesses)	
Determine what time of day inventory is performed	
Identify what each inventory number represents	
Determine how partial cases or containers are accounted for, and how and if carry over is recorded	
Determine if the facility links purchase orders, UPC codes, etc to supplier lot codes	
Ordering Practices:	
Determine how and when the product is ordered	
Determine shelf-life and average daily use	
Identify routine/regular suppliers	
Identify any non-routine suppliers or products used during time period of interest	
Other Information:	

Attachment F – Partnership for Food Protection (PFP) Job Aid

Information Needed to Determine if a Case is a Good Traceback Candidate

(to be completed by investigators at the state/local level during a multi-state outbreak)

This document provides a checklist of information that is helpful when a traceback for a food product of interest is being considered during an outbreak. The information below should not replace your State/local routine process for interviewing case patients, but can be used to supplement your existing agency procedures. Please share answers from this form (and requested attachments) with partners involved in the investigation such as the CDC point of contact (POC) and FDA District POC collecting outbreak information, especially when a traceback is being considered. This information is extremely helpful for FDA to have when FDA is considering embarking on a traceback.

Note: The below table should be filled out for each product of interest. **Product of interest (specify) and case patient identifier (specify):**_____

1. Is the case patient a part of the outbreak cluster (e.g. code assigned by PulseNet), if available?	Yes ☐ → Record PulseNet Cluster Code: _____ No ☐ → Describe cluster of interest: _____ Unknown ☐		
2. Residence of case patient?	Known ☐ → Document state and city/county of residence: _____ Unknown ☐		
3. From what source in the case patient was the pathogen identified?	Stool ☐ Blood ☐ Other ☐ → Specify: _____		
4. Case patent illness onset date	Known ☐ → Document mm/dd/yy: ____/____/____ Unknown ☐ → Enter 99/99/99 if unknown		
5. Is the case a secondary case? A secondary case is a case that became ill from being exposed to another ill case in the outbreak. For example, this can happen within a family, when certain pathogens are involved.	Yes ☐ → **If "Yes" stop here and do not continue with any of the below questions** No ☐ Unknown ☐		
6. Is out-of-country travel reported by case during the time frame of interest?	Yes ☐ → Document location of travel: _____ No ☐ Unknown ☐		
7. Did the case patient eat the product of interest during the time frame of interest (determined by pathogen)?	Yes ☐ No ☐ → **Stop here and do not continue with any of the below questions** Unknown ☐ → **Stop here and do not continue with any of the below questions**		
8. For each instance where the case patient reports eating the product of interest:	**Date case patient reports eating product of interest #1 (mm/dd/yy)** ____/____/____	**Date case patient reports eating product of interest #2 (mm/dd/yy)** ____/____/____	**Date case patient reports eating product of interest #3 (mm/dd/yy)** ____/____/____
A. Is the Point of Service (POS) where the case patient reports eating or buying the product of interest known?	Yes ☐ Possibly ☐ → Explain: _____ No ☐ → Skip 8A-E and continue 8F onward	Yes ☐ Possibly ☐ → Explain: _____ No ☐ → Skip 8A-E and continue 8F onward	Yes ☐ Possibly ☐ → Explain: _____ No ☐ → Skip 8A-E and continue 8F onward
B. What is the type of POS facility where the case patient reported eating/buying the product of interest?	Retail (e.g. grocery store) ☐ Restaurant item (restaurant) ☐ Institution (e.g. cafeteria) ☐ Other (e.g. picnic) ☐ Unknown ☐	Retail (e.g. grocery store) ☐ Restaurant item (restaurant) ☐ Institution (e.g. cafeteria) ☐ Other (e.g. picnic) ☐ Unknown ☐	Retail (e.g. grocery store) ☐ Restaurant item (restaurant) ☐ Institution (e.g. cafeteria) ☐ Other (e.g. picnic) ☐ Unknown ☐
C. Is there information on the name and address of this POS?	Yes ☐ → Include name, address: _____ No ☐	Yes ☐ → Include name, address: _____ No ☐	Yes ☐ → Include name, address: _____ No ☐

D. Is the purchase date for the product of interest at this POS known?	**Yes** ☐→ Include date: mm/dd/yy -verify with receipt and if able attach:_____ **No** ☐	**Yes** ☐→ Include date: mm/dd/yy -verify with receipt and if able attach:_____ **No** ☐	**Yes** ☐→ Include date: mm/dd/yy -verify with receipt and if able attach:_____ **No** ☐
E. Is there documentation confirming the purchase information for the product of interest at this POS (e.g. receipts/shopper card info, bank statement info)?	**Yes** ☐→ Please attach with personal info removed **No** ☐	**Yes** ☐→ Please attach with personal info removed **No** ☐	**Yes** ☐→ Please attach with personal info removed **No** ☐
***F.* Is there product information for the product of interest exposure?** e.g. for meal at POS include menu item consumed containing product interest & name/location POS; for purchase at a grocery store include: store name & location, type of product of interest; brand and variety, product package & description, UPC or PLU#s, lot code, sell-by date/best-by date/use by date if purchased	**Yes** ☐→ Specify: _____ **No** ☐ **Unknown** ☐	**Yes** ☐→ Specify: _____ **No** ☐ **Unknown** ☐	**Yes** ☐→ Specify: _____ **No** ☐ **Unknown** ☐
9. Did this case report exposure at a POS location associated with other cases in this outbreak (case cluster involving same POS location)?	**Yes** ☐→ Document # cases associated with POS, POS name/location, exposure at POS: _____ **No** ☐ **Unknown** ☐		
A. If yes, was cross-contamination at the POS ruled out?	**Yes** ☐ **No** ☐ **Unknown** ☐		
10. Does the case have any commonalities with other cases in the outbreak? (e.g. They share common POS exposure, brand/variety of suspect food product, same geographic area of case)	**Yes** ☐→ Provide details: _____ **No** ☐ **Unknown** ☐		
11. Is the product of interest still available for testing (e.g. in household)?	**Yes** ☐ **No** ☐ **Unknown** ☐		
A. If any of the product of interest is available, is your agency planning on collecting and testing it?	**Yes** ☐ **No** ☐ **Unknown** ☐		
12. Is the case a good candidate for traceback purposes? **Additional comments:** _____	**Yes** ☐→ Explain: _____ **No** ☐→ Explain: _____ **Unknown** ☐→ Explain: _____ *Below are some criteria considered when determining if a case is a good candidate for traceback, reflected in many of the specific questions listed above.* ***The first 5 bullets are all needed*** *to support the case being a good candidate for traceback. The remainder bullets are nice to have but are not always realistic under normal situations:* • ***Case is a confirmed, primary case (seen in above Question 1 and 5) in this outbreak who has a solid onset date (Question 4) and remembers specifically being exposed to the product of interest during the period of interest (Question 7) AND*** • ***He/she is a reliable food historian meaning he/she has a good memory of his/her food exposures and has limited exposures (seen in Question 7, and 8A-F) AND*** • ***Case can provide details about the exposure to the product of interest (Question 8A-F) AND*** • ***The case had only one exposure (or at most very few) to the product of interest, prior becoming ill (Question 7 and 8) AND*** • ***Solid documentation is able to verify case's exposure to product of interest (e.g. receipt/shopper card/bank statement seen in Question 8E)*** • *In this outbreak, the case is part of a case cluster (involving 2 or more cases) associated with the same POS location(Question 9). Ideally the case reported/consuming the product of interest at this POS. Traceback on sporadic cases is not ideal due to recall loss and other such factors.* • *If the case is not part of a case cluster, the case at least has commonalities with other cases in the outbreak such as reporting exposure to the same brand/variety of suspect food product (Question 10).* • *The case is geographically and/or temporally dispersed as opposed to other cases in the outbreak (Question 2) and/or reports exposure at a POS that is unique in nature (e.g. small independent restaurant as opposed to a chain-can be determined in Question 8). Therefore, the case's exposure could identify different distribution pathways leading to a common source.*		

Traceback/Investigational POS Reference Guide

At a minimum, collect the following information during informational traceback effort. Situation-specific information may be added as needed. Please remember to collect information corresponding to the time period of interest leading up to (and including) the date of exposure/purchase. Determining the shelf life of the product will help in bracketing the appropriate time frame of interest. When in doubt, it is always better to collect for a larger time period of interest.

Inspector Information: Inspector's name; phone #; email address, organization/agency; date of informational traceback effort

Observations at POS:

- Facility Type (Restaurant; Grocery Store; Other); name; permit #; address; phone #; manager name
- Any reported employee illnesses during the timeframe of interest? If ill, did they directly handle the product(s) of interest?
- Does the POS have an SOP for disposal of products too old to sell/use or an unwritten practice?
  - If so, please provide specifics on this.
- Were there any maintenance issues (e.g. rodent problems) in the facility during the timeframe of interest?
- Was there any new construction in the facility during the timeframe of interest?
- Has the POS received any reports of illness during the timeframe of interest? If so, please provide details on complaints
- Does the facility perform any environmental swabbing of their facility and product testing?
  - If so, please provide specifics on this, and information on any positive samples.
- Obtain information regarding the POS cleaning schedule and try and obtain SOPs showing when and how they clean.

Product Identifying Information:

- Product Category(Produce; Meat; Grain; Other), product description/ and how labeled at POS.
- Product Brand/Name. Was product(s) of interest renamed or rebranded at POS? If so, please provide details on this.
- Product Origin (if known)
- Product Lot # and code # (if any). Identify if lot # is assigned by POS or supplier/manufacturer
- Product Best Buy Date/ Sell by date and shelf life (if known)
- Product Packaging Type (Box; Bag; Loose; Clam Shell; Can; Other) and containers size/weight
- Can source of suspect product(s) be tracked by the use of a lot number or some other coding system?
  - If so, please describe the traceability process.

Handling and Storage Practices:

- Document storage temperature at POS
- Time and dates prepared, if prepared at POS
- Turn-around time (once received, how long till used/sold)?
- Does the facility have a FIFO policy? Is it closely adhered to? If not, what practice is followed?
- Once at the POS, what is the product(s) of interest used for? In what menu items is it used in and how prepared? Obtain copy of menu and recipes/ingredients.
- Does commingling occur? Does the POS repackage the product?
- Does the facility manipulate the product(s) of interest in any way? If manipulated, provide details regarding when manipulated, how, etc.

Stock Inventory:

- Quantity on site and lot #s available
- What are the stocking practices for the product(s) of interest at POS?
- Is a stock inventory taken at the POS and if so how often and what time day? Consider collecting for timeframe of interest.

Ordering Practices:

- How and when is product ordered? As needed or is there a schedule? Always use same suppliers?
- Did POS order stock from any new firms for product(s) of interest during timeframe of interest?
- Were there cash sales during this time frame for product(s) of interest, due to running out of product? Were these documented?

Shipping and Receiving Practices:

- How does the product arrive at the POS (e.g. diced; whole; shredded; portioned)
- Did POS pick up the order(s) associated with product of interest or was it received directly from the supplier/shipping company?
  - Does the POS have an SOP for truck cleaning or specifications required for suppliers and shipping companies?
- Obtain legible copies of invoices and bills of lading
  - Records received for all shipments of product(s) of interest that POS received starting with day of the patient purchase/exposure at POS, going back to first date of time period of interest. Explain any unusual findings from the record review.
- Product(s) labeling:
  - How is product(s) of interest labeled on the invoices/bills?
- Product(s) receipt dates
  - Are incoming shipments for product(s) of interest initialed or stamped with receipt date? If not, is there a way to determine receipt date at POS, if not on records?
- Were there any holidays or unusual occurrences that would have affected product(s) of interest being received?
- If known, what are the transit times from the suppliers for the product(s) of interest to the POS (if applicable)?
- What are the general delivery times (time of day) that suppliers deliver product(s) of interest to POS (if applicable)?
  - Could product(s) of interest be used/sold same day as it was received?
- How is the incoming product(s) of interest handled upon receipt?
  - Does POS have time/temperature logs for product(s) of interest? Consider collecting.
  - How is incoming product unloaded and added to existing inventory?
- During the timeframe of interest, were there any transfers of the product(s) of interest within the company?
- Shipping company for product(s) of interest: name, address, phone number (if known)
- Distributor for product(s) of interest: name, address, and phone number (if known)
- Manufacturer for product(s) of interest: name, address and phone number (if known)
- Identify role of each of the firms noted in the traceback records and whether these firms actually directly handled product
- Did the POS ship the suspect product(s) to any customers (e.g. other restaurants)? If so, do they have traceability?
- Points in supply chain, if any, where product(s) of interest was manipulated (if known)

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Attachment G – Routine Traceback Assignment Questions during Manufacturer Investigation

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Please refer to the April 2001 traceback procedures, which can be found at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm075005.htm, for the investigation methodology and reporting requirements. Ask the following questions of the firm and make observations at the firm to address the following. For the product of interest, obtain the following from the product manufacturer:

Product Identifying Information

- Collect product labeling information, brand names, and product descriptions for the product of interest.
    - How is the product of interest labeled in the records (outgoing) during the timeframe of interest?
    - Collect photos of packaging and labeling for product of interest.
- Determine size of package/quantity/type of packaging for the product of interest.
- Product identifiers
    - Determine what the manufacturing codes are used on the product of interest and its outgoing packaging.
    - Determine if there is an internal system of coding. Explain the system and include details especially if it is not a straight forward use by date or Julian date.
    - How are lot numbers/batch numbers generated? Decipher what the lot #/batch # means and how to read it.
- List of ingredients used in the product of interest during the designated timeframe.
    - Ultimate source of these ingredients (if known).
        - If produce, obtain grower information, harvest dates and locations, and cooling information (if known).
    - How are the ingredients labeled in the records for incoming shipments?

Product Manufacturing and Storage Practices

- Describe the manufacturing process used to create the product of interest.
- What ingredient formulation is used in the product of interest's manufacturing process?
- Does co-mingling occur during manufacture?
    - Is it comingled from several suppliers?
    - Is it comingled from multiple lots from the same grower? Do these lots represent product from different growing locations (ranches, fields)?
- Is the same equipment used to manufacture different products (list of items manufactured with the same equipment)? How often is this equipment cleaned? What is this equipment cleaned with? Is there an SOP for cleaning this equipment?
- Determine the firm's handling and storage practices for the product of interest and its' ingredients.
- Determine the quantity of product of interest produced in a production period (daily, weekly, or monthly)
- For produce, determine cooling and holding procedures.

Routine Traceback Assignment Questions during Manufacturer Investigation

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Distribution and Shipping Practices for Outgoing Shipments

- List of companies the firm sold product of interest to during the timeframe of interest.
    - Date of each outgoing shipment during the timeframe of interest and list of customers.
    - Determine receipt dates customers received product.
    - How do dates on records reflect the date product of interest are actually shipped or received?
    - Collect records, if available, for these outgoing shipments.
- Does the company export product? Where does the company export?
- Determine what time of day the product of interest is shipped and general shipping time till it arrives at the customer.
- Does the firm own trucks for product distribution or are they contracted out?
- How often are trucks cleaned and what are they cleaned with? Is there an SOP for this cleaning?
- Do the trucks have time/temperature controls? If so, describe this monitoring.
- Are other products shipped with the product of interest? Is there a risk of contamination?

Purchase and Receiving Practices for Incoming Shipments (if applicable):

- Does the firm produce/harvest/manufacture its' own ingredients used in the product of interest? If so, describe where produced/harvested/manufactured (ex. processing facility or farm owned by the company) and when produced/harvested/manufactured.
- If these ingredients are not produced at the firm, ask the following:
    - How and when are ingredients used in the product of interest ordered? As needed, or is there a schedule?
    - Does the firm always use the same suppliers for these ingredients, and if so, did they use different suppliers for ingredients that would have been used in the product of interest during the designated timeframe?
    - Are the suppliers for these ingredients contracted to only sell to the firm, or could they supply products of interest to other firms?
    - Were there any cash purchases made by the firm for the ingredients that would have been used in the product of interest during the designated timeframe? If so, were these documented? Is this the company's established business practice or were they making up for a shortage?
    - What are the company names (and locations) that supplied the ingredients that would have been used in the product of interest during the designated timeframe?
        - What are the receipt dates for when the ingredients (supplied by each supplier) arrived at the firm?
        - How do dates on records reflect the date product of interest are actually shipped or received?
        - Are there time temperature controls on the trucks that transported these ingredients to the firm?
        - Are their invoices/bills of lading records? Collect if available.

Routine Traceback Assignment Questions during Manufacturer Investigation

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- Are there other firms owned by the company that also received the ingredients from these same firms that supplied you with these ingredients during this timeframe? (If so, please provide firm names and locations)

- Does the company import any product/ingredient? What is the country of origin? What is the source of the product/ingredient?
- During the designated timeframe of interest, were there any transfers of these ingredients or the finished product of interest within the company from one manufacturer to another (if applicable)? If so, provide details on this and records for these transfers.
- Receiving Practices at the firm
    - What time of day do deliveries usually occur (morning, afternoon, evening) for the ingredients of interest?
    - How are deliveries documented or recorded?
    - How do dates on records reflect the date ingredients are actually shipped or received?

Stock Rotation Practices at the Firm

- The turnaround time for the ingredients used in the product of interest (how long once received before it is then used in the product of interest and shipped onward).
    - Could ingredients received be used that same day as they are received?
- Once product of interest is manufactured, how long is it before the product of interest is shipped onward to customers?
- Product of interest Best Buy Date/ Sell by date and shelf life. Likewise the best buy date/sell by date and shelf life for the ingredients used to make the product of interest.

Stock Inventory at the Firm

- Are inventory sheets kept for the ingredients used in the product of interest? Is it available and reliable?
    - How are the ingredients used in the product of interest unloaded and added to existing inventory?
    - What time of day is inventory performed?
    - What do inventory numbers represent?
    - How are partial cases or containers accounted for?
    - How is carry-over recorded?
    - Are retains held? For how long? Are they available for the time period of interest?
    - Obtain inventory sheets for ingredients in the product of interest used during the designated time period.

Routine Traceback Assignment Questions during Manufacturer Investigation

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Other Firm Practices

- Quality Control Practices.
    - Describe internal swabbing or laboratory testing routinely conducted?
        - Is the testing done by an external lab or by the company? If external, obtain laboratory name and address.
        - What pathogens or contaminants are tested for?
        - Provide testing done on the product of interest from the 3* months prior to the timeframe of interest to present and the results. Also provide the results and locations for environmental testing conducted during that same time period.
- Facility sanitation methods/practices.
    - How often is sanitizing performed? What is used to sanitize?
    - Collect SOPs for sanitizing processing areas and equipment?
- Provide information on any consumer complaints regarding the product of interest received by the firm within the 3* months prior to the timeframe of interest?
- How are returns handled for the ingredients used in the product of interest?
- Did the firm conduct audit checks of the suppliers for the ingredients used in the product of interest?

Traceability/Traceback

- Does the firm have a traceability system? If so, have the firm explain this thoroughly so you understand how the firm is able to link incoming ingredient shipments (used in producing the product of interest) to the finished product of interest outgoing shipments.
- Identify role of each of the firms noted in the traceback records and whether these firms actually directly handled the ingredients in the product of interest (if known).
- Ensure records are legible, comprehensive, and receipt dates are deciphered (if not stamped or on records)

***** 3 months is a standard length of time to request, however this timeframe may be changed based on recommendations of subject matter experts because of pathogen, commodity, or environment.

Version	Author	Date
2.0	Traceback WG (CORE, ORA)	4.8.15

Attachment H – Routine Traceback Assignment Questions during Distributor/Supplier Investigation

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Please refer to the April 2001 traceback procedures, which can be found at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm075005.htm, for the investigation methodology and reporting requirements. Ask the following questions of the firm and make observations at the firm to address the following. For the product of interest, obtain the following from the product distributor/supplier:

Product Identifying Information

- Collect product labeling information, brand names, and product descriptions for the product of interest.
    - How is the product of interest labeled in the records (incoming and outgoing) during the timeframe of interest?
    - Collect photos of packaging and labeling for product of interest.
- Product identifiers.
    - Determine what the manufacturing codes are used on the product of interest and its outgoing packaging.
    - Determine if there is an internal system of coding. Explain the system and include details especially if it is not a straight forward use by date or Julian date.
    - How are lot numbers/batch numbers generated? Decipher what the lot #/batch # means and how to read it.
- Determine size of package/quantity/type of packaging for the product of interest.
- Determine product origin, if known.
- Determine ingredients in product of interest (if applicable)

Product Handling and Storage Practices

- Does the firm manipulate the product of interest at all (repackage/re-label)? If so, explain.
    - If repackaging occurs:
        - Are products co-mingled?
        - Is the same equipment used to repackage different items (list of items repackaged with the same equipment)?
- Determine the firm's handling and storage practices for the product of interest.

Distribution and Shipping Practices for Outgoing Shipments

- List the companies the firm sold the product of interest to during the timeframe of interest.
    - Date of each outgoing shipment during the timeframe of interest and list of customers.
    - How do dates on records reflect the date product of interest are actually shipped or received?
    - Collect records, if available, for these outgoing shipments.
- Does the company export product of interest? Where does it export?
- Determine what time of day the product of interest is shipped and general shipping time till it arrives at the customer.
- Does the firm own trucks for product distribution or are they contracted to a different company?

Routine Traceback Assignment Questions during Distributor/Supplier Investigation

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- How often are trucks cleaned and what are they cleaned with? Is there an SOP for this cleaning?
- Do the trucks have time/temperature controls? If so, describe this monitoring?
- Are other products shipped with the product of interest? If so, which ones, and is there a risk of cross contamination?

Purchase and Receiving Practices for Incoming Shipments

- How and when is the product of interest ordered? As needed or is there a schedule?
- Does the firm always use the same suppliers for the product of interest and if so, did they use different suppliers for the product of interest during the designated timeframe?
- Are the suppliers for the product of interest contracted to only sell to this firm, or could they supply products of interest to other firms?
- Were there any cash purchases made by the firm for the product of interest during the designated timeframe? If so, were these documented? Is this the company's established business practice or were they making up for a shortage?
- What are the company names (and locations) that supplied the product of interest to the firm during the timeframe of interest?
    - What are the receipt dates for when the product of interest (supplied by each supplier) arrived at the firm?
    - How do dates on records reflect the date product of interest are actually shipped or received?
    - Collect invoices/bills of lading records, if available.
- Are there other firms owned by the company that also received the product of interest from these same suppliers that supplied the product of interest during this timeframe? (If so, provide firm names and locations).
- Does the company import any product of interest? What is the country of origin? What is the source of the product of interest?
- During the timeframe of interest, were there any transfers of the product of interest within the company from one distributor/supplier to another (if applicable)?

Receiving Practices at the Firm

- What time of day do deliveries usually occur (morning, afternoon, evening)?
- How are deliveries documented or recorded?
- How do dates on records reflect the date product of interest are actually shipped or received?

Stock Rotation Practices at the Firm

- How are products of interest unloaded and added to existing inventory?
    - Does the firm utilize first in first out practices?
- The turnaround time for the product of interest (how long is the product of interest held on site between being received and shipped).
    - Could the firm sell and ship the product of interest onward the same day as it was received by the firm?
- Product Best Buy Date/ Sell by date and shelf life (if known).

Routine Traceback Assignment Questions during Distributor/Supplier Investigation

Version 3.0, Page 3 of 3

Stock Inventory at the Firm

- Are inventory sheets kept for the product of interest? Is it available and reliable?
  - What time of day is inventory performed?
  - What do inventory numbers represent?
  - How are partial cases or containers accounted for?
  - How is carry-over recorded?
  - Are retains held? For how long? Are they available for the time period of interest?
  - Obtain inventory sheets for product of interest during the designated time period.

Other Firm Practices

- Quality Control Practices.
  - Describe internal swabbing or laboratory testing routinely conducted?
    - Is the testing done by an external lab or by the company? If external, obtain laboratory name and address.
    - What pathogens or contaminants are being tested for?
    - Provide testing done on the product of interest from the 3* months prior to the timeframe of interest to present and the results. Also provide the results and locations for environmental testing conducted during that same time period.
- Facility sanitation methods/practices.
  - How often is sanitizing performed? What is used to sanitize?
  - Collect SOPs for sanitizing processing areas and equipment?
- Provide information on any consumer complaints regarding the product of interest received by the firm within the 3* months prior to the timeframe of interest?
- How are returns handled for the product of interest?
- Did the firm conduct audit checks of their suppliers for the product of interest?

Traceability/Traceback

- Does the firm have a traceability system? If so, how do they trace products (especially if they comingle and/or relabel products)? This process should be thoroughly explained to you.
- Identify role of each of the firms noted in the traceback records and whether these firms actually directly handled product (if known).
- Ensure records are legible, comprehensive, and receipt dates are deciphered (if not stamped or on records).

***** 3 months is a standard length of time to request, however this timeframe may be changed based on recommendations of subject matter experts because of pathogen, commodity, or environment.

Version	Author	Date
2.0	Traceback WG (CORE, ORA)	4.8.15
3.0	Traceback WG	7.7.15

Attachment I – Routine Traceback Assignment Questions during Point of Service Investigation

Version 2.0, Page 1 of 3

Please refer to the April 2001 traceback procedures, which can be found at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm075005.htm, for the investigation methodology and reporting requirements. Ask the following questions of the firm and make observations at the firm to address the following. For the product of interest, obtain the following from the point of service (POS):

Begin to Collecting Records When:

1. You have a cluster at an establishment (smaller clusters might be appropriate on a case by case basis)
2. The cases have ideally one food item in common or there are multiple food items but they all have one ingredient of interest in common

There are exceptions to this on case by case basis after discussion with subject matter experts.

Collect the Following Information Before Requesting Records:

The following questions are important as the information received may:

- *identify particular ingredients in a prepared food item consumed by the cluster case patient(s) that matches other clusters or case reports. This will allow you to target collection to only the ingredients of interest as opposed to collecting records for all ingredients used in the food item.*
- *identify unique practices by the firm that may cause you to extend (or shorten) your time period for record collection; ex. ingredients in facility are used over a 3 week time period for different purposes (the freshest tomatoes may be used in salads and older tomatoes blended to make a salsa or a garnish) or the firm uses all ingredients in one day for certain menu items, etc.*

1. What are the normal ingredients in the items of interest (as well as any garnishes)? If the information is in written form, please request a copy of it or copy the information verbatim. Be sure to include all handwritten notations on the documents. If you do not understand any part of the information please ask for clarification.

2. If the items of interest are made from a formulation or recipe, request permission to copy the formulation/recipe. Please provide a written comment if the formulation/recipe is proprietary or secret.

   - Please provide the ingredients, amount of ingredient, and ingredient type (fresh, frozen, canned etc.). Also, annotate whether the item has gone through a temperature change that may suggest bacterial lethality (e.g., a cooking step, a drying step, etc.)

   If you do not understand any part of the information please ask for clarification.

3. Were the products of interest fresh raw, whole, or pre-sliced or cut? If possible, please provide the following information:
   - Container type
   - Size
   - Color
   - Grade
   - Lot Codes
   - Production date

Routine Traceback Assignment Questions during Point of Service Investigation

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- Pull date
- Product Origin
- Brand(s) – Ask if there has been a brand substitution for the timeframe in question.
- Fresh or processed (packaged precut)
- Photo of the original container label

4. Does the restaurant keep track of the manufacturer lot numbers of the ingredients of interest?

5. Determine the receiving dates of each shipment in the timeframe of interest.

6. Indicate how the dates on the shipping records reflect the date the products were received.

7. How are the products ordered? (One person orders/ person doing inventory orders)
   - When are products ordered? (Is there a min-max limit for the item or ordered?)
   - Are orders made or received on specific day of the week?
   - What is the average daily use of each item?

8. What supplier(s) does the restaurant use for the items of interest and was there any variance in the normal suppliers during the timeframe of interest?
   - Did the restaurant receive product from a different supplier(s) during this timeframe?
   - Were there cash purchases from a grocery store, farmers market, or other source made during this time frame for products of interest, due to running out of product? Were these documented?
   - Did the restaurant make any changes to distributors during the timeframe of interest?
   - Does the restaurant keep track of the lot #'s of the product products of interest that they use daily or every other day? If so, can this information be provided?

9. Determine how the product of interest is unloaded (is it left outside for any period, who unloads the items, when the items are unloaded are they immediately placed in their final storage spot?

10. How does the firm rotate their stock?
    - Is a FIFO (first-In-first out) rotation used?
      - How closely does the restaurant follow the rotation?
    - Are there any other qualifications for use (degree of ripeness, condition of item etc.)
    - Is there any inventory record available for the time period?
    - If yes, on a separate piece of paper describe what each inventory number means.
    - What time of day is inventory taken?
    - How are partial cases accounted?
    - How is carry-over recorded?

10. Did the preparers note anything unusual about the product of interest (i.e., cooking time, color, odor, taste, etc.) during preparation?

Routine Traceback Assignment Questions during Point of Service Investigation

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Records to Collect

Provide explanations for any abbreviations or codes on the records collected on a separate sheet of paper. Do not write on the invoices.

1. Any records showing movement in commerce such as:
    - purchase invoices
    - purchase orders
    - shipping and receiving records,
    - bills of lading, and/or
    - inventory records
    - Grocery store receipts (alternate supplier source)

2. The records should show
    - the supplier's name
    - supplier contact information and address (if not provided on invoice obtain information from establishment)
    - the name of product(s) received
    - the date received and
    - amount received

3. Time frames for record collection can vary by suspect food item and organism. For collection of records at point of sale for Cyclospora 2014, it is recommended to collect applicable records for 4 weeks prior to the earliest exposure date through the latest onset date associated with the cluster.

4. Records collected should be sent to:
    a. If sent via email:
        i. Scan records
        ii. Name pdf file as detailed below:

At (space) Name of firm records were collected (space)From(space) Name of Supplier (space) time bracket of record collection mmddyyy_mmddyyy.
Ex: At Krandalls1401 From Alite Produce 06012014_06142014

Version	Author	Date
2.0	Traceback WG (CORE, ORA, OEO, DHRD), TX RRT	5.15.15

Chapter 11. Joint Inspections & Investigations

TABLE OF CONTENTS

1. PURPOSE

Investigations of human and animal food incidents events are often complex and require that multiple agencies conduct activities jointly. This chapter identifies some best practices, basic policies, and important considerations for federal, state, and local agencies that conduct joint investigations and inspections for human and animal food incidents. This may help groups conducting these activities to develop and improve policy and procedures for this work.

2. SCOPE

These best practices apply to situations in which multiple regulatory agencies are on-site at an establishment or when multiple agencies are conducting separate but closely related visits.

This chapter also establishes basic procedures for the agencies involved in these joint responses and investigations, including that they:

- Meet in advance;
- Work through legal authorities and policy documents; and
- Develop shared plans, training, and exercises.

These procedures also outline that these plans, training courses, exercises, and real world responses utilize the concepts of the Incident Command System (ICS), particularly focusing on Unified Command scenarios where multiple agencies and jurisdictions work together.

This chapter speaks directly to how state human and animal food regulatory programs can coordinate joint inspections and investigations with the U.S. Food and Drug Administration's (FDA's) District/Program Offices. However, the principles within this chapter are applicable to other federal, state, and local agencies that have shared regulatory authorities and duties. State, local, and federal agencies seeking to improve multi-agency food emergency responses (e.g., States, FDA field offices) may utilize this chapter to assess and improve their response capabilities. Agencies with varying responsibilities (e.g., regulatory, public health, feed/animal health, law enforcement, laboratory) and target response capability levels may differ in how they customize and apply these best practices.

3. RESPONSIBILITY

3.1. Agency Leadership (All agencies involved)

Leaders of the involved agencies are responsible for effectively coordinating with each other. Agency administrators are responsible for providing support for joint training, planning, exercises and responses. This can be accomplished in a number of ways, ranging from Governors' directives to personal commitments of program leadership to work cooperatively.

3.2. Response/Investigation Team Members

Team members are responsible for ensuring that they are familiar with any agency joint investigation policies and procedures, and can fulfill their assigned roles during joint inspections/investigations.

4. DEFINITIONS

See "Glossary of Key Terms" for definitions of terms used in this chapter.

The following terms are used uniquely in this Chapter:

4.1. Joint investigation – A multi-agency effort to respond to a disease outbreak, contamination, or other incident within the human and animal food supply.

4.2. Joint inspection – Two or more agencies working together in a regularly scheduled routine review of a facility where each agency has regulatory authority or duties.

5. BACKGROUND

Investigations of foodborne illness outbreaks or contamination of livestock feed events are often complex and take several weeks to months to complete. Investigations involve completing epidemiologic studies of ill individuals or animals, tracing products from table-to-farm, seeking contamination sources/modes, testing numerous samples, and writing detailed reports. Public health agencies face significant challenges in determining the exact source(s) and mode of contamination because of the scope and complexity of these investigations and because the contamination events likely happened weeks or months in the past. Additionally, possible duplication of efforts by various involved agencies reduces efficiency and impedes the implementation of targeted preventive measures to prevent recurrence.

In response to the need to improve these kinds of investigations, agencies have developed a variety of approaches. In the late 1990s, the California Department of Public Health and the FDA District Offices (now termed Program Division Offices) piloted the California Food Emergency Response Team (CalFERT) to increase efficiency, improve communication and increase the effectiveness of investigations. In 2008, FDA initiated the Rapid Response Team (RRT) pilot program with six states to increase collaboration, improve the response to human and animal food emergencies, and reduce inefficiencies as part of the ongoing effort to achieve an integrated national food safety system. In 2009, three additional states were added to the project. This chapter describes the best practices for joint inspections and investigations from the work and experiences of these pilot programs.

6. SAFETY

Safety considerations must be addressed jointly before staff respond to an event. Agencies must ensure that staff entering a facility have the equipment and training necessary to safely complete their tasks and that joint teams have comparable (and interchangeable, when possible) equipment.

7. EQUIPMENT/MATERIALS

Equipment will vary depending on the inspectional or investigational activity. See attachments for additional details.

8. PROCESS DESCRIPTION

8.1. General

It is important to develop an interagency team with appropriate representation of skills and authorities that can respond to emergencies that arise. The agencies involved may need to pre-establish legal arrangements (e.g., memorandam of understanding) to ensure information sharing is as efficient and effective as possible. These agencies can then coordinate limited resources to efficiently investigate numerous leads; increase sampling collection capacity; increase opportunities to find clues to contamination source(s); reduce redundancy; and improve overall efficiency and effectiveness of investigations, enforcement actions, and public health interventions. This joint approach also provides opportunities for investigators to meet and train together to develop trust, expertise, and shared experiences. This results in a highly specialized and experienced investigation team. Please see “Working with Other Agencies, 12.2 –

Building Relationships" for background and details on concepts/activities important for joint inspections.

8.2. Joint Management Team

The Joint Management Team is composed of designated individuals or leads from all agencies involved in conducting joint investigations and inspections.

When not engaged in an outbreak or event, these agency designees are responsible for maintaining a properly planned, organized, equipped, trained, and exercised team by:

- Scheduling and facilitating meetings for team members.
- Setting thresholds for joint agency response.
- Providing updates to the agencies' senior leadership and other parties.
- Coordinating with agencies' training and exercising officers to develop programs for field team and support team members.
- Setting standards for approval of reports and other documentation.
- Ensuring that an after action meeting ("Hot Wash") takes place and that lessons learned are integrated into future operations.
- Identifying staff to relieve personnel during extended operations and planning for the transition to normal operations after the incident.
- Establishing a process or method for working through disagreements and disputes.

During an investigation, these team members may be assigned to a variety of different tasks, including inspections, sampling, records review, laboratory testing, compliance, and enforcement. Team members should receive training in all of the assigned tasks and disciplines together including the following: office procedures and field activities such as sampling techniques at the retailer, distributor, processor, and farm levels.

Teams need to engage in regular exercises using realistic scenarios to continually refine existing procedures and develop new techniques.

8.3. Initial Briefing and Ongoing Information

Each agency will be responsible for preparing and sharing summaries of relevant information (e.g., epidemiological investigations, law enforcement investigations, past regulatory history of the firm) during initial investigation planning sessions. Written summaries are preferable whenever possible. It is important to identify how updates will be provided among involved agencies, particularly if the investigations will take more than one day. Also, agencies must clarify any information sharing constraints (e.g., information that can only be shared with state and local officials holding an FDA commission) ahead of time.

8.4. Documentation

Pre-established procedures should specify whether team members will use a jointly developed form (i.e., common form agreed upon by all agencies) or the forms required within their respective agencies. Designating a lead agency for issuing notices of violations to the firm may ensure that the agency leading follow-up regulatory action has sufficient documentation to support its actions.

Prior to completing inspectional reports, inspectors should strive to coordinate their factual observations with those of other agencies performing joint inspections or investigations. This should be done verbally, on-site at the end of each joint visit, and include additional follow-up communication as necessary. This will help provide establishments with consistent information on violations, recommendations, and corrections.

All involved agencies should have copies of each other's regulatory forms used during the inspection and a set of any records collected during the inspection. To facilitate this sharing of information, agencies may wish to invest in appropriate technologies. For example, a high speed scanner can be used in conjunction with a laptop to convert all records to electronic form for easy sharing among involved agencies. Team members should also establish a clear, mutual understanding of what, how, and when information will be shared with the firm.

8.5. Seizures, Embargoes, Condemnation, Destruction of Products & Other Regulatory Actions

During joint activities, an agency with the appropriate legal authority may embargo or seize product for suspected adulteration, order condemnation and destruction of products, or take other regulatory actions. Because legal authorities and required levels of evidence to take these actions may differ between agencies participating in the investigation, team members should be aware of both their own authorities and those of cooperating agencies (e.g., the Environmental Protection Agency).

When taking these actions, it is important to:

- Identify or immediately request adequate supporting documentation so the agency taking the regulatory action possesses the information necessary to support the action. These documents should be obtained in advance of taking regulatory action (e.g., embargo or seizure) as long as the delay will not create a public health hazard.
- Develop a plan identifying follow up actions to be taken (e.g., inspections, sampling, obtaining process authority input, destruction) and assign team members for completion of those tasks. The plan should consider and identify expected actions for release of embargoed or seized products, product reconditioning, and product disposal or destruction.

8.6. Recalls

Some of the involved agencies may have a responsibility to work with manufacturers and/or distributors to initiate a recall to protect the public health from products that present a risk of injury or gross deception, or are otherwise defective. The legal authority to initiate or require a recall varies. In the joint planning process, the involved agencies need to predetermine their policies, procedures, and thresholds for recalls. Cooperating agencies should be familiar with each other's standard operating procedures or with a jointly developed or shared procedure.

8.7. Environmental Sampling

Environmental sampling activities require multiple person teams with specialized training or experience. Staff may be asked to serve on sampling teams with staff from more than one regulatory agency. Leadership from all involved agencies should consider the size and complexity of each sampling assignment when forming sampling teams. The role of each team member should be clearly defined before sampling teams arrive at the food establishment. This includes chain of custody protocols, labeling, documentation, and related procedures. To be most effective, these multi-agency teams should train and exercise together. Teams should also consult laboratories to ensure appropriate use of sampling protocols and sample shipment.

8.8. Environmental Assessments[1]

Multiple agencies (e.g., FDA, state) may also be involved in conducting joint environmental assessments to determine the root causes of contamination as part of a long-term response effort. The same principles of joint planning and communication covered elsewhere in this chapter apply.

8.9. Public Information

During a joint investigation, the cooperating agencies need to:

- Know their procedures and rules/constraints for release of public information and integrate this into their joint planning efforts;
- Utilize the ICS concepts of a Joint Information Center (e.g., designated interface with media, coordinated communication) to ensure accurate and reliable information is disseminated and to ensure that all agencies have input into any public communication.

ICS functions and roles such as public information officer and liaison can assist with coordination to address and overcome these communication issues.

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

The levels described below assume that agencies with higher level capacities meet all the elements for lower level capacities.

Level	Description

[1]Also termed "Environmental Health Assessments"

1	Joint inspections not conducted with other agencies.
2	Joint inspections are conducted, but there is no formal written procedure for conducting joint inspections and investigations with other agencies exist.
3	Formal written procedure for conducting joint inspections and investigations with other agencies is in place.
4	Formal written procedure is in place and a joint inspection or investigation or exercise has been conducted within the last 12 months.
5	Formal written procedure is in place, a joint inspection or investigation or exercise has been conducted within the last 12 months, and a formal review process with implementation of lessons learned is in place.

10. RELATED DOCUMENTS

Other RRT Manual Chapters: Incident Command System, Working with Other Agencies, Communication SOPs, and Training.

11. REFERENCES AND OTHER RESOURCES

(Full citations are in the References Section, "List of Reference Documents," listed by author.)

11.1. State-specific manuals (to request, email op.feedback@fda.hhs.gov)
- **11.1.1.** CalFERT Manual
- **11.1.2.** Michigan Department of Agriculture's Food & Dairy Division Manual
- **11.1.3.** Minnesota Department of Agriculture's RRT Investigations SOP

11.2. FDA Investigations Operations Manual (IOM), 2017 (http://www.fda.gov/ICECI/Inspections/IOM/default.htm)

11.3. Food and Agriculture Sector Specific Plan: An Annex to the National Infrastructure Protection Plan, 2015 (https://www.dhs.gov/publication/nipp-ssp-food-ag-2015).

12. ATTACHMENTS

12.1. Attachment A – Draft Field Joint Investigation Checklist

12.2. Attachment B – Inspection Equipment Example

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	9/26/2011	RRT Joint Investigations/Inspections WG (MI**, WA, CA, MN)
1.1	R	2/1/2012	ORA/OP
1.2	R	1/24/13	ORA/OP
1.3	R	5/26/17	ORA/OP

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)
**Workgroup Lead

Change History

1.1 – Editorial revisions made by ORA for document clearance.

1.2 – Revisions to achievement levels (Section 3) based on recommendations from the RRT 2012 Face to Face Meeting (November, 2012).
1.3 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.

Attachment A – Draft Field Joint Investigations Checklist

Investigation Field-Team Procedures (SAMPLE)

Planning

- ☐ Meet with supervisors or Unified Command to develop a plan to clearly identify investigation activities.
- ☐ Identify team leaders and members and define roles or responsibilities for each.
- ☐ Obtain contact information for all those involved.
- ☐ Ensure that there will be enough team members to complete the objectives by the deadline.
- ☐ Determine need for specialized equipment and ensure that it is made available for the team (i.e., sampling supplies, pH meter, protective equipment).
- ☐ Plan to meet before the investigation at an offsite location to review/confirm pertinent information, create a strategy, and coordinate arrival at the firm.
- ☐ Review facility history, layout, and sample collection objectives.
- ☐ Review epidemiological information and identify potential products of interest.
- ☐ Review laws, guidance documents, policies and protocol.
- ☐ Inform facility management of the purpose and timeframe for investigation.
- ☐ If collecting samples, notify laboratory of the estimated time of arrival for samples. Determine sample sizes, amounts, and special techniques required. Arrange to drop off or send samples to lab.
- ☐ Use principles of ICS and Unified Command.

Objectives

- ☐ Identify objectives and tactics (e.g., complete an assessment, collect 100 environmental samples, conduct traceback investigation).
- ☐ Document objectives, tactics, and timeframes for the investigation

Onsite

- ☐ Complete investigation as agreed upon during the planning meeting (e.g., split assessment and traceback assignments)
- ☐ Designate a single point of contact for communications with the firm (if possible)
- ☐ Coordinate any multi-agency requests for information from the firm (e.g., invoices, production logs).
- ☐ Document investigational findings on appropriate Inspectional, Special, Sample, or Seizure reports to provide to the firm.
- ☐ Team leaders provide updates as necessary to Supervisor or Unified Command.
- ☐ Team leaders ensure assignments will be completed in accordance with policies and protocols.
- ☐ Request information and assistance as necessary.
- ☐ Compare investigational findings with other agencies involved to ensure consistent findings, recommendations, and actions are documented.
- ☐ Mutually agree upon information sharing details (e.g., what will be shared, with whom, how often, what format, and when), including coordination with supervisors.

Post Investigation Activities

- ☐ Finalize and submit all reports to Supervisor or Unified Command for review.
- ☐ Document specialized details of the joint investigation on an internal memo.
- ☐ Provide information with other agencies (per agreement with supervisor approval).
- ☐ Retain records in accordance with agency policy.
- ☐ Participate in after action reporting or other authorized information sharing of lessons learned during the investigation.

Attachment B – Inspection Equipment Example

Inspection Equipment Example	Agency A	Agency B	Needed
Computer and printer			
Camera			
Digital camera			
Credentials			
Important phone numbers (supervisor and servicing laboratory)			
Regulation and policies			
Paper, pen, masking tape, and permanent marker			
Clipboard			
Required forms			
Alcohol swabs and wipes			
Flashlight and holder			
Blacklight			
Light meter			
Thermometer			
Infrared thermometer			
Exacto knife and scissors			
Putty knife and scraper			
Sampling devices (sieves, triers, probes, and swabs)			
Sampling equipment (sterile containers and scoops)			
Coolant (ice and freezer paks)			
Shipping containers			
Appropriate sanitizer test strips			
Official seals			
Protective clothing (lab coat, gloves, and boots)			
Eye protection			
Hair restraint			
Hearing protection			
Hard hat			
Safety shoes			
Respirator			
Other recommended equipment:			
Portable high speed scanner			
Cell phone			

Chapter 12. Environmental Sampling and Records Collection

TABLE OF CONTENTS

1. PURPOSE

This document provides a template for Rapid Response Teams (RRTs) to create standard operating procedures (SOPs) for conducting human and animal food investigations specifically the collection of environmental samples and documents at designated facilities or growing areas.

Sampling of the production environment is an important aspect of an environmental assessment. Sampling may provide evidence of how the causative agent, such as pathogenic bacteria, was introduced and proliferated in a food chain (farm-to-table). Sampling may also demonstate the effectiveness of controls, preventive measures, and/or overall sanitary conditions of the processing environment.

In the context of this chapter, environmental sampling and records collection are conducted when a food or feed operation has been associated with an ongoing foodborne illness outbreak, a human or animal food contamination event has been identified, or when there are other indications that a contamination event may have taken place.

2. SCOPE

This chapter primarily focuses on environmental sampling and records collection as part of the investigations involving bacterial (e.g., *Salmonella*, *Listeria*, *E. coli*) and non-bacterial (e.g., viruses, parasites) pathogens. This chapter provides supporting materials and procedures to conduct environmental sampling during an investigation linked to a foodborne illness outbreak or other human or animal food contamination event.

Although this document is intended for emergency responses, the procedures can be used for routine environmental sampling as well. This chapter does not cover commodity specific investigation procedures and environmental assessment activities that may require specific and unique approaches (e.g., meat processors, egg farms, sprout harvesters, or low-acid canneries). Please also refer to the FDA FSMA webpage for the latest guidances (https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm).

3. RESPONSIBILITY

3.1. Steering Committee/Guiding Members Responsibilities

In order to build a RRT sampling team; a RRT Steering Committee, Guiding Members, or Emergency Response Coordinators (ERCs) may want to consider the following:

3.1.1. Team Information

1. Identify a list of individuals with job titles that may serve on a RRT sampling team (i.e., roster) and include depth at each team position.
2. Ensure that the individuals receive proper training and instruction prior to deployment on a team. This may include a combination of classroom, equipment demonstration and practice, joint FDA/State training, and exercises.

3.1.2. Development of SOPs and Policies

1. Consider how to structure a sampling team to meet investigative goals and where this would fit if the Incident Command System (ICS) is implemented.
2. Discuss preparation, coordination, sampling techniques, and post-sampling activities (for example, see FL: Environmental Sampling Operating Procedures posted in FoodSHIELD).
3. Consider compatibility with other agencies and mutual agreements such as the Partnership for Food Protection (PFP) Food/Feed Testing Laboratory Best Practices Manual.
4. Ensure procedures and policies are correct and current so all team members are performing their roles correctly and consistently. Set timeframes for reviewing these documents.
5. Determine triggers and activation procedures for the team (i.e., analytical results, epidemiology, or investigational evidence will necessitate sampling).

3.1.3. Identifying Equipment Needs

1. Identify types and sources for approved aseptic sampling equipment (see Attachment A for a list of suggested supplies) and how long it might take to receive each item once ordered. Ongoing dialogue should be used to determine if agencies have complimentary equipment or if similar equipment can be used if needed.
2. Determine how much inventory to keep in stock for each agency (i.e., enough supplies for 1–2 assignments). Keep in mind that some equipment has special storage requirements and limited shelf life. Check expiration date of supplies often.
3. Determine logistical needs such as packing/delivering the sampling kits to the sampling team (if necessary).

3.1.4. Assignment Details and Coordination

1. Provide assignment background and briefing to team members (i.e., past violations, causative agent, and facility layout).
2. Deploy the team:

   a. Identify the participants, assignment details, and roles and responsibilities.
   b. Coordinate with the RRT sampling team to provide instructions as needed for sample collection, transportation, and appropriate laboratory receiving samples.
3. Coordinate with other agencies (Community Health, FDA, State Ag, State/Federal Food Emergency Response Network (FERN) laboratories, etc.) to determine what to collect, sample size, capacity to analyze, and analytical laboratories, including:
   a. Is the laboratory able to run the number of sample collected?
   b. Is the laboratory accredited to run the type of test needed?
   c. Are there special requirements for the type of sample?
   d. What are the chain-of-custody requirements?
   e. When samples are arriving at the lab?
   f. What is the timeframe to release the results?

3.1.5. Post Sampling Response

1. Provide notifications to regulatory partners that may have jurisdiction of the product sampled.
   a. Internal - within the agency
   b. External agencies
   c. Affected firm(s)
2. Initiate and coordinate response activities.
   a. Coordinate teleconferences with internal and external partners (if necessary) to cover issues such as:
      i. Regulatory contact information for those involved
      ii. Reports of alleged illness associated with the samples
      iii. Jurisdiction or lead agency
      iv. Joint investigation, traceback, environmental assessment, or sampling plans
      v. Pre-established procedures for Chain of Custody needs for each agency
      vi. Enforcement, corrective action (i.e., recall, Reportable Food Registry (RFR), etc.), and recovery plans
      vii. Press talking points or press point of contact
3. Ensure that sample report(s) and analyses are obtained and shared with appropriate agencies (and industry), as necessary.

3.2. Sampling Team Responsibilities

Ideally, sampling teams consist of a team leader and 2–3 other sampling team members. At a minimum, the sampling team should include a Collector, Assistant, and Scribe (one of those members must be designated as team leader). While not

ideal, in some circumstances it may be necessary for only one person to conduct the sampling. In that case, the individual must perform all necessary functions.

All sampling team members must be properly trained with updated sampling SOPs (including labeling and pre-labelling) and samples collection forms.

The sampling team should arrive at the facility (after holding a brief planning meeting when possible) or sampling location well prepared and in plenty of time to conduct sampling with consideration to lost production time for employees and the operator.

The following is an example of sampling team roles and responsibilities (may be combined or expanded depending on available resources and needs).

3.2.1. Sampling Team Leader

The Sampling Team Leader designation may be assigned to one of the following positions: Sampler, Assistant, or Scribe. Under ICS, the Sample Team Leader may be designated a strike team or task force leader and report to the Operations Section Chief (or Division or Group Supervisor, if assigned).

The Sampling Team Leader will be responsible for the completion of each of the following, or delegate these tasks as appropriate:

1. Manages communications between the sampling team prior to sample collection (i.e., hold a pre-meeting conference call, review procedures, review forms etc).
2. Manages communications among multiple teams under the same outbreak response, if necessary.
3. Notifies the laboratory personnel of quantity and types of samples and when they may arrive.
4. Ensures sampling supply kit delivery, pickup, or transport to sampling site.
5. Ensures the team has the necessary equipment and forms for the assignment.
6. Prepares sample labels prior to sample collection. Prepares for contingencies regarding sample labeling.
7. Reviews the firm's file and map of the facility (if available) to identify sampling sites.
8. Ensures all significant sites are sampled and that minimum sample quantities are met per sampling assignment or laboratory requirements.
9. Ensures timeliness of sample delivery to the laboratory.

10. Ensures chain-of-custody is maintained throughout the entire sampling assignment.
11. Prepares a brief summary of daily activities.
12. Communicates final laboratory results to the firm, if appropriate.

3.2.2. Sampler (or Collector)

1. Identifies sampling site (considers location, type, and number of samples to be collected).
2. Aseptically collects samples (don sterile gloves, use sterile equipment, and sterile Whirl-Pak® bags or other sterile containers).
3. Ensures collection of necessary control samples to send to the laboratory.

3.2.3. Assistant (Handler, Sample Preparation/ Supply Manager)

1. Dons sterile gloves.
2. Assists the Sampler with donning of gloves.
3. Prepares and presents sampling implement to Sampler.
4. Prepares and presents sterile container (e.g., Whirl-Pak® bag) to the Sampler.
5. Labels samples and all sterile containers.
6. Seals samples and places them in cooler.
7. Manages sample preparation area, sample storage, supplies and waste disposal.
8. Verifies that all samples are labeled correctly (match each sample with the report).
9. Packs and ships samples; maintains chain of custody.

3.2.4. Scribe (Documenter or Recorder)

1. Verifies and records sample identifier, temperature, time, sampling implement, and sampling location on sample submission form.
2. Takes photographs of each sample locations/collection.
3. Takes Global Positioning System (GPS) readings (using GPS units or cameras with GPS capabilities) of each sample collection when appropriate.
4. Completes sample record and sample submission form (for an example, see FL RRT's Scribe Sheet, posted in FoodSHIELD [1]).

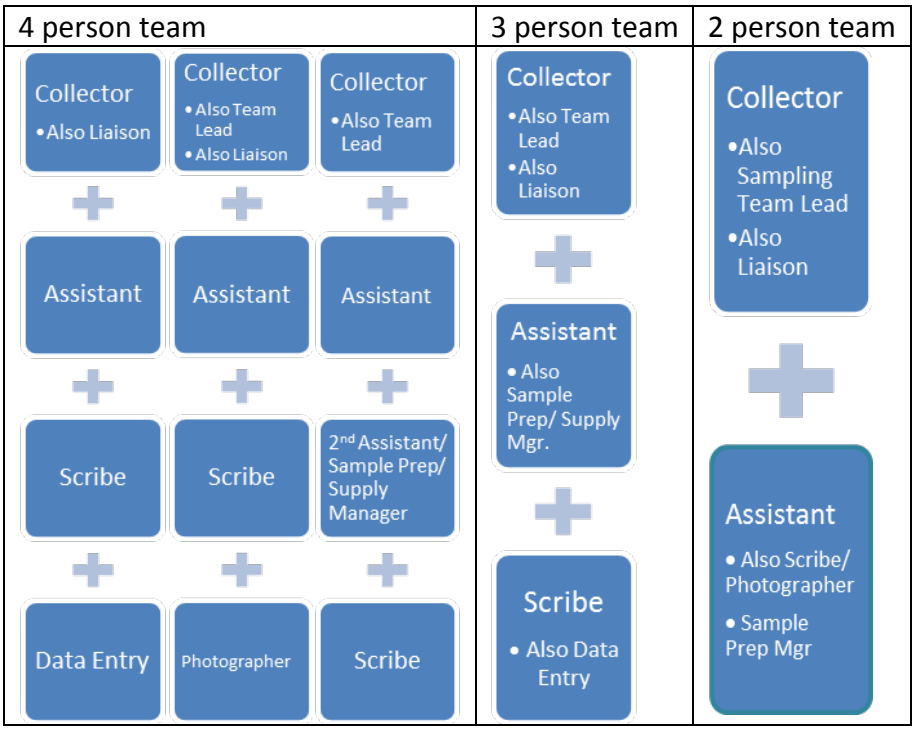
3.2.5. Other Roles

[1] FoodSHIELD website information: https://www.foodshield.org/, RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Sampling, Subfolder: FL ES Documents. File Name: FL-Scribe_Log_Sheet_FIMSversionMay2015.pdf. Note that access to the related documents is limited to personnel participating in the RRT Program.

These are additional roles that have been utilized by various RRTs to better serve their team or situation. One or more team members may be added based on the circumstances, team experience, size of the facility, or other factors such as:

1. **Liaison:** The liaison will usually act as the main point of contact between the firm and the sampling team. This role may also be combined into one of the common roles listed above.
2. **Second Assistant:** Some RRTs split the responsibilities of the assistant and assign two people to perform these tasks. The RRTs should ensure that each assistant understands what each is responsible for prior to deployment.
3. **Photographer**: A photographer may be assigned to capture the photographic evidence for the sampling assignment. This helps to alleviate the workload of the Scribe.
4. **Inspector**: A separate inspector may be needed to conduct an environmental assessment or investigation. Any violations or significant findings should be reported to the Sampling Team Leader to ensure sampling of violative areas.
5. **Sample Preparation/Supply Manager:** This individual manages the sample preparation area, sample storage supplies and waste disposal. The Sample Preparation/Supply Manager also ensures chain-of-custody is maintained throughout the entire sampling assignment as well as proper packing/sealing/labeling for transport. The individual communicates with the laboratory (time of arrival, number and type of samples to be delivered, etc.).
6. **Data Entry:** This team member is responsible for data entry and ensures that sample collection reports are emailed to the laboratory prior to the laboratory's receipt of the environmental samples. The person is also responsible for:
    a. Keeping the Incident Management Team (IMT) informed.
    b. Ensuring sample numbers on samples match the Scribe Sheet before and after entering data.
    c. Ensuring pre-generated sample numbers are properly transferred to the Official Sample Bag and Scribe Sheet.

Because each assignment is different, there is no sampling team structure that will fit all RRTs. The following schematic demonstrates potential examples of various team sizes and structures. Each RRT must determine which team structure will best fit their needs.



4. DEFINITIONS

4.1. Lot – A single grouping of manufactured or processed goods that is identified with a single lot code.

4.2. Non-funded Rapid Response Team (RRT) – A Rapid Response Team that is not receiving funds through the FDA RRT cooperative agreement program.

4.3. Rapid Response Team (RRT) – The group of state and federal partners associated with each Rapid Response Team. This team is responsible for developing and implementing improved rapid response to human and animal food incidents.

4.4. RRT Steering Committee – A selected number of key representatives from core RRT member agencies that provide oversight and strategic direction to the RRT (development and function). Must include at least a representative from the State Food Regulatory Agency and corresponding FDA District/Program Division Office.

4.5. Sample – A single container of a collected substance submitted for analysis labeled with a single identifier.

4.6. Sampling Kit – A prepared collection of sampling supplies and equipment that is ready-to-go. This kit should undergo periodic preventive maintenance with consideration towards interoperability with RRT investigative partners.

4.7. Subsample ("Sub") – The FDA's term for one or more containers of product collected under a single sample number. A FDA sample represented by a single number routinely consists of multiple subsamples or "subs". Other agencies use a single identifier for each individual container.

4.8. Swab or sponge – Generic term for a specialized tool for collecting pathogens that has been wiped over a surface and submitted for analysis.

4.9. Whirl-Pak® bags – Sterile plastic bags used to transport samples to the laboratory.

5. BACKGROUND

During a response to a human or animal food related incident, the environmental investigation or its environmental assessment component may necessitate environmental sampling. Under those circumstances, a sampling plan is devised that encompasses objectives of the sampling activity, sampling locations/areas, sampling team(s), types of samples to be collected, analytical laboratories involved, list of resources/needs, collection and maintenance of records, updates, deadlines, and restrictions and considerations such as the release of commercial confidential information (CCI).

For a given sampling event, selection of the RRT sampling team members should be based on their specific skills and the requirements of the assignment. It is important to brief the team on all available aspects of the incident to best prepare members for environmental sampling and record collection activities. The RRT also needs to be apprised of any pending and forthcoming information as well as any foreseen knowledge gaps since this may affect ongoing activities (e.g., compliance actions) and investigations. As a reminder, it is important to understand the laws governing the release of Personally Identifiable Information (PII), Commercial Confidential Information (CCI), and trade secrets (e.g., product composition and manufacturing methods) when sharing investigatory information.

Prior to the sampling event, the RRT will review the etiology of the causative agent and suspect human or animal food vehicle. This will help in the response planning process and assist to refine sampling approaches to areas that may potentially harbor the causative agent, contribute to product contamination, and in the case of some pathogens allow for growth and possible proliferation. Consideration should be given to novel potential points of contamination including air, water, soil, soil amendments and ingredients.

As samples are collected, the process must be conducted in a manner that prevents contamination. It is critical that the RRT use “aseptic technique” in all sampling environments, even while on a farm. Aseptic sampling entails collecting a sample while avoiding contamination by actions of the collector or sampler. Using aseptic technique is important as it prevents contamination of the sample by microorganisms (or other agents of concern), maintains integrity of the sample being handled, and protects the collector, sampler, or handler from contracting infectious agents, if sample is contaminated. Use of aseptic sampling equipment is a top priority for personal safety and sample integrity during any sampling activity.

Being efficient and effective during a sampling activity necessitates:

- Adequate knowledge of the situation being addressed;

- Clarity on the goals of the assignment;
- A detailed and comprehensive sampling plan;
- A cohesive sampling team structure with clear roles and responsibilities identified;
- An effective communication plan;
    - For examples, see FoodSHIELD Website[2]:
        - Michigan (MI) Sample Frequently Asked Questions (FAQ) to Industry. File name: MDARD Environmental Sampling Fact Sheet for Industry.doc. Also see Attachment B of this chapter.
        - Florida (FL) Information Handout for Industry. File name: FL_ES_Handout_Operators_June2014.pdf.
- A clear safety plan; and
- Robust documentation system to support activities and respective findings.

For additional information on planning environmental sampling and record collection activities, RRTs can refer to the latest State and FDA procedural documents such as the FDA Investigations Operations Manual (IOM, Chapter 4). Additionally, RRTs can access the 2009 FDA training video covering general sampling techniques for indoor facilities, which is geared towards State and FDA/ORA investigators (http:// www.accessdata.fda.gov/Videos/ORA/Sampling- 11-05-09-508.wmv).

6. SAFETY

See Section 8.9.

7. EQUIPMENT/MATERIALS

Extensive sampling assignments entail the use of a variety of tools and detailed procedures (see Attachment A: Sample Equipment List for a more information).

7.1. Routine Equipment – It is the responsibility of each agency to order and maintain sampling equipment for sampling assignments.

7.2. Sampling Kit – Supplies for the environmental sampling kits need to be ordered and maintained. The kits should be stocked for each assignment with a variety of pre-moistened sponges, sponges-on-stick, Dacron tip swabs, pipets, sterile scoops, sterile and non-sterile gloves, sharpie, labels, buffer, Tyvek® suits, booties, protective eye wear, bags, buffers, etc. Upon receiving a sampling kit, the buffer, pre-moistened Dacron tip swabs must be refrigerated. Each kit should also contain several freezer packs (refer to FoodSHIELD for MI: Sample Kit Equipment Usage Guide for an example).

[2] FoodSHIELD website information: https://www.foodshield.org/; RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Sampling. Note that access to the related documents is limited to personnel participating in the RRT Program.

7.3. Buffers – Sampling kits may be stocked with Dey/Engley (D/E) neutralizing broth because it is known to have worked well to recover both *Salmonella* and *Listeria* in food processing environments. The vast majority of environmental samples collected from these environments will originate from non-food contact surfaces, but the D/E neutralizing broth should not present a risk of contamination even to food contact surfaces. Any residue of the ingredients in D/E neutralizing broth that might remain on a food contact surface is trivial and presents no risk of food product contamination. D/E neutralizing broth has been used by many in the food industry for environmental sample collection and has not been associated with instances of product contamination.

Other types of buffers may be included in the sampling kit depending on the sampling assignment (e.g., pH buffers).

8. PROCESS DESCRIPTION

There will normally be specific instructions regarding the collection of non-routine samples. This type of sampling is often associated with contract work, foodborne illness investigations, suspected adulteration, or monitoring of a facility or product. Sample collection activities may also be increased when the associated risk of a facility, product, or process is increased due to recent outbreaks, previous sampling or assessment findings. In a processing environment, it is important to have a clear understanding of the sampling zones.

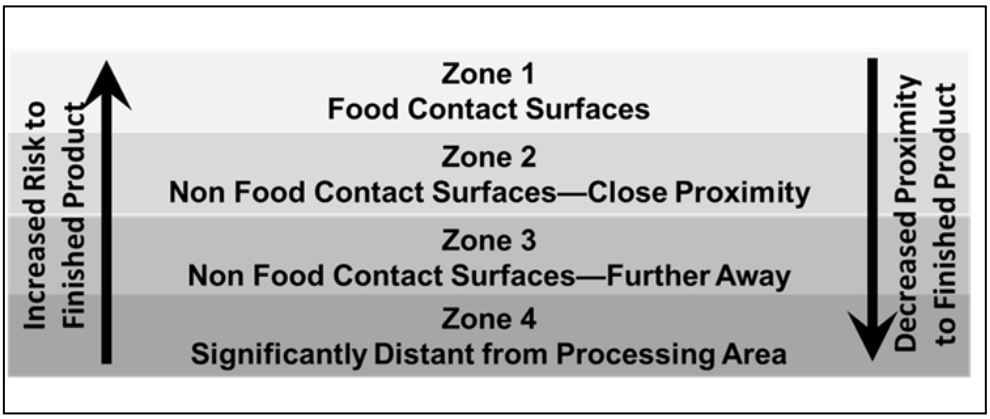
8.1. Sampling Zones (Specific to Processing Operations)

This section was primarily obtained from the October 2014 FDA Division of Field Investigations (DFI) Bulletin 30 Food Program Area – Instructions for Environmental Sampling (see FoodSHIELD for a copy of DFI 30, instructions on how to access in Section 6 References), and **modified** for RRT functions. RRTs should periodically check for a more current version. This section has been designed to address situations at manufacturing or processing facilities although some of the discussed concepts do apply to farm-related operations such as drying, cooling and harvesting.

Prior to the collection of environmental samples, the sampling team should review a map of the facility and/or conduct a walk-through assessment. This helps identify areas for observation, understand the firm's operational flow, as well as identify areas to concentrate sampling activities. The team should note any significant changes (e.g., renovations) at the facility that may affect the map. The review of the map can be done in advance of the investigation if the appropriate information is available or at the firm upon arrival. If a map is not available prior to or at the opening interview of the investigation, a map of the facility may need to be generated by the RRT to document all sampling points within the facility. Often, if a firm is using an outside pest control operator (PCO), the PCO log will have a basic

map of the facility that can be copied with permission from the firm for the purposes of sampling point documentation. A production line flow chart may also be beneficial when sampling from equipment surfaces.

The "Zone Concept" identifies and prioritizes processing areas from highest risk/proximity to the product to lowest risk/distance to the product for potential contamination and harboring growth and niches for the targeted pathogen and therefore should be implemented upon conducting environmental sampling as follows:



Zone 1 and Special Investigation ("For-Cause") Sampling: Zone 1 refers to all direct food contact surfaces such as slicers, mixers, conveyors, utensils, racks, worktables, etc. Gloves must be aseptically changed between each sample. If *Salmonella* is the pathogen of concern, food contact surfaces are normally not sampled unless specifically requested under the sampling plan (Section 11.2.1). In contrast, when *Listeria monocytogenes* is determined to be the pathogen of concern, the sampling of food contact surfaces is essential.

Zone 2: Zone 2 encompasses the areas directly adjacent to food contact surfaces (Zone 1). For investigations focusing on *Salmonella*, this is the area where environmental contamination is most likely to directly affect safety of the product. In a small production room, Zone 2 encompasses all non-food contact surfaces in the processing area, such as the exterior of equipment, framework, food carts, equipment housing, gears, ventilation and air handling equipment, and floors. In a much larger room (e.g., 20,000 square feet), Zone 2 is the area around the exposed product in which you could envision a pathway to product contamination either through the actions of man or machine. For example, even a far corner of the room could be considered Zone 2 if foot traffic or forklifts move through that area and these traffic patterns also go very near a line where exposed food is conveyed or held, or ventilation patterns cause airflow from these remote areas.

Zone 3: Zone 3 is the area immediately surrounding Zone 2. Zone 3 is an area that, if contaminated with a pathogen, could lead to contamination of Zone 2 via

actions of humans or movement of machinery. Examples of Zone 3 areas include corridors and doorways leading into food production areas or areas in a large production room that are further away from food handling equipment than typical Zone 2 areas. Walls, phones, forklifts and "mules", even if physically located in Zone 2, should be considered Zone 3 due to a decreased likelihood of cross-contamination.

Zone 4: Zone 4 is the area immediately surrounding Zone 3, generally considered a remote area. Zone 4 is an area which, if contaminated with a pathogen, could lead to contamination of Zone 3 via the actions of humans or machinery. Examples of Zone 4 areas include an employee locker room if not immediately adjacent to food production rooms, dry goods storage warehouse, finished product warehouse, cafeterias, hallways, and loading dock area.

A large majority of the environmental samples collected should be taken from Zones 1 (when directed and depending on the organism in question) and 2, and to a lesser degree Zone 3 areas. Very few, if any, environmental samples should be taken from Zone 4 areas.

When taking multiple swabs in an area within the firm, the RRT should always try to sample from the bottom up rather than from the top down in the area to avoid cross-contamination of sampling areas. For example, if it has been determined that sampling will include the floor, equipment, and overheads in a given area, the sampling should start with the floor first, then the equipment, and finally the overheads.

8.2. Sampling Approaches Specific to Select Bacterial Pathogens

8.2.1. Sampling for *Salmonella*

Salmonellae survive well in low moisture environments, especially those that are dry for long periods of time and occasionally get wet. For salmonellae detection, all environmental samples should be taken from Zones 2 and 3. Generally Zone 1 areas are unproductive for salmonellae because these areas are not areas where the organism can find harborage; they are usually cleaned too frequently or flushed with product to become harborage areas. Zone 4 areas can be productive sites for the detection of salmonellae; however, it can be difficult to link positive findings in Zone 4 areas to a direct risk of product contamination. For this reason, it is recommended that no environmental samples be collected from Zone 4.

For salmonellae, the most productive sample sites tend to be on the floor, or very near the floor on equipment surfaces and potential harborage areas. Thus, potential harborage areas in low-lying areas

should be given the greatest emphasis. However, because food processing plants differ greatly in their design, construction and manufacturing processes, investigators should exercise discretion and sample any site that may have collected airborne *Salmonella* or that could be a harborage/growth site for the pathogen. Areas for sampling include:

- Floors and related areas – under floor mounted equipment, scales (floor and table mounted)
- Sanitizing foot mats (if dry)
- Cleaning equipment – central vacuum systems, automated floor cleaning equipment (e.g., Tenet type walk-behind or riding sweepers, brooms, mops, etc.). Sample collector should pay attention to the collection of floor sweepings or the dry contents of vacuum cleaner bags or tanks.
- Air conveying equipment – air filters, air ducts, intake and exhaust vents, food residue on equipment and floors
- Product conveyors – cables, belts, joints where product residue accumulates (if the residue is old and dry)
- Unsealed control and drive changers, electrical/mechanical service boxes that are not cleaned and/or sanitized. The sample collector should look for dry dust and residue in these boxes.
- Cracked equipment – boots (shock absorbing devices), metal joints, etc.
- Under sinks/safety stations – under hand wash or eye wash stations of they appear to be cracked, leaking, etc.
- Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks and crannies (if dry)
- Doorways – floor area in doorways leading into or out of the production facility or onto the roof
- Pallets – floor under wooden pallets and pallets themselves
- Floor drains – use a sponge to scrub dry residue from floor drain grids and walls
- Pallet jacks, forklifts, carts, dollies, etc.

8.2.2. Sampling for *Listeria*

In contrast to *Salmonella* and pathogenic *E. coli*, the sampling of food contact surfaces (Zone 1) is essential when the implicated pathogen is *Listeria*. *Listeria* grows and survives well in a wide range of environmental conditions, especially those that are moist and cool. In general, when sampling for *Listeria* the majority of samples should be collected from Zones 1 and 2, and less collected from Zone 3. Generally, Zone 4 areas are unproductive for *Listeria* and positive findings are difficult to link to a risk of contamination; thus no environmental samples should be taken from Zone 4 areas.

Perform most of the sampling for *Listeria* detection in, on and around food contact equipment; focus on areas where food is exposed and being processed, particularly post-treatment/pasteurization. Every effort should be made to conduct sampling when the facility has been in production for at least four hours and before any wet cleaning is performed. Areas to collect samples from include:

- Moist/wet areas, particularly those with standing water
- Floors and related areas – under floor mounted equipment, scales (floor and table mounted)
- Sanitizing foot mats – can be a harborage area and point of transfer to other areas of the facility if proper sanitizer levels are not maintained
- Cleaning equipment – automated floor cleaning equipment, brooms, mops, and waste containers (especially the underside)
- Air conveying equipment – pressurized air lines, air hoses, condensate from pressurized air lines, HVAC evaporators, and evaporator condensate pans
- Product conveyors – cables, belts, joints where product residue accumulates, exposed bearings and rollers, sponge or felt rollers used to remove moisture from product
- Motor and electrical housings – especially those which do not appear to be routinely cleaned and sanitized
- Cracked equipment – boots (shock absorbing devices), metal joints, etc.
- Under sinks/safety stations – under hand wash or eye wash stations if they appear to be cracked, leaking, etc.
- Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks and crannies
- Doorways – floor area leading directly into production areas
- Drains – not during production
- Ice makers – inside, scoops, underside of top of ice chamber

- Ceilings, product storage shelving, and walls – in production areas, coolers, and freezers
- Pallet jacks, forklifts, carts, dollies, etc.
- Door gaskets to coolers and freezers, and damp insulation around pipes

8.2.3. Sampling for Shiga toxin-producing *Escherichia coli* (STEC)

Historically, environmental sampling at a processor for Shiga toxin-producing *E. coli* during outbreak investigations has proven to be an ineffective procedure (all environmental sampling up to 2011 conducted by FDA has been negative for the organism). *E. coli* does not usually colonize processing areas but seems to be more of a contaminated ingredient issue or an opportunistic cross-contamination type event, and in these latter situations, environmental sampling should only be considered on a case-by-case basis.

At this time, instructions are not included for collecting environmental samples for *E. coli* O157:H7. *Currently there are no FDA validated methods for analyzing these environmental samples.* Should there be a for-cause basis identified, consult with the Unified Command to obtain concurrence and instructions.

8.3. Control Samples

It is important to submit unopened sampling materials as controls. Team Leaders should check with the laboratory in advance regarding specific requirements. This must be done at the start of the sampling process by placing an unopened product in a Whirl-Pak® bag, assign a sample identifier and applying a sample sticker to the bag and clearly label as 'Control'. Additional controls must be submitted for each lot number of supplies that are used, including for each lot and size of equipment used where noted below. Submit for the same analysis as other environmental samples collected.

An open control is an empty sterile container which has been opened/ closed in the sampling area and could be collected during for-cause investigations (to be done only when specifically directed). Unless otherwise noted, FDA and some states do not routinely analyze or collect open controls. Please check with any assignments details as well as your servicing lab(s) prior to collection.

8.4. Sponge/Swab Sampling

Most environmental samples should be collected using either hand held sponges or sponges on a stick. The sampler should collect as much sample material as possible. The sampler may have to use multiple swabs for a large area especially if it is heavily soiled. Larger samples or larger areas sampled are more likely to be

positive. Swabs are suitable for sampling only very small areas that cannot be accessed any other way.

8.4.1. Sampling Using Non-Hydrated Sponge-Stick® on a Dry Surface

Although the description provided below is limited to the Sponge-Stick® procedure, some RRTs may be using other swabbing products.

1. All members of the sampling team must wash and sanitize hands thoroughly before collecting any samples. Any member of the team involved in preparation of Sponge-Sticks® and swabs, sample handling and collection, or sample packaging must follow their own protocols on sterile sampling.
2. Samplers should label the sterile bag containing the Sponge-Stick® with appropriate reference information.
3. From the outside of the Sponge-Stick® bag, the Sampler should manipulate the handle toward one side. Then, pull off the top of the Whirl-Pak®bag holding the Sponge-Stick® along the perforation. Following that, the bag should be opened gently. No attempts at this point should be made to remove the Sponge-Stick® as this will occur at a later step.
4. The Sampler should carefully open a 10 mL tube of D/E neutralizing broth and pour the contents of the tube into the Sponge-Stick® bag; away from the handle of the Sponge-Stick®. The opening of the D/E neutralizing broth tube must not touch any non-sterile surface. No parts of the non-sterile broth tube should come in contact with the sterile parts of the Sponge-Stick® bag and vice versa. Aseptic technique must be followed.
5. The Sampler should massage the Sponge-Stick® from the outside of the bag to facilitate absorption of the D/E neutralizing broth.
6. From the outside of the bag, the Sponge-Stick® is then pushed upward toward the bag opening while gently squeezing excess broth from the sponge.
7. The team member that is collecting the swab samples must aseptically place a sterile glove on the hand used for swabbing prior to grabbing the swab stick. This Sampler must not touch any non-sterile surface with the glove.
8. The Sponge-Stick® is removed from the bag with the sterile gloved hand. Only the mounted stick portion of the sponge is to be touched (i.e., above the thumb stop line mark).
9. An even and firm pressure is to be applied to the Sponge-Stick® while swabbing an environmental surface 10 times vertically, and 10 times horizontally. If visible soil or residue is present, the sponge should be

rubbed vigorously over the designated area until the soil or residue is removed.

10. Large flat surfaces should be sampled to cover areas as follows: 1ft × 1ft for unclean surfaces, 3 ft × 3 ft for cleaned and/or sanitized surfaces. Information on the swabbed approximate area should be documented particularly if smaller than the recommended values.
11. The sample sponge should remain hydrated enough to glide smoothly over the sampling surface. In the event a large or porous area is sampled and the sponge begins to dry, you may re-wet the sponge with additional D/E neutralizing broth by aseptically dipping the sponge back into the bag.
12. After the area sampling is done, the Sponge-Stick® is aseptically returned to the original Whirl-Pak® bag by placing the sponge portion and stick only as far as the thumb stop inside the bag. The Sampler should then grasp the sponge from outside the bag and begin to move the handle of the Sponge-Stick® back and forth with the gloved hand to break the Sponge-Stic®k at a point below the thumb stop; allowing the sponge to drop into the excess D/E neutralizing broth in the Whirl-Pak® bag.
13. The Sampler should then eliminate any excess air in the Whirl-Pak® bag by rolling the top portion of the bag down all the way to the sponge and folding in the bag tabs. The bag containing the sponge sample is then placed into another sterile Whirl-Pak® bag, with its excess air eliminated and bag closed by rolling the top down far enough to provide a leak-proof seal.
14. Discard any used sterile gloves in the sample team trash bag.
15. All gloves must be changed if they become contaminated, between samples, or if the sampling team has moved between zones (also see FDA IOM Chapter 4). For Zone 1:
    a. Between every sub when sampling Zone 1 Food Contact Surfaces, an outbreak follow up, or if sampling is “for cause”
    b. When sterility may be compromised (i.e., touching clothing, area you are sampling, equipment, floor, non-sterile surfaces, or if glove is damaged)
    c. When sampling a lower numbered Zone after a higher numbered one (i.e., collecting a Zone 1 sample after collecting a zone 2 sample)
    d. Sanitize gloved hands between every sub when sampling in Zones 2-4.
16. Collected samples must be placed in a dedicated cooler with ice packs in order to keep samples cold but not frozen.
17. Collected samples (up to 20; any combination including control samples, sponges, and swabs) are placed into a re-sealable plastic bag

with an official sample seal placed around the opening of the re-sealable bag. Maintaining chain of custody and sample integrity is crucial to sample collection.

18. Submit samples to the laboratory as soon as possible. No more than 24 hours from the time of collection should lapse otherwise the laboratory may reject the sample. Under certain circumstances, depending on the type of sample and analysis requested, there may not be a 24 hr restriction. It is imperative that the RRT coordinates with the laboratory before deviating from standard protocols.

8.4.2. Sampling Using a Non-hydrated Sponge-Stick® on a Wet Surface

The protocol used to collect a sample using a non-hydrated Sponge-Stick® is similar to that utilized with a hydrated Sponge-Stick® (discussed in the previous section). However, when a non-hydrated Sponge-Stick® is used, sampling occurs first and the 10 mL of D/E neutralizing broth is then added afterwards, placing the Sponge-Stick® back into its original Whirl-Pak® bag. There is no pre-moistening of the sponge before a sample is collected (see 11.4.1 Step 4 for non-hydrated sponge-stick® on Dry Surface).

8.4.3. Sampling Using a Pre-hydrated Swab Tube

Swab tubes are pre-hydrated with a D/E neutralizing broth. Again, these swabs should be used for sampling small areas that cannot be accessed any other way. Examples include a hole in the floor, cracks or insides of tubular equipment mounts. The following is a summary of steps to follow when collecting samples using a pre-hydrated swab tube.

1. Sampler's hands should be washed and sanitized thoroughly before beginning to collect sample(s).
2. Aseptically, a sterile glove is placed on the hand used for swabbing.
3. The cap of swab tube is then loosened and the swab removed in preparation for sample collection. It is imperative that the sampler does not touch any portion of the swab except the cap.
4. An environmental sample is collected by using even, firm pressure to glide the swab 10 times vertically, 10 times horizontally, and 10 times diagonally over the designated sample area.
5. Each time the swabbing direction is changed, the sampler should re-insert the tip of the swab into the swab tube containing the D/E neutralizing broth to re-hydrate the swab. If visible soil or residue is present, the swab should be vigorously rubbed over the designated area until the soil or residue is removed.
6. After completion of swabbing, the swab is returned to its tube.

7. Each tube is to be tightened, labeled with information identifying the specific sample collected, and placed in a Whirl-Pak® bag. Tubes containing sampling swabs do not need to be double bagged.
8. Collected samples should be placed immediately in a dedicated cooler with ice packs in order to keep samples cold but not frozen.
9. Collected samples (up to 20) (any combination including control samples, sponges, and swabs) are placed into a re-sealable plastic bag with an official sample seal placed around the opening of the re-sealable bag. Again, the maintenance of chain of custody as well as sample integrity is crucial.

8.4.4. Special Instructions for Sampling in Kosher Establishments or Other Facilities Where Milk Proteins May Not be Used

Kosher processors may prohibit the use of a sampling medium such as D/E that contains a milk protein when swabbing Zone 1 surfaces for *Listeria*.

Should this occur, the following method may be used as a substitute:

1. Moisten a dry sponge with sterile water, sterile saline, or sterile phosphate buffer (any of these are acceptable).
2. Swab the surface.
3. Immediately put the sponge into the Whirl-Pak® bag and add two 10 ml tubes (total of 20 ml) of D/E neutralizing Broth and repeatedly squeeze the sponge to equilibrate the liquid in the sponge.

This procedure will not have a significant negative impact on recovery of the organism as the entire sponge and volume of buffer is cultured in the laboratory. In this situation the D/E buffer will be diluted (about 66% strength) but it will still be effective.

8.4.5. Collection of Residues and Environmental Matter

When collecting residue, debris can be scraped out using a sterile implement, such as a small, sterile metal spatula or scraper. Also, it may be useful to use a sterile cotton or Dacron™ swab as a tool to remove debris from cracks and crevices for sampling. In this case, use aseptic technique to break the cotton or Dacron head off the swab and use the remaining stick as a scraping or gouging tool, then use a sponge or swab to gather the material – place the stick, sponge and any debris or residue into the Whirl-Pak® bag.

Important: Firms may question whether or not areas that have been sampled by investigators – (especially food contact surfaces) need to be cleaned and sanitized before resuming production due to concerns of D/E

residue left behind as a result of the sampling process. It is the opinion of FDA scientists that residues potentially left behind by D/E broth are negligible and present no risk to the contamination of food and food products that may come into contact with the sampled area. While a firm may opt to wash, rinse, and sanitize an area that has been swabbed before resuming production, it is not required (for an example, see Attachment B, MDARD Environmental Sampling Fact Sheet for Industry).

8.5. Sample Numbers

Environmental samples are collected from the processing plant environment in order to fully evaluate the environment and detect even low levels of contamination. It is not unusual for a contaminated plant to yield only 1-2% positive environmental subsamples. The number of samples taken during an environmental investigation will vary depending on factors such as: target pathogen, the number of affected products, production lines and production sites, etc. A sample will consist of multiple subsamples containing sponge and/or swab samples from specific sample sites. Salmonellae tend to be more difficult to detect in a contaminated plant vs. *Listeria* and a greater number of samples are needed for *Salmonella* environmental sampling in order to have confidence in negative findings.

8.5.1. Salmonellae Sampling

Collect at least 100 subsamples and ideally 300 subsamples if possible depending on facility size and process complexity.

8.5.2. *Listeria* Sampling

Collect at least 50 swabs and ideally 100 or more subs if there are a sufficient number of promising sampling sites. The number of swabs would also depend on facility size and process complexity.

8.6. Sample Documentation

Proper documentation of sample details is crucial for chain of custody and validity of the sample results. Handwrite details if necessary, but follow-up with electronic copies.

For each investigation, an electronic “Master Sample Spreadsheet” should be implemented that tracks the collected samples, including the incident name, location of the investigation, sample collection specifics such as description of sample, sampling site, sample type, collector information, analytical laboratory, analysis requested, analytical findings, and Global Positioning System (GPS) coordinates (if appropriate). An example of this is the FL-RRT’s and MI-RRT’s Scribe Sheets (see Section 6: Related Documents). A hardcopy of the spreadsheet will follow the sample to the servicing laboratory and the electronic spreadsheet will

serve as the reporting vehicle for analytical results. Depending on the magnitude of response, collected samples may be delivered to several laboratories (determined in advance such as an earlier operational period). Some laboratories may need additional documentation for sample submission. Laboratory routine requirements should be determined in advance to avoid possible rejection of samples.

During the course of an environmental sampling investigation, it is important to document the possible link between the source of an environmental sample and contamination of the food product. A description of the sample location in relation to areas, where food may have been potentially exposed and any observed mechanical/ human activities that might cause an organism to be spread, should be noted. Documentation, illustration of observations, and environmental sample locations using sample collection records, facility maps, diagrams, photographs, and journal notes are important.

8.6.1. Documentation of Collected Samples

To further document environmental sampling activities, the data elements contained within an “Environmental Sample Collection Record" spreadsheet should include:

1. Date/ Time and Outbreak name in the record's header.
2. Manufacturer’s lot numbers of control samples.
3. Detailed documentation of environmental samples.
4. Information on whether or not the sample was taken from a food contact surface (FCS) in addition to the zone number the sample was collected from, if applicable.
5. Photo file name captured by the digital camera for each sample.
6. Signature of person delivering samples to the laboratory, or an authorized person at the shipping location on the bottom of each record.
7. Sample identification system used during the investigation. RRTs may have different numbering schemes accounting for investigations that last longer than one day. Each sample should have a unique identifier irrespective of sampling day or incident.
8. Documentation linking sample number to the location of each sample taken on the facility map (investigation site).
9. After the “Environmental Sample Collection Record” form is complete, copies of the form(s) should be included with the samples when delivering them to the laboratory. The Field Team Lead should retain the original copies.

8.6.2. Photo Documentation

Digital photographs should be taken of each sampling location and stored at the end of each day to a pre-determined location. When downloading photographs, it is important to maintain the integrity of the original file. Additionally, contextual information on the collected photographs should be recorded detailing the activity being photographed as well as sampling location in relation to the implicated product's manufacturing process such as the processing area, storage area, coolers, etc.

8.7. Sample Collection Clothing

8.7.1. Footwear

The investigator will take measures before and after entering a facility or field location to collect samples to ensure that materials and outerwear are free from contamination. This may include using designated footwear provided by the firm. If designated footwear is not provided by the firm, the investigator will clean and disinfect footwear prior to entering an area of sample collection. Footwear must be covered with disposable coverings provided in the sampling kit or by the firm. Investigative footwear must not be worn outside the facility. For investigations lasting longer than one day, footwear must be re-cleaned and re-sanitized as needed. Disposable coverings and any trash generated by the RRT (e.g., packaging of sampling materials) must all be removed by the team and disposed of appropriately off-site.

8.7.2. Garments

1. Clean pants and shirt shall be worn to the investigation site and on each day of the investigation.
2. Clean or disposable lab coats must be worn within the facility. The facility may require that they provide lab coats for sampling team. If not, the RRT should be ready with their own supply of clean clothes or lab coats.
3. Laboratory coats must not be worn outside the facility. For investigations lasting longer than one day, a clean lab coat (or new disposable lab coat) must be worn each day.

8.8. Post Sampling Activity

After all samples are collected, the team verifies that each subsample is accounted for, properly sealed, properly labeled, and ready for transport. The team verifies that the sample information corresponds to the accompanying paperwork to prevent problems with interpretation or enforcement actions. Take all sampling waste, wrappers, and used Tyvek® suits offsite for disposal (do not leave in the firm's dumpster).

8.8.1. Onsite Packing

Samples must be closed, sealed, labeled, and double bagged (in sterile bag) to establish chain of custody, and then they may be grouped in packs of 10-15 subs into large labeled zip-top bag. Make sure there are no damaged subs that will leak onto others. Package samples neatly so the lab can access them easily, and arrange them to avoid spillage or leakage. Place samples in a clean cooler, lined with a clean plastic bag. Include bagged or artificial ice and insure that the samples are not in contact with water or coolant.

8.8.2. Transport Samples to Laboratory

The samples must be transported or shipped to the designated laboratory in accordance with the assignment instructions and with all due chain of custody considerations. All efforts should be made to ship or transport samples to the laboratory the same day they are collected. Samples must be packed with enough coolant to ensure proper temperature during transit. Generally, samples must be received at the laboratory within 24 hours of sample collection or per lab recommendation.

8.9. Safety

Employee safety is always the top priority during any type of field work. During a response, RRTs should review all facility safety requirements and inquire about any site-specific hazards during your initial check-in with facility management. The sampling team should comply with all facility personal protective equipment (PPE) requirements (glasses, safety shoes, hard-hat, etc.) and stay in contact with the facility representative throughout the inspection process.

In addition, the following precautions should also be taken.

- Listening to local radio and television stations for up-to-date weather and road conditions prior to driving to or from facilities.
- Remaining continuously aware of your footings and surroundings (slippery, snowy, and icy and uneven surfaces).
- Constantly maintaining a three-point contact when going up or down ladders and stairs.
- Exercising caution and use good judgment while working at elevated heights. Ensuring that all work areas are properly guarded with railings, guardrails, for example, before accessing that area of the facility.
- Following RRT training protocols and not entering any areas of the facility or performing any operations that are outside the scope of RRT position and training.
- Be prepared for emergencies at the facility. Response team members should ask proactive questions such as “Where do I go if there’s an emergency, injury, evacuation, etc.?”

SAFETY NOTICE: All injuries, incidents, and unsafe conditions occurring on the investigation site should be reported to the facility management and team member supervisor as soon as possible after the event. The response team should always be aware of the surroundings at all times and maintain regular communication with their supervisor.

Additional Instructions for Non-routine Sampling Environments

In the past, investigative field teams have operated in a variety of environments that ranged from processing plants to wooded hillsides. RRT operations have occurred during extreme weather (e.g., 90° F temperatures, hail) as well as potentially dangerous situations (e.g., wildlife animal activity, disgruntled people, fumigant or pesticide exposure, or airborne pathogens such as *Salmonella* in pepper dust). Where appropriate, the proper safety precautions should be taken in order to mitigate these potential hazards. It is the duty and responsibility of each individual member to maintain situational awareness for themselves and their co-workers. Additionally, a Safety Officer should be designated (member of the response team other than the Field Team Lead or the Operations Chief (see ICS Chapter). This person would oversee the safety of all RRT members in the field. Per ICS, the Safety Officer possesses the authority to terminate operations if there is a reasonable hazard to any team member and can override the Incident Coordinator/ Unified Command, if necessary.

8.10. Commodity Specific Field Investigations

Investigations at growing fields, for example, constitute a significant portion of environmental investigations regarding different food commodities. In many cases, investigations at the implicated processing location are conducted concurrently with growing field investigations. In most cases, once the implicated commodity is identified, the implicated field (where that product was harvested) is often fallow or planted with a new crop. Although the original implicated product has been harvested, valuable information and documents can still be collected that may provide critical information for developing an appropriate environmental sampling plan to investigate potential contamination source(s).

The following information needs to be considered when conducting a field investigation and supporting records should be requested:

- General overview of weather during the time in question – any flooding, seasonal lakes, water pooling, or drought conditions
- Water use on the farm and its source – irrigation from well, municipal, or open sources, use of recycled water, etc.
- Animal activity (wild and/or domestic) on the farm – crop damage, fencing
- Any employee training protocols; inquire if language appropriate.
- Farm/operations map

- General description of the operation including the use of a cooling facility
- Details regarding the field preparation and planting of the implicated product
- Information regarding the application of pesticides,fertilizers, or other soil amendments – who applied each, when, and sources of water used to mix, and what products specifically
- Product harvest information – dates of harvest, harvester, harvest equipment, harvest crew, worker health and hygiene
- Assessment of the visited fields – perimeter, photographs, GPS of the corners and well-heads, unusual activities or observations adjacent to the field(s) in question
- Prior crop information and adjacent land use – any significant differences in production with the prior crop relative to the crop in question
- Third party audit information – (e.g., the CA or AZ Leafy Greens Marketing Agreement – LGMA)
- Previous laboratory results or findings in response to sampling of produce, water

Examples of different questionnaires and assessment forms can be found under Attachment D. These questionnaires are intended to address multiple commodities and various growing, cooling and harvesting practices with some emphasis on produce. The questionnaires can be modified to meet other RRT needs due to expected regional differences in approach and types of commodities grown.

8.11. Records Collection and Document Review

Another aspect of developing an effective environmental sampling plan is the review of the firm's documentation. This has the dual role of reviewing historical practices for past deficiencies as well as laying the foundation for future activities such as enforcement actions and/or recalls. Ensuring that all document requests made to the firm are fulfilled is also important. This includes working with the firm to photocopy or scan any documents as necessary. When multiple agencies are involved in the investigation, there may be a need to request multiple copies of a document.

Although environmental sampling is a major part of an investigation, observations and record collection (including SOPs documents) are crucial as well. Prior to any sampling activities, the team should consider collecting and reviewing the documents listed below. Througout the collection and review process, the team should attempt to identify any gaps that may have led or contributed to the incident.

- Invoices, Bills of Lading, Purchase Orders, shipping records focused on time period of interest and the implicated product or lot.

- Hazard Analysis Critical Control Point (HACCP) or Food Safety Plans (if available; some firms have voluntarily developed plans as part of their food safety system). Record Keeping is mandated per FSMA.
- Sanitation records including temperature logs and quality control (QC) checks.
- Food handling process records from receipt of ingredients/raw materials to shipment of final product.
- Farming/growing practice SOPs including harvest and cooling operations.
- The production operation, cleaning/sanitation, and maintenance of the firm's equipment.
- Employee food safety training, food handling techniques and employee health.
- Potential cross-contamination opportunities.
- Sanitation practices – including post-production and between unique products.
- Pest control practices
- Records on sampling and testing conducted by the firm including reports of firm history in terms of positive analytical findings.

The creation of a dedicated document reviewer as part of the investigative team has proven to be very useful. Responsibilities of this person include:

- Create and maintain a list of all requested and obtained documents.
- Ensure that both State and FDA investigators have complete sets of documents, files, and photographs.
- Review receiving and distribution documents for traceback, traceforward, recall, and regulatory considerations.
- Verify collected information by reviewing provided documents/ photos and determining if there are any gaps or issues that may have led to contamination.
- Inform the Field Team Leaders of any significant findings.
- Ensure the completion of questionnaires by the field staff (see Attachment D).

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

The levels assume that agencies with higher level capacities meet all the elements for lover level capacities.

Level	Description
1	The team has written environmental sampling and records collection procedures.
2	The team has conducted and documented an assessment (reviewed within the last 12 months) of their environmental sampling and records collection procedures against a recognized national multi-jurisdictional best practice (e.g., this RRT Manual Environmental Sampling and Records Collection chapter) to identify and prioritize future environmental sampling capacity development efforts.
3	The team has implemented an environmental sampling and records collection capacity development plan that is current and will result in achieving level 4 or level 5 capacities.
4	The team has documented the capacity, within the past 12 months, to conduct environmental sampling and records collection investigations consistent with FDA procedures[3] – either in response to an actual investigation or through an exercise.
5	The team conducts regular audits of its members per a written audit plan and maintains documentation of results.

9.2. Process Overview

9.2.1. Review the steps identified in the RRT FERP Chapter which are appropriate for agencies interested in developing any RRT Capacity.

9.2.2. Determine which environmental sampling and records collection capacity level your agency needs to develop/maintain based on agency objectives, identified risks, past experiences, and availability of resources.

9.2.3. Consider how to most effectively use staff training, supervision, jurisdictional authorities, and other resources to achieve desired environmental sampling and records collection capacity level. This is often best accomplished through agency involvement in a comprehensive process improvement initiative (e.g., enrollment in the Manufactured Food Regulatory Program Standards (MFRPS).

9.2.4. Use information from exercises and actual responses to assess the cost/benefit of developing a higher environmental sampling and records collection capacity level.

[3] U.S. Food and Drug Administration (FDA) Investigations Operations Manual (IOM) http://www.fda.gov/ICECI/Inspections/IOM/default.htm

10. RELATED DOCUMENTS

See FoodSHIELD Website[4]

10.1. RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Sampling, Subfolder: FL ES Documents.

10.1.1. FL: ICS Check List for Environmental Sampling.

1. File name: FL_ICS Roles_Responsibilities_FDACS_V4_May 2015.pdf

10.1.2. FL: RRT Scribe Sheet.

1. File name: FL_Scribe_Log_Sheet_FIMSversionMay2015.pdf

10.1.3. FL: Environmental Sampling Information Handout.

1. File name: FL_ES_Handout_Operators_June2014.pdf

10.1.4. FL: Environmental Sampling Operating Procedures.

1. File name: FLIRRT_ESprotocolMay2015.pdf

10.1.5. FL: Environmental Sampling – Competency Requirements for Staff.

1. File name: FL_Environmental Sampling Comptency Level_V2.0May2015.pdf

10.2. RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Sampling, Subfolder: MI Sampling Resources

10.2.1. MI: Sample Kit Equipment Usage Guide

1. File Name: MDARD Sample Kit Equipment Usage Guide.doc

10.2.2. MI: MDARD Environmental Sampling Fact Sheet for Industry

1. File Name: MDARD Environmental Sampling Fact Sheet for Industry.doc

10.3. RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Sampling.

10.3.1. FDA Field Alert 41 - Collecting Surveillance Samples on Farms

1. File name: FA41-On Farm Sample Collection_Nov2014.docx

10.3.2. FDA Division of Field Investigations Bulletin 30 (2014) – Food Program Area – Instructions for Environmental Sampling.

1. File name: DFI Field Bulletin_Oct2014.pdf.

10.4. RRT Program Workgroup, Folder: Best Practices Manual.

10.4.1. Communications Chapter of this RRT Best Practices Manual

10.4.2. ICS Chapter of this RRT Best Practices Manual

10.4.3. Training Chapter of this RRT Best Practice Manual

11. REFERENCES AND OTHER RESOURCES

11.1. CalFERT Manual v. 5-5 (2017)[5]

11.2. FDA Investigations Operations Manual: Chapter 4[6]

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[4] FoodSHIELD website information: https://www.foodshield.org/. Note that access to the related documents is limited to personnel participating in the RRT Program.

[5] Located in FoodSHIELD: https://www.foodshield.org/; Rapid Response Teams (RRT) Program Workgroup, Folder: Examples and Sharing, Subfolder: RRT SOGManualPlaybook, File name: 2017 CalFERT Manual v5-5.pdf. Note that access to the related documents is limited to personnel participating in the RRT Program.

[6] http://www.fda.gov/ICECI/Inspections/IOM/default.htm

12. ATTACHMENTS

12.1. Attachment A – Sample Equipment List
12.2. Attachment B – Michigan Dept. of Agriculture and Rural Development Environmental Sampling Fact Sheet for Industry
12.3. Attachment C – Suggested Resources to Inform RRT Chain of Custody Procedures
12.4. Attachment D – Examples of Generic and Commodity Specific Questionnaires

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	10/26/12	RRT Environmental Sampling WG (PAR-RO**, CA, MN, LOS-DO, SAN-DO)
1.1	R	01/24/13	ORA/OP
2.0	R	5/26/17	RRT Environmental Sampling WG (PAR-RO**, CA**, ORA, CORE, CFSAN)

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)
**Workgroup Lead

Change History

1.1 – Editorial revisions to achievement levels for clarification purposes made based on RRT recommendations.
1.2 – Revisions to the chapter based on recommendations from the RRT Environmental Sampling Chapter Revision Workgroup (January-May, 2015).
2.0 – Revised for the 2017 Edition of the RRT Manual by the RRT Environmental Sampling Chapter Revision Workgroup.

Attachment A – Sample Equipment List

The following items are suggested specialized sampling supplies and equipment. Also see examples in FoodSHIELD (see Section 6 References; e.g., Florida Sampling SOP and Michigan Sample Kit Equipment Usage Guide).

Sterile sampling bags (e.g., Whirl-Pak® bags – various sizes)
Sterile gloves – various sizes
Non-sterile gloves – various sizes
Sterile sponge swabs
Sponge sticks
Drag swabs with string (dry)
Swab sampler with D/E neutralizing broth
Hydra sponge with 10 mL DE neutralizing buffer with gloves
Swab tubes with screw-cap
Mini flip top vial with D/E broth
Sterile water bottles (120 ml vessels)
Sodium thiosulfate 300 ml bags (3 pills per bag)
Total chlorine test strips
Free chlorine test strips – (0–6 ppm)
Free chlorine test strips – (0–10 ppm)
Free chlorine test strips – (0–25 ppm)
Free chlorine test strips – (0–120 ppm)
Free chlorine test strips – (0–750 ppm)
Oxidation reduction potential (ORP) meter – waterproof
ORP calibration solution
pH meter – waterproof
pH test strips (100 strips per box)
Sanitizer measure
Liquid sodium hypochlorite (5%, 1.42 gal)
Ethyl alcohol (70%, 1 gal)
Plastic tub
Moist wipes
Alcohol wipes
Spray bottle with isopropyl alcohol
Plastic cart (foldable)
Spatula – stainless steel 18"
Sterile scoops – various sizes
Deionized distilled water (500 ml bottles)
Sterile water bottles (1 liter)
Pump – peristaltic (85 ml/min), variable speed pump medium flow
Pump tubing – 1000 50ft/Pack, sterilized
Thermocouple
Thermocouple probe
Scale – tubular spring scale 250 grams
Balance – 200 x .01 grams

Balance – 600 x .01 grams
Boot covers
Hair nets (white and black)
Beard nets
Hand sanitizer
Coolers
Markers
Labels (adhesive)
Clipboard
Rubber bands
Paper towels
Cotton twine, medium duty 410 ft.
Cotton thread in spool
Duct tape/packing tape
Evidence tape
Sample/evidence tags
Shipping labels and shipping label holders
Video recorder and related accessories
Electrical outlet adapter for car plug-in
Flash drives (4 GB or higher)
GPS cameras (or standard cameras)
Camera charging cable
Camera charging wall adapter
GPS units – high sensitivity; preferably
Printer/scanner/copier
Radios – two-way radio sets (2 radios per set)
Software – GPS photo link
Software – Data manager software
Surge protector/power strips
Batteries (e.g., AA for handheld GPS units) – various sizes
Software – wireless PC card
Software – operation manual
County or regional topographical maps
Back support belts
Knee pads – fabric
Knee Pads – hard plastic
Clean lab coats
Trash bags – various sizes

Attachment B – Michigan Dept. of Agriculture and Rural Development Environmental Sampling Fact Sheet for Industry

Background: Environmental samples are collected from food processing or retail environments in order to fully evaluate the environment and detect low levels of contamination. In recent years, there has been an increased emphasis on conducting bacteriological inspections, as certain foods pose an increased risk of association with *Listeria* or *Salmonella*.

What to Expect: MDARD Inspectors will conduct an assessment to observe and map operations and to consider sampling locations. Locations are based on the target organism and are prioritized from highest to lowest risk of possible existing contamination of food. This may include food contact and non-food contact surfaces. During sampling, MDARD will use of a variety of sterile sampling implements and D/E neutralizing broth (purple liquid). The broth neutralizes sanitizer that may be on surfaces sampled and allows the organism to survive transit to the laboratory. D/E broth has been used by many in the food industry for environmental sample collection and has not been associated with instances of product contamination.

Frequently Asked Questions:

Q. How many samples will MDARD collect?
A. Normally about 100 samples; however certain circumstances may increase or decrease that number.

Q. Why do so many MDARD Inspectors need to be here at one time?
A. MDARD deploys a team to ensure samples are collected as quickly as possible, so you may resume normal operations.

Q. Is the Broth (purple liquid) safe?
A. CFSAN has determined that residual ingredients from D/E broth that might remain on a food contact surface are trivial and present no risk of food product contamination.

Q. Do I (or MDARD) have to clean the Broth immediately after sampling?
A. No, normal cleaning and sanitizing procedures after processing are sufficient.

Q. Can I keep operating during sampling?
A. Yes, MDARD will do their best to work around your process, equipment, and employees to ensure proper sample collection.

Q. Where will MDARD sample?
A. In wet environments, most samples will be collected from food contact surfaces. For dry environments, most samples will be collected in areas adjacent to food contact surfaces.

Q. Can my firm collect companion samples during MDARD sample collection?
A. Yes, your firm can collect samples; however MDARD cannot provide personnel or equipment for collecting companion samples.

Q. What happens if results come back positive?
A. Sample results are usually confirmed within 7-10 days. MDARD will notify your firm with any positive sample results. If you would like notification of negative results, then contact your Inspector. If a positive result is confirmed then MDARD will notify your firm and work to assist your firm in determining the possible extent and source of contamination. Possible actions may include environmental assessment, additional sampling, recall, traceback/forward, ceasing processing until contamination is eliminated, or others.

Q. Should my firm be conducting routine environmental sampling?
A. A comprehensive food safety system includes effective cleaning and sanitizing, compliance with laws, proper training and supervision, and verification that all is working. An environmental sampling program may help you find sources and extent of contamination, identify areas with special maintenance requirements, assess sanitation and hygiene procedures, evaluate plant and equipment design, and comply with customer requirements.

Attachment C – Suggested Resources to Inform RRT Chain of Custody Procedures

Background

Chain of custody refers to policies and procedures that document the identity and authenticity of samples and associated data from collection through reporting of the test results for legal defensibility. Chain of Custody is part of the 2016 MFRPS and 2017 AFRPS, and is an important consideration for Federal/State/Local agencies that may wish to have the analytical data associated with their sample collection considered for potential compliance, enforcement, or other regulatory action by another agency (e.g., a sample in interstate commerce collected by State A, manufactured in State B, where State A would like State B and/or the appropriate Federal regulatory authority to take action on the sample results).

Sample Collection/Handling/Submission Chain of Custody (CoC) Resources

- FDA Investigations Operations Manual (IOM) section 4.3 Collection Technique; section 4.4 Documentation & CR; example collection report; example affidavit; section 4.5 Sampling: preparation, handling, shipping
- MFRPS/Standards Implementation Staff Food and Environmental Sampling Resources document
- Contact your FDA Program Division's DIB, Deputy DIB or a SCSO for their input/suggestions regarding sample collection and chain of custody. It may be worthwhile to discuss opportunities for joint training on food/environmental/aseptic sampling techniques.
- Some states may be willing to share their sample submission forms. Consider reaching out to other RRT states to ask what they use and whether they've encountered issues in the past. Some RRTs have posted their chain of custody forms in FoodSHIELD, RRT Program WG, Folder: Examples and Sharing, Subfolder: Sampling, Subfolder: Chain of Custody.
- An FSIS speaker at the 2013 InFORM meeting gave a presentation detailing FSIS' Chain of Custody guidance, policy and resources.

Laboratory Chain of Custody (CoC) Resources

- Office of Regulatory Affairs (ORA) Office of Regulatory Science (ORS)/Food Emergency Response Network (FERN) has a general chain of custody form that they have shared with FERN laboratories (based on the FDA 431, called GEN-COC-001, there is also an accompanying form that explains how to complete the GEN-COC-001), it is posted in eLEXNET, and also in the MFRPS FoodSHIELD WG under Standard 10 state resources folder. There is also a general template CoC form for sample transfer (for subsequent PFGE or serotyping analysis). Contact: Ruiqing.Pamboukian@fda.hhs.gov and Donald.burr@fda.hhs.gov.
    - Please note that the LRN Chain of Custody form is also posted in the MFRPS WG in FoodSHIELD
- Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories

  - Section III Quality Management Systems, Pre-Analytical Phase, Requirements for Chain of Custody
  - Appendix B: Sample Chain of Custody Form (GEN-COC-001)
- PFP Food/Feed Testing Laboratories Best Practices Manual:
  - Sampling Chapter (starts on page 20, see page 26 'Sample Custody' and 'Records/Documentation' in particular)
  - Analytical worksheet packages chapter (starts on page 35, see page 36 for a listing of sample chain of custody data fields to be included on the analytical worksheet).
- FDA ORA Laboratory Manual Vol. 3 – Section 2 Chain of Custody – Sample Handling
- Guidance for Industry - Submission Of Laboratory Packages By Accredited Laboratories
  - Note that this resource is specific for industry's use of an accredited laboratory (typically a private laboratory) to provide proof to FDA to support admissibility of imported products (removing a product from import alert for detention without physical examination).
- VA DCLS' presentation on chain of custody at the laboratory (slide presentation posted on FoodSHIELD in the RRT Program WG as part of the June 2014 RRT Monthly Meeting slide deck).
- An FSIS speaker at the 2013 InFORM meeting gave a presentation detailing FSIS' policy on the use of sample results from non-FSIS laboratories (including a review of sample integrity/chain of custody and the method of analysis, etc.).

Resources to inform content/submission of a State sample package to support FDA regulatory action (especially laboratory data):

- FDA Regulatory Procedures Manual (RPM) Chapter 4-3 "Use of State Evidence for FDA Warning Letters and Untitled Letters": http://www.fda.gov/iceci/compliancemanuals/regulatoryproceduresmanual/ucm205501.htm
  - This provides the criteria for evaluating use of state inspectional observations and/or state laboratory data to support FDA warning letters and untitled letters.
- The "Analytical Worksheet Packages" chapter of the PFP Food/Feed Testing Laboratories Best Practices Manual includes a list of elements that should be contained in the analytical worksheet package to be submitted to FDA for potential regulatory action (pages 36-38).
- Although not included in the "Analytical Worksheet Packages" chapter, that group also developed template analytical worksheets that adhere to the best practices outlined in the PFP Food/Feed Testing Laboratories Best Practices Manual, but are specific to a few common analyses (See list below). These are not currently posted anywhere, but are available upon request. Contact: Ruiqing.Pamboukian@fda.hhs.gov and Donald.burr@fda.hhs.gov.
  - SLM-PREP (sample prep worksheet for *Salmonella* analysis following BAM/AOAC/FERN methods using BAX, VIDAS or qPCR)
  - SLM-QC (quality control worksheet for *Salmonella* analysis following BAM/AOAC/FERN methods using BAX, VIDAS or qPCR)

    - BAM-SLM-VID (*Salmonella* analysis following BAM/AOAC Official Method 2004.03 [VIDAS])
    - BAM-SLM-CON-VID (*Salmonella* controls worksheet for BAM/AOAC Official Method 2004.03 [VIDAS])
    - AOAC-SLM-BAX (*Salmonella* analysis following BAM/AOAC Official Method 2003.09 [BAX])
    - AOAC-SLM-CON-BAX (*Salmonella* controls worksheet for BAM/AOAC Official Method 2003.09 [BAX])
    - FERN-SLM-QPCR (*Salmonella* analysis following BAM/FERN-MIC.0008.01 [qPCR])
    - FERN-SLM-CON-QPCR (*Salmonella* controls worksheet for BAM/FERN-MIC.0008.01 [qPCR]))
- Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories
- Some states may be willing to share a basic breakdown of what they submitted for a sample that was successfully used to support FDA regulatory action (e.g., analyst certification, analytical worksheets, details on methodology, collection report, chain of custody).
- It's important to note that depending on the incident, FDA may request additional information (depends on the technology/method/analyte/matrix and other contextual details).
- Guidance for Industry - Submission Of Laboratory Packages By Accredited Laboratories
    - Note that this resource is specific for industry's use of an accredited laboratory (typically a private laboratory) to provide proof to FDA to support admissibility of imported products (removing a product from import alert for detention without physical examination).

Attachment D – Examples of General and Commodity-specific Questionnaires for Various Food Operations

- FDA Office of Regulatory Affairs (ORA) Outbreak Response Field Guides:
  - http://www.fda.gov/ICECI/Inspections/ucm211781.htm

- FDA Farm Investigation Questionnaire (Nov. 2014):
  - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072131.pdf
  - Also available in FoodSHIELD, RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Investigations and Traceback, Subfolder: Revised FDA FIQ (2014)

- FL Dept. of Ag. and Consumer Services:
  - Tomato Audit Checklists (FL RRT): http://www.freshfromflorida.com/Business-Services/Fruit-and-Vegetables/Tomato-Good-Agricultural-Practices-T-GAP
    - Food Safety Audit - Field Packing [PDF] : http://forms.freshfromflorida.com/07081.pdf
    - Food Safety Audit - Greenhouse [PDF] : http://forms.freshfromflorida.com/07083.pdf
    - Food Safety Audit - Packinghouse [PDF] : http://forms.freshfromflorida.com/07085.pdf
    - Food Safety Audit - Repacker [PDF]: http://forms.freshfromflorida.com/07086.pdf

- Colorado Integrated Food Safety Center of Excellence (see 'Toolbox'):
  - https://www.softchalkcloud.com/lesson/serve/RoSKFB5g9ZtmN2/html

- Commodity Specific Investigation Guides (MI RRT). Available in FoodSHIELD, RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Investigations and Traceback, Subfolder: MI RRT Commodity Specific and EA Documents.
  - MDARD Investigator Guidelines for LACF Low Acid Canned Foods.doc
  - MDARD Investigator Guidelines for leafy green producers.doc
  - MDARD Investigator Guidelines for Food Manufacturers.doc
  - MDARD Investigator Guidelines for Acidified Food Manufacturers.doc
  - MDARD Investigator Guidelines for Sprout Producers.doc

- General Food Establishment Environmental Assessment Tools (MI RRT). Available in FoodSHIELD, RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Investigations and Traceback, Subfolder: MI RRT Commodity Specific and EA Documents.
  - Part 1 (Attachment D-1): Food Establishment Environmental Assessment Quick Reference Tool for Foodborne Illness Investigation (Not Routine Inspections)
    - File name: Food Establishment Environmental Assessment Quick Reference Tool MI RRT.pdf
  - Part 2 (Attachment D-2): Environmental Assessment Generic Worksheet
    - File name: Environmental Assessment Generic Worksheet MI RRT.pdf

- FDA Environmental Assessment Process Overview (Attachment D-3)
  - Available in FoodSHIELD, RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Investigations and Traceback, Subfolder: FDA Environmental Assessment Process Overview

Attachment D-1 – Food Establishment Environmental Assessment Quick Reference Tool for Foodborne Illness Investigation (Not Routine Inspections)

Environmental Assessment Reference Tool
Not Routine Inspections!

I. *Objectives*

- Identify foods and beverages matching description of foods reportedly consumed by ill persons
- Reconstruct past events (i.e. when implicated foods were produced)
- Identify contributing factor(s) leading to outbreak
  - i. **C**ontamination
  - ii. **S**urvival
  - iii. **P**roliferation
- Implement effective control actions

II. *Systems Approach to Environmental Assessments*

"When you have a foodborne outbreak, more than one thing went wrong." *Dr. Frank Bryan, Centers for Disease Control and Prevention*

Take time to look for interactions!

- Agent (Review IAFP *Procedures to Investigation Foodborne Illness*; *Control of Communicable Diseases Manual*, etc.)
- Employee Health, Hygiene and Education
  - i. Food handler illness
  - ii. Work practices (SOP)
  - iii. Sick worker policy
  - iv. Hand washing policy
  - v. Employee traffic patterns
  - vi. Food safety education provided
- Food
  - i. Menu – foods and beverages
  - ii. Quantities produced
  - iii. Ingredients
  - iv. Food characteristics (e.g.: pH, A_w)
  - v. Expected microbial content
  - vi. Intended use and consumers
- Facility
  - i. Floor plan
  - ii. Equipment design and maintenance
  - iii. Equipment location and use
  - iv. Food flow patterns
  - v. Sanitation
  - vi. Segregation
  - vii. Packaging
  - viii. Conditions of storage

III. *Stages of Typical Assessments*

- Planning
  - i. Pre-meeting
  - ii. Review of available information
    1. Epi, facility history, agent
  - iii. Identify scope and objectives
  - iv. Gather resources
- Preliminary Onsite Data Gathering
  - i. Meet and Interview manager(s)
    1. Explain reason for the investigation
    2. Outline objectives
    3. Create cooperative relationship
    4. Assess
       - a. Food safety knowledge
       - b. Attitude
       - c. Credibility
  - ii. Clarify Time Frame of Interest
    1. Range of purchase dates
    2. Describe implicated food
       - a. List of ingredients
       - b. Sources
       - c. Delivery times and dates
       - d. Physical characteristics
  - iii. Gather facility information
    1. Production lots involved
    2. Ongoing production of product?
  - iv. Observe operations (start to finish or "clean" to "dirty")
    1. Initial walk through
    2. Measure critical operations before modified
  - v. Collect samples while available
  - vi. Interview food workers who prepared food
  - vii. Review available records
    1. SOPs – intended procedures
    2. Processing records
    3. Collect copies of invoices (if commercially processed is food implicated)
       - a. Batch or lot #s
       - b. Dates shipped and received
       - c. Quantities received
  - viii. Compile information
    1. Consistency?
    2. Level of confidence in information gathered?
    3. What is known and what remains unknown?
  - ix. Make flow diagram
    1. Name of food workers

Environmental Assessment Reference Tool
Not Routine Inspections!

2. Results of measurements (e.g. temp)
3. Equipment used

- Hazard Analysis: IAFP Process
  - i. Build on preliminary information
  - ii. Identify contributing factor(s) leading to outbreak (C, S, or P)
  - iii. Steps
    1. Observation of operations
    2. Assess controls
    3. Collect additional samples
    4. Additional employees interviews
- Take Needed Control Actions
  - i. Hold
  - ii. Seize
  - iii. Licence/menu limitation
  - iv. Exclusions/Restrictions
  - v. Traceback or Recalls
- Documentation
  - i. Food flow chart
  - ii. Facility diagram tracing food flow
  - iii. Laboratory test results
  - iv. Written narratives
    1. methods
    2. observations and results
    3. conclusions
  - v. Other: photographs

IV. Interviewing Principles

- Establish Rapport
  - i. Identify yourself, your organization, and reason for investigation
  - ii. Inform individuals – multiple re-interviews might be needed
  - iii. Start with easy questions
- Practice effective listening skills
- Interview person in charge and others with direct food contact
  - i. Interview (directed and purposeful)
  - ii. Observation (non-verbal clues)
  - iii. Consistency of information and reaction to questions?
- Food Worker Interview Hints
  - i. Reconstruct timeline
  - ii. Let them tell their story
  - iii. When they cannot remember specific details:
    1. Ask about typical work practices and routines
    2. Any unusual events or changes during time period?
    3. Outbreaks occur when process "stressed"
  - iv. Reword questions as needed
  - v. Be persistent, patient and respectful
- Conclude the Interview
  - i. Ask if individuals have unanswered questions or additional comments
  - ii. May have information not previously considered
  - iii. Thank them for their time & give them your contact information

V. Food Samples

- Documented epidemiological associations required prior to testing foods
- Consult Supervisor or Lansing and lab staff
- The lab will examine most likely suspect foods first
- Jurisdiction
  - i. MDCH lab responsible for testing foods implicated by investigation. Exception – histamine testing in fish done by MDARD
  - ii. MDARD lab responsible for:
    1. Routine regulatory sampling
    2. Determining food characteristics (pH, water activity)
- Hand Hygiene
  - i. Wash hands before gloving
  - ii. Recommend use of hand sanitizer
  - iii. Put gloves on without contaminating them
- Aseptic Sampling—assure sampling method does not increase microbial load
  - i. Typical Sampling Equipment (request sampling kit)
  - ii. Sampling Strategies (refer to sampling protocol for various sampling possibilities)

VI. Food Worker Health

- Specimens from food workers
  - i. Ill during time period of interest, and
  - ii. Still experiencing symptoms
- Reconcile supervisor and coworker recollections
- Document

January 2012

Attachment D-2 – Environmental Assessment Generic Worksheet

Use this worksheet to aid in conducting Environmental Assessments (EA). An EA is not a routine evaluation, but an attempt to identify and document events that occurred when the product of interest was handled, processed, or served. Each EA is different and this worksheet is not all inclusive. Document violations on FI-101 and document significant information obtain during the EA on a Special Report.	
Off-site planning. Pre-plan with the assessment team, sample team, and supervisors to identify the product and timeframe of interest and to set the objectives for the EA. Review facility history, commodity details, past outbreaks, laws, and policies as appropriate.	
Product of Interest:	
Timeframe of Interest:	
Assessment Objectives:	
On-site assessment. Interview person(s) in charge (PIC), managers, and food handlers to determine operational details and to document what procedures in firm has in place:	
Meet with PIC:	Conduct interview, assessment, and timeline reconstruction with the PIC. Inform PIC of the purpose of the assessment. Obtain menu and description of product of interest.
Walkthrough facility:	Complete (or verify existing) facility layout diagram to identify food flow, food processes, production rooms, and equipment location.
Assess managers:	Assess manager knowledge of procedures for supervising employee health, hygiene, and handling practices, training, compliance with laws, and etc.…
Assess food handlers:	Assess employee health, hygiene, handling practices, and knowledge. Determine the total number of employees and the number of employees that directly handled product of interest, turnover rate, and recent employee changes.
Observe and document the process. During the assessment, make observations to verify that procedures described during interviews are actually in place and followed. Describe the process, food handlers, critical control points, critical limits, equipment, contamination sources, and opportunities for pathogen survival at each step. **Collect and assess information to describe and document each of the following steps (as applicable):**	
Overall process:	Develop (or verify) flow chart and identify ingredients, outputs, characteristics and times.
Receiving or shipping:	Describe schedules and amounts, sources, usage, product specifications, rejected product, etc.
Storage:	Assess location, capacity, temperature, adequate separation, contamination prevention, and etc… for raw materials and finished product storage.
Processing or handling:	Describe times and temperatures relationships, cleaning and sanitizing, employee handling, hand-washing, cross-contamination opportunities, contamination sources, recent changes to procedures, batch sizes, critical operations, and etc… for each step of the process.
Finished product:	Describe product (i.e. finished packaging, intended storage and use, shelf life, method of sale, label instructions, code information, packaging conditions, and contamination sources).
Facility details:	Describe equipment, security controls, contamination sources, sanitation, related firms, vermin activity, chemical usage, employee traffic, air system, water and wastewater systems,
Records or evidence:	Collect photos, logs (i.e. temperature, cleaning, usage), test results, SOPS, HACCP plan, complaints, third party audits, LACF process schedule, corrective action taken by firm, and etc.
Organize, document, and communicate findings. Document violations on an FI-101 evaluation form and summarize other findings on a Special Report. Include Facility layout, flowchart, narrative, sample report, photos, invoices, logs, and etc… collected during the EA. Include immediate and long term controls, corrective actions, seizure, or risk control plans.	
Related Assignments. Collect samples or conduct traceback, traceforward, or recall activities as assigned.	

Attachment D-3 – FDA Environmental Assessment Process Overview

U.S. FOOD & DRUG ADMINISTRATION

Environmental Assessment Process Overview

February 9, 2017; Version 1.0

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
FDA.GOV

Table of Contents

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
FDA.GOV

INTRODUCTION

An environmental assessment (EA) is an in-depth investigation of the environments associated with a food that is implicated in a foodborne illness outbreak or other food contamination incident. The purpose of an EA is to identify *contributing factors* and *environmental antecedents* that led to the contamination or food safety event, and to provide recommendations to prevent reoccurrence, otherwise known as root cause analysis. EA activities may be conducted as either a Regulatory Environmental Assessment or a Non-Regulatory (i.e. Cooperative/Research) Environmental Assessment[1].

During an EA, internal and external experts, known as Subject Matter Experts (SMEs), from the Office of Regulatory Affairs (ORA), the Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), other Federal, State, Tribal, and local agencies and/or industry as appropriate, perform EA activities to investigate an outbreak or food contamination event and used to assess the findings when needed.

An EA will routinely have an initial focus upon the immediate environments within farms and food firms that are associated with the implicated food, but as an EA progresses potentially connected environments outside of an implicated farm or firm may be identified and included in the assessment.

I. PURPOSE OF THE ENVIRONMENTAL ASSESSMENT OVERVIEW DOCUMENT

In this document, we outline the process for proposing and initiating an EA (Section III), preparing for an EA once the decision has been made (Section IV), planning and executing EA activities (Section V), and reporting once the EA is completed (Section VI). Because an EA requires various types of expertise, we also outline the process for assembling a team in Section IV. Identifying lessons learned is discussed in Section VII.

The data and information collected during an EA are intended to be utilized to assist Agency's policy, regulatory procedures, and agency stakeholders, including the regulated industry, regarding appropriate preventive controls that can be implemented to prevent food contamination.

[1] The decision factors and how to determine which method to use can be found in [CPG xxx link to be provided when published].

II. FACTORS TO CONSIDER WHEN REQUESTING/INTITIATING EA ACTIVITIES

Various entities within FDA may request to initiate an EA, including ORA Headquarters (HQ) Offices (i.e. Office of Food Feed Operations (OFFO)), Centers (e.g. CFSAN, CVM), Coordinated Outbreak Response and Evaluation (CORE) Network, and District Offices (DO). EA activities may also be initiated by a state. In addition, the requesting entity may collaborate with others, as appropriate, on specific EA activities (which may include academia or industry as Special Government Employees (SGEs) or to commission other federal agencies or state/local partners to conduct an EA).

Funding could be a consideration when deciding whether to initiate an EA or not. EAs are not centrally funded, so all travel expenses are typically covered by each team members' respective office(s).

The requesting entity (in consultation with FDA partners, such as Office of the Chief Counsel (OCC), ORA HQ, CFSAN's Office of Compliance (OC), and CVM's Office of Surveillance and Compliance (OSC), if animal related, will consider certain factors to determine if FDA will request to initiate EA Activities. These factors and the Agency's current thinking can be found in the EA Compliance Policy Guide that will be published by OPRM.

After all pertinent factors have been considered, FDA partners from ORA OFFO, CFSAN OC, CVM OSC (if animal related), and the Coordinated Outbreak Response and Evaluation (CORE) Network Senior Leadership, if related to an ongoing outbreak, should reach consensus on whether to request to initiate an EA or not. If a consensus cannot be reached, the requesting entity will draft a memo as identified in Section III for review by the ORA Office of Operations (OO) Assistant Commissioner for Operations (ACO) for final determination whether to initiate an EA.

When the requesting entity is a State partner, it is recommended that these factors, along with the procedures outlined in this document, be used as a guide in their decision to conduct the EA. If FDA is invited to accompany the State team or if this is associated with an outbreak being investigated by FDA CORE, FDA recommends that the State coordinates with CORE and the FDA home office, as appropriate.

III. REQUEST AND INITITATION OF AN EA

Once the initial decision has been made that an EA should be conducted (or consensus cannot be reached to conduct an EA), the entity that would like to initiate the EA will prepare a memo to the Assistant Commissioner for Operations (ACO) (ORA/OO) which includes the following:

- Objectives

- Factors considered for proposing an EA
  - Laboratory Data/Evidence
  - Trace back Data
  - Epidemiological Data
  - Historical Outbreak Data related to the suspected commodity and pathogen
  - Historical Research on the Area(s) Affected
  - Timing of Outbreak and Contamination
  - Scope of EA suggested
  - Recurrence
- A history of the firm/farm/commodity implicated
- (ANY OTHER DATA NEEDED TO SUPPORT THE REQUEST)

As the ACO is the decision maker for expending field resources, this memo will be used by the ACO to determine if an EA is warranted and if field resources will be expended. The ACO may request a meeting to discuss and ask questions. If the ACO determines the EA is warranted, the ACO will provide concurrence in writing (such as a signature on the memo, email, etc.).

IV. ENVIRONMENTAL ASSESSMENT PREPARATION

After approval by the ACO, the entity who will initiate the EA will then provide a written document to ORA/OFFO, OFFO/DFFPOI, CFSAN OC, CVM OSC (if animal related), CORE and the affected DOs outlining the information provided to the ACO as well as identifying the next steps and further information. These next steps may be known or gathered through collaboration with ORA HQ, CFSAN, CVM, and/or CORE personnel. The next steps may include:

- Establishment of a ICS structure or steering committee for the actual planning of the EA
  - ORA HQ (OFFO/DFFPOI)
  - CFSAN OC and SMEs
  - CVM OSC and SMEs (If animal related)
  - CORE
- Identify Team Members
- Identify Specific Locations
- Identify Specific Questions to be answered
- Timeline
- Samples/Supplies needed
- Funding

Further information to be included in the written packet includes:

- Etiological Agent Background Information
  - Consult with SMEs and use available guidance, information, and research reports to assemble a dossier of pertinent information regarding the agent associated with the incident.
  - If limited data and information are available regarding the agent of interest, the initiating entity will attempt to conduct and compile a review of the scientific and technical literature.
  - Data and information should include environmental conditions that are conducive to the persistence, growth and spread of the agent of interest, with particular emphasis given to the growing, harvesting, packing, processing, and holding conditions that are employed by the firm (if known).
  - Identify and compile known preventive controls for the specific food vehicle / agent combination associated with the incident.

- Relevant Incident and Resource Documents
  - Obtain a written summary of all available trace back, inspection and compliance history of firm or farm, and laboratory data from the affected state(s) and the District(s), as appropriate.
  - Obtain a current line list of cases of illness, excluding patient identifiers, with exposure dates, onset dates, isolation dates, clinical isolate data, and food exposure history from CORE, as appropriate.
  - Review appropriate guidance documents for the implicated commodity, as appropriate.
  - If possible, obtain food safety plans and third party audit reports.
  - Prepare a trace back document for the EA team to use during the on-site visit at the firm, as appropriate.
  - Prepare redacted establishment inspection reports (EIR) and trace back documents for EA team members, as necessary.

- Information Sharing
  - Prepare redacted EIR and trace back documents to EA team members, as necessary
  - Prepare information to be shared with individuals included under confidentiality agreements, 20.88, or FDA commissioned state representatives.

After supporting documentation is gathered, it is important to identify the appropriate team members. Team members may be from Federal/State/Local government, Academia, etc. Members of the EA team will have responsibilities based on their expertise and the needs of the team. The EA team will typically consist of FDA staff (field and/or Headquarters) and state and local partners. Depending on the agent and food vehicle combination, the team members may consist of the following:

- Lead ORA District Investigator/Consumer Safety Officer
- Environmental Health Specialist
- Epidemiologist
- Microbiologist /Virologist/Chemist
- ORA National Expert or SME*
- Commodity Specific SME*
- Pathogen Specific Sampling SME*
- Federal, State, Tribal, and/or Local Health Department Emergency Response/food regulatory, laboratory or epidemiology personnel**

- Other expert consultants that are Special Government Employee (SGE) as needed (wildlife expert, veterinarian, hydrologist)

*-If a Subject Matter Expert (SME) is unable to be physically present during an EA, arrangements should be made to have the SME(s) available by phone to answer questions during the EA.
**-Rapid Response Team (RRT) should be utilized when available.

The Initiating Entity in coordination with ORA HQ (OFFO/DFFPOI) will create an assignment for the EA. In addition, the initiating entity and the EA Team will:

- Schedule an EA team planning meeting (See Section VI.A below)
- Establish timeframe and dates of the EA.
- Coordinate EA planning conference call with EA team and other identified parties involved in the planning process.
- Define the scope of the EA as determined by a joint collaboration call.
- Plan EA team logistics and travel plans.
- Schedule meetings with the firm as needed to include appropriate team members.
- Identify points of contact within the initiating entity, ORA, and Center for subsequent follow-up to answer questions/provide resources
- Determine what supplies are needed (see IOM section 5.2.1, "Pre-Inspectional Activities") and determine if resources are available. Make arrangements for obtaining needed supplies not readily available.
- Discuss the sample collection process and sampling procedures (See Section VI.B below).
- If an SME and/or a SGE are unable to join the EA team in the field, plan for the SME/SGE to be available via teleconference.
- See IOM 5.2.1.2 Personal Safety to determine whether a Personal Safety Plan (see IOM 5.2.1.4) is appropriate.

It will be important to ensure laboratory capacity and testing capability based on types and number of samples collected through ORA Office of Regulatory Science (ORS), CFSAN ORS, CVM Office of Research (OR) if animal related, and/or other laboratories (Food Emergency Response Network (FERN)) as appropriate. It is expected that samples will be collected. NOTE: If an EA is conducted outside of the continental United States, contact DFDT to assist with obtaining prior notice for any samples sent back to the United States.

As part of the preparation phase, the team should (certain items below may be conducted for the EA team by the initiating entity):

- Identify types of samples to collect at the firm or farm (ingredient, finished product, water, environmental swabs, animal feces, soil, others, etc.).
- Identify location of overnight shipping offices (FedEx, UPS, U.S. Post Office).
- Identify ORA, State, Center, or other laboratories to conduct analysis.
- If Saturday delivery to a laboratory is necessary, ensure personnel support of such delivery, receipt, and acceptance of samples to initiate analysis.
- Determine if use of multiple laboratories is indicated.

V. ENVIRONMENTAL ASSESSMENT ACTIVITIES

Environmental Assessment Team Planning Meeting

The EA team chosen to participate will meet to discuss information sharing, hypothesis generation and planning. This meeting will take place prior to the pre-meeting with the firm. The documents that have been gathered as part of the assignment and provided to the team should be reviewed prior to meeting. Items to review, discuss, and update if needed include:

- Review the epidemiologic data,(if EA is being conducted in response to an outbreak if available, and environment-related data (e.g., for farms - soil, water, workers, animals; for manufacturing/processing - raw materials and ingredients, water, employees, facility environment, manufacturing procedures and equipment used) as a group.
- Use appropriate guidance and principles to develop hypotheses regarding potential routes for contamination.
- Determine the role of each EA team member.
- Review satellite imagery, topographical and hydrographical maps, etc.
- Review the layout of the firm/farm.
    - Outline potential contributing factors to contamination and environmental antecedents.
- Review applicable guidance documents, regulations, other regulatory requirements, and available firm history
- Obtain and review recent weather patterns, weather records, weather-related phenomenon (e.g., flooding, etc.).
- Consider additional questions to ask beyond established questionnaire (see Appendix B).
- Consider questions to ask related to environment, manufacturing processes and equipment that are theorized to be potential contributing factors.
- Develop causal diagram and possible hypothesis to review during EA, if possible.
- Determine pre notification of EA to the firm/farm.

Sample Collection Logistics

Based on the types of samples identified to be collected at the firm/farm (ingredient, finished product, water, environmental swabs, animal feces, soil, other):

- Use the causal diagram, if developed that shows the potential causes of the specific event (i.e. fishbone diagram or FMEA diagram).
- Identify specific locations to sample. Review in conjunction with facility floor plans and other firm/farm layout information.
- Discuss the sample collection process and ensure team members possess any necessary training.

  - Determine who will conduct the sampling (the number of people conducting the sampling will be determined by the size of the area to be sampled and the type of samples being collected). See "Sample Collection" – Section V.C.6.a-c.
- Determine if Documentary (DOC) samples will be obtained.
- Refer to the IOM Chapter 4, Sampling. If the EA is being conducted as a regulatory inspection, follow IOM procedures for collection of Official Samples.
- It is important to know, if OCONUS, the nearest international shipper due to importation requirements.

Pre-Environmental Assessment Meeting/Interview with the Firm/Opening Meeting

Once the EA team has arrived at the firm/farm, the initial interview/opening meeting with the firm/farm (appropriate, responsible individuals) will be conducted:

- The entire EA team will be present during the interview with the firm/farm (if possible).
- The lead CSO or designated spokesperson will be the main conductor of the interview.
- During the interview, brief the firm regarding the EA procedures including sample collection process and timeline.
- Allow the firm/farm to ask questions.
- Record information and take notes. See IOM 2.1 Regulatory Notes for guidance on note taking.
- Refer to IOM Chapter 5.2.7, Discussions with Management, for guidance on interacting with firm officials and discussions with management.

The opening meeting is to gather information and ask questions of the firm/farm. During the opening meeting, the EA team will perform the items listed above.

Conduct Environmental Assessment Activities

The EA Team will conduct the environmental assessment as planned. If modifications are necessary, the team may make those modifications on site as long as there is a reason to do so.

Post-EA Meeting/Interview with the Firm/Farm

- Brief the firm's/farm's most responsible management representative(s) on the preliminary observations and findings throughout the EA and upon closing out the EA.
- Ask any additional follow up questions.
- Allow the firm/farm to ask follow up questions.
- Document information and take notes. See IOM 2.1 Regulatory Notes for guidance on note taking.
- Refer to IOM Section 5.2.7, Discussions with Management for guidance.

VI. ENVIRONMENTAL ASSESSMENT FINAL REPORT

The purpose of the EA Report is to provide a record of any findings as well as any hypotheses regarding environmental antecedents and contributing factors that may have led to a contamination event. The EA Report focuses on contributing factors and environmental antecedents and is intended to prevent future instances by not only informing industry as part of best practices recommendations (e.g. Appendix B4 -GAPS), but to also serve as a training resource for future investigations.

What is in the EA Report? (See Appendices C & D for formats)

This report should include a brief background, observations relevant to the incident, summary of significant sample results, in addition to predominant theories, supporting analysis of data, and conclusions from the EA. The EA report is intended to be a stand-alone document that compliments, but is not based on, an EIR (Establishment Inspection Report, if completed). EA Reports differ from EIR in that the EA Team will develop and record their theories as to the source and route of contamination and discuss analysis of findings supporting identification of potential causes of contamination and factors leading to the survival/proliferation/distribution of the implicated pathogen.

Differences between an EIR and an EA Report

The EA report is an investigative report and contains hypotheses, findings and conclusions that are not traditionally included in an EIR. Although there may seem to be much overlap between an EIR and an EA Report, they serve different functions. As such, they will differ both in content and in format. For instance, an EIR should adhere to the format and content as specified in the IOM Section 5.10.3.1. The EA Report should follow the appropriate format as outlined in Appendices C & D. In essence, the EA Report will not cover the following topics which are to be covered in the EIR:

- Business practices that do not bear impact on the investigation
- Jurisdiction
- Interstate Commerce
- Refusals (unless this affected conduct of the EA)

IOM required EIR headings are not normally used in an EA report; the format in either Appendix C or D should be followed to the extent possible

An EA final report will be written by the EA team. The lead CSO is to ensure that the report is reviewed and approved by the supervisors of the EA team members (only required for FDA employees). This report will include observations, sample results, and conclusions from the EA. The EA report will be a stand-alone report and not part of any EIR.

A. Upon completion of the EA, the EA team will prepare a draft of the final report. The team will draft the final report using the final report template (Appendix C/D).[2]
    1. The EA final report template may be adjusted, as necessary, by the EA team, to eliminate non-relevant sections or to add additional information.

B. Once sample results are available, the EA team will reconvene (via teleconference) to add the results and interpretations to the EA final report draft. At this time, the draft final report will undergo a final revision by the EA team prior to being finalized and signed by participating EA team members. As per FDA policy, the signatures may be electronic.

C. An EA final report should be completed by the team typically within one week of receipt of final sample results or at a date established by participating agencies.

D. After the EA Report is completed by the EA team, the EA Report will be reviewed by the EA Team and submitted to the District/Direct Supervisors of the EA Team. Depending on the EA approach, the EA Report should be reviewed by all participating agencies.
    - All direct supervisors should have one chance to comment on the final report. Their comments will be evaluated and incorporated if needed. This review is not expected to be a recurring review.

E. The District/Direct Supervisor (of the lead CSO) will submit the approved EA Report to ORA HQ DFFPOI and the home DO, CFSAN OFS and OC, CFSAN, CVM (if animal related) OSC, and the assigned CORE Post Response team, if outbreak related , for review and comment. This should be completed within one week and comments in track changes should be returned to the CORE Post Response Team for outbreaks, and the district for non-outbreak related EAs.

F. All participating entities (EA Team, District, CORE, and HQ SMEs) should concur with the final draft of the report.

G. Publications utilizing the EA report as a reference material may be generated – redacted EA reports and other publications will typically be posted on FDA's website. A portion or abstract of the report may be published online. This can be a shortened or redacted version of the report, but the original report will be maintained by the district office for future use and reference. In this case, the initiating entity will determine additional parties to review the report for support of public document generation; including but not limited to OCC. Communications will use appropriate and clearance procedures to post the report on FDA's website, as appropriate.

The review process described in Bullets D and E above is necessary as a "check and balance" to ensure that critical information is not edited out of the report for brevity or other reasons. The EA Team and SMEs review are essential prior to finalization of the report and their concurrence is required. However, it is expected that an abstract of this report providing a summary of the incident, observations and critical findings will be posted on the FDA Website and not the entire report.

[2] The EA templates were developed in the context of an EA regulatory inspection. To the extent a Cooperative/Research EA inspection is conducted, these templates may be modified accordingly. [4]CORE may be involved if an EA is part of an outbreak investigation, or follow up to an outbreak investigation.

VII. AFTER ACTION REVIEW

The EA team will conduct an after action review to review where the process worked well and areas for process improvement. The lessons learned review will be led by the initiating entity.

Notes will be taken during the review and distributed to all affected parties. Where appropriate, corrective actions may be undertaken by the responsible office. Proposed revisions of procedural documents and processes will be initiated by the responsible office and circulated to ORA HQ, CFSAN OC, CVM OSC (when appropriate), and OCC.

This is intended to be a living document that can be updated and improved after every use. Update requests/suggestions to this EA document can be directed to Eric Pittman, Director, DFFPOI.

APPENDIX A: ACRONYMS AND DEFINITIONS

Acronyms

ACO – Assistant Commissioner for Operations
CDC – Centers for Disease Control and Prevention
CFSAN – Center for Food Safety and Applied Nutrition
CORE – Coordinated Outbreak Response and Evaluation
CSO – Consumer Safety Officer
CVM – Center for Veterinary Medicine
DFFPOI – Division of Food and Feed Program Operations and Inspections (ORA)
DO – District Office
DOC – Documentary Sample
EA – Environmental Assessment
EIR – Establishment Inspection Report
EPA – Environmental Protection Agency
FACTS – Field Accomplishment Compliance Tracking System
FDA – Food and Drug Administration
FERN - Food Emergency Response Network
FFPOB – Food and Feed Program Operations Branch (ORA)
FMEA Diagram – Failure Mode Effects Analysis Diagram
GAPs – Good Agricultural Practices
CGMPs – Current Good Manufacturing Practices
GPS – Global Positioning System
IOM – Investigations Operations Manual
ISO – International Organization for Standardization
OC – Office of Compliance (CFSAN)
OCC – Office of the Chief Counsel
OFFO – Office of Food and Feed Operations (ORA)
OO – Office of Operations (ORA)
OR – Office of Research (CVM)
ORA – Office of Regulatory Affairs
ORAHQ – Office of Regulatory Affairs Headquarters
ORS – Office of Regulatory Science
OSC – Office of Surveillance and Compliance (CVM)
RFR – Reportable Food Registry
RRT – Rapid Response Team
SGE – Special Government Employee
SME – Subject Matter Expert
UPS – United Parcel Service

USDA – United States Department of Agriculture

Definitions for Purposes of This Document

Contributing Factors: Determinants that directly or indirectly cause an outbreak/product contamination. Contributing factor can be biological, behavioral, or attitudinal; or an element of the physical or social environment; or the result of policies related to the problem. Contributing factors are those that led to a foodborne illness outbreak or food contamination event.

- Example: Lack of proper training led the food preparer to undercook the food that led to a foodborne outbreak.
- Contributing Factor: Undercooked food
- Environmental Antecedent: Lack of proper training

Documentary (DOC) Sample: An official sample (as defined in the 2014 IOM) where no actual physical product is taken. A DOC sample is collected based upon the documents accompanying the shipment, such as freight bills, bills of lading, etc., or any other record or document related to the lot or item involved. DOC samples are collected in situations where an actual physical sample is not practical or where there is little or no need for laboratory analysis. In addition to copies of transportation records, this official sample may consist of labels, photos of the product, drawings, sketches, etc.

Environmental Antecedents: Supporting factors to the contamination, survival or increase of biological or chemical agents in food. They may be related to people, equipment, food process, food type, economics, or other circumstances. In other words, they are why the contributing factors happened. Antecedents are sometimes referred to as **root causes** of foodborne outbreaks. Factors that most likely caused the contributing factors.

- Example: Lack of proper training led the food preparer to undercook the food that led to a foodborne outbreak.
- Contributing Factor: Undercooked food
- Environmental Antecedent: Lack of proper training

Environmental Assessment: In a foodborne illness outbreak or contamination event, the systems based component that fully describes how the environment contributed to the introduction and or transmission of agents that cause illness or could cause illness. Environment is everything external to the host, including air, food, water, animals, plants, climate, etc. as well as people, social and built environments. All aspects of the external environment can be listed as variables that, in relation to transmission are neutral, conducive or protective. From this description, contributing factors and environmental antecedents to an outbreak or food contamination event can be determined.

- **Environmental Assessment Activities (EA Activities)**: Any event, task, or endeavor related to an environmental assessment, including but not limited to, an inspection, an investigation, or an on-site visit.

- **Initiating Entity:** Any FDA Office, Center, District Office, or other agency that proposes to conduct an EA.

- **Inspection:** Section 704 of the FD&C Act [21 U.S.C. 374] provides the basic authority for establishment inspections. This authorizes you to enter, and to inspect at reasonable times, within reasonable limits,

and in a reasonable manner, establishments and vehicles being used to process, hold or transport food, drugs, devices, tobacco products, or cosmetics.

- An EA may be conducted following a report of a foodborne illness outbreak or food contamination event and is focused on identifying the immediate on-site cause of the contamination, and in particular those findings that can be cited on a 483 report as well as in an EIR. These findings would pertain to requirements in either the relevant statute or implementing regulations, such as 21 CFR 110 or other section of the CFR as appropriate. The findings of the EA activities are documented in ways intended to demonstrate that violations of the regulations have occurred. Additionally, an EA may provide information that is not necessarily associated with a violation of the law; and this information can be addressed in the EA report in addition to findings that support violations

- Cooperative EA--Need to make sure definition from CPG matches
- Regulatory EA-Need to make sure definition from CPG matches

Investigation: Information gathering activity conducted for many different reasons. The purpose of an investigation is to determine and document facts concerning a particular issue so the agency can make informed and sound decisions. Investigation is a general term and can apply to a very general activity or a specific type of information gathering process.

Special Government Employees (SGE): An SGE is a member, consultant or expert appointed to serve a specific Center and/or an advisory committee(s) on an intermittent basis to provide specialized knowledge.

Subject Matter Expert (SME): experts in specific areas of knowledge or practice.

APPENDIX B: REFERENCES AND SUPPORTING DOCUMENTS

1. FDA'S Risk-Based Model for Prioritizing Inspections of Domestic Food Establishments At-a-Glance. http://www.fda.gov/downloads/Food/ComplianceEnforcement/UCM227828.pdf.

2. Form FDA 3623 Farm Investigation Questionnaire
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072131.pdf

3. FDA Investigations Operations Manual
http://www.fda.gov/ICECI/Inspections/IOM/default.htm

4. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, 1998
http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM169112.pdf

5. Guide to Produce Farm Investigations, 2005
http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074962.htm

6. IAFP "Procedures to Investigate Foodborne Illness – Sixth Edition 2011"
http://www.foodprotection.org/files/other-publications/procedures-forms.pdf

7. CDC Environmental Health Services: Systems Theory: http://www.cdc.gov/nceh/ehs/EHSNet/system-theory.htm

8. FDA Environnemental Assessment:
http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm235425.htm

9. Dippold L, Lee R, Selman C, Monroe S, Henry C. A gastroenteritis outbreak due to norovirus associated with a Colorado hotel. J Environ Health. 2003;66(3):13-7

10. Gelting R, Sarisky J, Selman C, Otto C, Higgins C, Bohan PO, Buchanan SB, Meehan PJ. Use of a systems-based approach to an environmental health assessment for a waterborne disease outbreak investigation at a snowmobile lodge in Wyoming. Int J Hyg Environ Health. 2005; 208(1–2):67–73.

11. Higgins CL, Hartfield, BS. A systems-based food safety evaluation: an experimental approach. J Environ Health. 2004; 67(4) 9–14.

12. Field Bulletins Index: http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/FieldInvestigations/ucm010365.htm .

13. Centers for Disease Control and Prevention: National Center for Environmental Health. Health Studies Branch – Promoting Clean Water for Health. http://www.cdc.gov/nceh/hsb/cwh/default.htm.

14. ORAU Investigator New Hire Training – Glossary. http://inside.fda.gov:9003/InsideFDA/downloads/EmployeeResources/Training/ORAUNewHires/UCM056024.pdf.

15. E-Learning on Environmental Assessment of Foodborne Illness Outbreaks. http://www.cdc.gov/nceh/ehs/eLearn/EA_FIO/index.htm

16. RRT Resources Manual – (RRT) http://www.afdo.org/Resources/Documents/6-resources/The%20RRT%20Manual_2013_FINAL.pdf

APPENDIX C: ENVIRONMENTAL ASSESSMENT FINAL REPORT TEMPLATE FOR FARMS

Environmental Assessment: Factors Potentially Contributing to the Contamination of *Insert Food/Product* Implicated in an Incident Event (outbreak, positive product and/or environment) (Insert *Pathogen/Illness/Agent)*

Background

- Brief history of the contamination incident (outbreak, positive product and/or environment)including:
  - Pathogen or Agent
  - Why the firm was implicated (e.g., by epidemiological/product trace back?)
  - Actions from the Firm (stopped distribution, market withdrawal, recall, etc.)
  - Product/retail samples
  - Previous firm inspections conducted by FDA or State partners related to the current outbreak
    - Briefly describe findings (and any onsite corrections made by the firm)
- Observations from initial regulatory inspection (if available)
- Epidemiology of the outbreak (if applicable)
- Explain why an EA is being conducted

Environmental Assessment Team Approach

The environmental assessment was completed by a multi-disciplinary team with expertise *in produce safety, agriculture, epidemiology, microbiology, environmental health, and sanitation* (modify as necessary) from FDA and *state partners, etc.*

The team used the Produce Safety Rule and produce-related guidance and principles to develop hypotheses regarding potential routes for contamination of *insert product*. Areas of focus for the agricultural production operations included:

The following list should be modified as appropriate for the specific activities:

- agricultural water
- biological soil amendments
- harvesting and transporting to the packinghouse
- animal intrusion
- adjacent land use

- employee health and hygiene practices

Similarly, the team used the Produce Safety Rule and produce-related guidance and principles to develop hypotheses for potential routes of contamination during operations in the packinghouse area. Areas of focus for the packinghouse included:

The following list should be modified as appropriate for the specific activities:

- packinghouse and equipment sanitary design
- pest control/intrusion
- cleaning and sanitizing practices
- washing and drying of <insert commodity>
- cooling <insert commodity>
- packing and holding of <insert commodity>
- transportation of <insert commodity>

I. Factors Potentially Contributing to the Introduction, Growth, and Spread of *Agent*.
   A. Growing Environment
      I. Fields and Adjacent Land Use
         I. Description of observations from each field/parcel
            I. Sample Results
      II. Field Product
         I. Descriptions
            I. Sample Results
      III. Agricultural Water
         I. Description/observation of each water source sampled
            I. Sample results
   B. Packing and Holding
      I. Packinghouse Design
      II. Equipment Design
         I. Sample Results
      III. Packing and Holding Practices

II. Summary and Conclusions
   A. Growing Environment
   B. Packing and Holding

III. Recommendations for Prevention of Pathogen or *Agent* Contamination Based on these Findings
   A. Refer to guidance documents as appropriate

IV. Table of Sample Results by Location *(as appropriate)*

References *(as needed)*

Exhibits *(as needed)*

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
FDA.GOV

APPENDIX D: ENVIRONMENTAL ASSESSMENT FINAL REPORT TEMPLATE FOR A FIRM THAT MANUFACTURES, PROCESSES, PACKS, OR HOLDS FOOD

Environmental Assessment: Factors Potentially Contributing to the Contamination of *Insert Food/Product* Implicated in an Incident Event (outbreak, positive product and/or environment (*Insert Pathogen/Illness/Agent)*

Background

- Brief history of the incident (outbreak, positive product and/or environment) including:
  - Agent
  - Why the firm was implicated (e.g., by epidemiological/product trace back?)
  - Actions from the Firm (stopped distribution, market withdrawal, recall, etc.)
  - Product/retail samples
  - Previous firm inspections conducted by FDA or State partners related to the current outbreak
    - Briefly describe findings (and any onsite corrections made by the firm)
- Observations from initial regulatory inspection (if available)
- Epidemiology of the outbreak (if applicable)
- Explain why an EA is being conducted

Environmental Assessment Team Approach

The environmental assessment was completed by a multi-disciplinary team with expertise *in food safety, epidemiology, microbiology, process engineering, environmental health, and sanitation* (modify as necessary) from FDA and *state partners, etc.*

The team used Preventive Controls, Good Manufacturing Practices (GMP), or other appropriate regulatory requirements (state which) and principles to develop hypotheses regarding potential routes for contamination of *insert product*. Areas of focus for the manufacturing, processing, and holding operations included:

The following list should be modified as appropriate for the specific activities:

- raw materials and ingredients
- water
- employee health and hygiene practices

- facility environment
- processing and handling practices
- sanitation practices
- pest control
- storage controls
- transportation controls
- supplier controls
- environmental monitoring
- finished product testing

V. Factors Potentially Contributing to the Introduction, Growth, and Spread of *Agent*.
   A. Raw Materials and other Ingredients
   B. Employees
   C. Processing Assessment
   D. Plant Environment: Post-process Contamination Assessment
   E. Finished Product Testing
   F. Other factors

VI. Summary and Conclusions

VII. Recommendations for Prevention of Pathogen or *Agent* Contamination Based on these Findings
   A. Refer to guidance documents as appropriate

VIII. Table of Sample Results by Location *(as appropriate)*

References *(as needed)*

Exhibits *(as needed)*

APPENDIX E: EA WORKGROUP MEMBERS

CFSAN

- DPS: Mike Mahovic, Amber Nair
- OC: Crystal McKenna
- OFS: Kathy Gombas (ret.)

CORE

- Kari Irvin, Susan Lance

ORA

- DO: James Chris Yee
- OP: Lauren Yeung, Travis Goodman
- OCC: Gloria Overholser
- HQ: Norm Fogg (ret.), Eric Pittman, Melanie Mayor, Margaret Persich, Rebecca Dreisch, Carla Tuite, E. Ashley Grant
- DHRD: Janet Williams, Audrey Vigil

Mitigation and Control

Chapter 13. Food Recalls

TABLE OF CONTENTS

1. PURPOSE

This chapter outlines and provides best practices for key areas of a recall strategy, and can be used by regulatory agencies when developing their own recall processes and procedures.

2. SCOPE

This chapter is focused on foods that are subject to FDA's jurisdiction.

3. RESPONSIBILITY

3.1. RRT (or investigatory team, in states without an RRT) Leadership

RRT leadership is responsible for ensuring that personnel assigned to perform tasks within a recall strategy have been provided with appropriate training.

3.2. RRT Members

RRT members are responsible for playing an active role in maintaining both their subject matter expertise and ability to work effectively in multidisciplinary and multi-agency response teams.

4. DEFINITIONS

4.1. Recall – A firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. *Recall* does not include a market withdrawal or a stock recovery.

4.2. Market Withdrawal – A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

4.3. Stock Recovery – A firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

4.4. Recall Classifications – The numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a product recall to indicate the relative degree of health hazard presented by the product being recalled (Refer to Attachment A for examples).

- **4.4.1.** Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- **4.4.2.** Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences. or where the probability of serious adverse health consequences is remote.
- **4.4.3.** Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

4.5. Consignee – Anyone who received, purchased, distributed or used the product being recalled.

4.6. Depth of Recall – The level of product distribution to which the recall is to extend:

4.6.1. Consumer or User level – All end users of a product including households and all levels of distribution which can include: hotels, restaurants, and other food service institutional consignees.

4.6.2. Retail level – This includes all retail sales of the recalled product.

4.6.3. Wholesale level – This is the distribution level between the manufacturer and the retailer. This level may not be encountered in every recall situation (e.g., the recalling firm may sell directly to the retail or consumer level).

4.7. Scope – This defines the amount and kind of product in question. For example, all products of a specific lot number produced during a specific date range. Distribution of the product can also be a factor in determining the scope of the recall.

4.8. Correction – The repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

4.9. Product – An article subject to the jurisdiction of the Food and Drug Administration, including any food intended for human or animal use.

4.10. Recall Effectiveness Check – Effectiveness checks assist in the verification that all known, affected consignees have received notification about a recall and have taken appropriate action. The firm has an obligation to conduct recall effectiveness checks as part of its recall strategy.

4.11. Audit Check – A personal visit, telephone call, letter or combination thereof, to a consignee of a recalling firm, or user or consumer in the chain of distribution made to verify all consignees at the recall depth specified by the firm's recall strategy have received notification about the recall and have taken appropriate action. Audit checks are selectively carried out by food regulatory agencies, separate from the effectiveness checks of the recalling firm, to assess the adequacy of a firm's recall efforts.

5. BACKGROUND

A food recall refers to a firm's removal or correction of marketed food products from commerce when there is evidence of a violation, such as products that are adulterated or misbranded under the provisions of applicable state and federal laws. Manufacturers and/or distributors may voluntarily initiate a recall at any time to fulfill their responsibility to protect human and animal health from products that present a risk of injury, gross deception, or are otherwise defective. Firms may also initiate a recall following notification of a problem by FDA or a state agency. Additionally, firms may initiate a recall in response to a formal or informal request by FDA or state agency, a mandatory recall statute, or an order issued by FDA or a state agency.

6. SAFETY

N/A

7. EQUIPMENT/MATERIALS

N/A

8. PROCESS DESCRIPTION

8.1. Product Recall Triggers

Issues that can trigger a product recall include:

- Epidemiological evidence demonstrating that a product may be linked to an outbreak;
- Laboratory results indicating that a product is contaminated and may be potentially hazardous;
- Regulatory evidence obtained during a facility inspection;
- Industry monitoring and reporting (e.g., Reportable Food Registry/RFR); and/or
- Consumer complaint investigations indicating that a product may be potentially hazardous.

8.2. Regulators' Roles and Authority

State regulatory agencies generally do not have the authority to order a recall. With the enactment of the Food Safety Modernization Act (FSMA), FDA was endowed with the authority to order a recall of a food where there is reasonable probability that the food (other than infant formula) is adulterated or misbranded and the use of or exposure to such food will cause serious adverse health consequences or death to humans or animals. Recalls are typically voluntary actions carried out by the manufacturer or distributors of the food product. In some cases, a company will discover one of its products is defective and conducts a recall entirely on its own volition. In other cases, the federal or state regulatory agency notifies a company that one of its products is defective and suggests, requests, or orders a recall. If the company does not recall the product, the regulatory agency may seek legal action, which may include seizure of available product and public notification of risk associated with the product. State or Federal agencies may request assistance from local regulatory agencies in a recall investigation or response when the degree of risk to the public warrants widespread and immediate action to prevent further exposure to adulterated products in commerce.

Cooperation between industry and regulatory agencies has proven to be very effective and efficient in removing potentially dangerous products from the market. Both industry and regulatory agencies benefit when a potentially harmful product is prevented from reaching consumers.

During a recall, the company takes full responsibility for product recalls, including follow-up (effectiveness) checks to assure that recalls are successful. Regulatory

agencies may assess the adequacy of the recall by conducting audit checks on a portion of the firms that received the recalled product. The need for and the number of audit checks to be conducted should be prioritized based on the level of health hazard, the remaining product that may exist in the marketplace, and the recall effectiveness data.

8.2.1. Federal Roles

The FDA has District (Field) Recall Coordinators (DRC) whose job is to serve as the primary contact for industry, other FDA Office of Regulatory Affairs (ORA) staff, and the various FDA Centers concerning recall activities. A listing of recall coordinators is available at: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm. DRCs are aligned in compliance branches reporting to the Director of Compliance (DCB). Recall Coordinators specialize in the same programs as their DCB. They are typically the States' primary recall contact with the Agency. If FDA requests State assistance to (or a State wishes to) conduct recall audit checks, all information will typically be funneled through the DRC to FDA Commissioned officials in the State agency in accordance with applicable rules for FDA Commissioned Officers and FDA Division procedures.

FDA responsibilities are summarized below

- **Initiation of a Recall**. FDA may mandate recalls under their authority as referenced above, however, recalls can also be voluntary or FDA requested.
- **Classification and Strategy.** FDA formalizes the recall action by reviewing the information, including the recall strategy provided by the firm, assessing the health hazard presented by the recalled product, and classifying the recall.
- **Notification and Public Warning.** For those recalls mandated or formally requested by FDA, FDA will issue a written notification to the firm with the recall request or recall order. FDA notifies the firm that their action meets the definition of a recall and notifies the firm of the hazard level (classification) of each product under recall. FDA assesses the need for public notification, usually a press release, which may be issued by the recalling firm or by FDA. As appropriate, primarily for Class I recalls, FDA posts these recall announcements on FDA's website. State-issued press releases announcing a firm's recall may also be posted. FDA also tries to obtain an image of the recalled product to post along with the recall announcement. For all recalls, FDA lists the recall in the FDA Enforcement Report after the recall has been classified. FDA also shares distribution information for recalled

products, as needed and as per agreement, with other federal and state agencies and with foreign governments.

- **Monitoring and Auditing the Recall.** FDA develops and implements a recall audit strategy to ensure that the recall action has been effective. FDA will take appropriate regulatory action or other measures when the firm fails to recall violative product or when a recall action fails. Additionally, FDA asks that firms submit periodic status reports to the FDA Division office monitoring the recall. These status reports contain information on the progress of the firm's recall action including the number of consignees responding to the recall notification and the number of products returned or corrected.
- **Termination of a Recall.** FDA determines when a recall should be terminated and, upon such determination, provides written notification of termination to the recalling firm.

8.2.2. State Roles

- **Initiation of a Recall:** Often done in collaboration with FDA Division offices. Includes voluntary, State requested, and State mandated (where state law allows the regulatory authority to mandate recalls within their jurisdiction).
- **Classification and Strategy:** If the State leads the government recall action by mutual decision with their Federal counterparts, they may coordinate with FDA to classify the recall after assessing the health hazard presented by the recalled product. States without authority to mandate recalls in their jurisdiction must allow FDA to make the final determination of classification.
- **Notification and Public Warning:** The State may publish recalls on their website or through alternate means, such as social media. While it is the firm's responsibility to ensure distribution of the press release to the public and FDA, the State may assist the firm in formulating and distributing the message within its borders to the appropriate media channels.
- **Monitoring and Auditing the Recall:** States may elect to develop and implement a recall audit strategy to ensure that the recall action has been effective for the product distributed within their jurisdiction. Alternatively, the State may choose to assist FDA in conducting recall audit checks if resources are available, preferably using a reporting mechanism similar to the FDA 3177 form that will accurately collect the necessary information to insure the effectiveness of the recall.
- **Termination of a Recall:** FDA determines when a recall should be terminated and, upon such determination, provides written notification of termination to the recalling firm. States with recall authority will work with FDA and industry to terminate a recall. States with the

authority may work with industry partners to terminate recalls for products sold exclusively within that state's boundaries.

8.2.3. Local Roles

Local agencies typically have regulatory jurisdiction over food service establishments and have variable recall authorities. Recall activities are often done in collaboration with state and Federal agencies when adulterated products originated from establishments under local jurisdiction

- **Classification and Strategy:** State and Federal authorities may depend on epidemiologic information collected by local agencies in their classification and review of a firms' recall strategy.
- **Notification and Public Warning**: Local agencies can play important roles in further disseminating recall information and answering questions from concerned citizens if recall information is shared with them in a timely manner.
- **Monitoring and Auditing the Recall.** Local agency involvement in recall audit checks often is dependent on the severity of the hazard and the availability of resources. Locals can conduct audit checks independently or in coordination with state and federal agencies to ensure that the recall action has been effective for the product distributed within their jurisdiction.
- **Termination of a Recall.** Local agencies may report their recall audit check findings to State and Federal authorities, which may be used in their determination of if a recall may be terminated.

8.3. General Principles of Immediate Risk Management Decisions

If the product is still on-site at the facility/firm, it can be controlled by:

8.3.1. Seizure of existing product

FDA has the authority to seize or embargo food, but it is often more expedient to rely on states' authorities in this matter, because it may be done much more quickly and with fewer legal hurdles. States and the FDA Division Offices should be aware of each other's authorities in this capacity and work collaboratively to ensure measures like seizures, embargos or other regulatory actions within the food chain are initiated as quickly as possible to control violative foods.

8.3.2. Limitation of future production

Regulatory agencies may have the authority to limit the products a firm may produce temporarily or permanently through license limitation or other means. If this authority is available, FDA in coordination with the

State (and local agencies when applicable) should determine if production limitation would be the most expedient control.

8.3.3. Control of product in distribution channels

If product has not left the direct control of the firm, it is possible for the firm to control the product using procedures other than a recall by performing a stock recovery operation.

When product is in commerce and has left the direct control of the firm, it is necessary to conduct a recall to regain control of the product. States and Federal agencies should coordinate their actions to make best use of their respective authorities and resources in exercising appropriate regulatory controls over recalled products.

8.4. Recall Strategy

Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, i.e., wholesaler, retailer, user/consumer. This is known as the "depth of recall". If the recall extends below the wholesaler depth, the recall strategy should ensure that wholesalers conduct sub-recalls of the product to the appropriate recall depth.

Food recalls require that specific information be obtained from firms which have used recalled material in the production of another product. This is necessary to decide if the recall must be extended to a new product(s). In those instances, the following are some areas to be covered:

- Determine what the firm's quality control procedures are for incoming ingredients.
- Ascertain the quality control over ingredients at the time of use, and obtain a list of the products in which the ingredients are used.
- Obtain a detailed description of the methods used in the preparation and packaging of the processed product.
- Determine how the finished product is stored and shipped.
- Obtain copies or photographs of the labeling of the product and any cooking instructions for consumer or purchaser.
- Determine what quality control testing is done on the finished product. Detail any test(s) performed by firm.
- For products produced in USDA plants, determine if the USDA was notified of the suspect incoming ingredient? If notification was provided, did USDA determine what testing was done by the firm?
- Determine the impact/effect of any additional manufacturing processes on adulterated ingredients. If the firm incorporated an adulterated ingredient into

a new food, assess whether the manufacturing process of the new product mitigated the adulteration.

- If the ingredient was contaminated with a pathogen, was there a validated kill step for the pathogen during the manufacture of the new product?
- If the ingredient was adulterated with extraneous material, was there a step, like sifting, that could have eliminated the extraneous material.
- For those ingredients that are misbranded, is there labeling on the finished product that could mitigate the misbranding of the ingredient? The ingredient may be contaminated with peanut residue but if the finished product is meant to and labeled as containing peanuts, then the misbranding of the ingredient is mitigated.

8.4.1. Federal Roles

Federal agencies have established protocols for obtaining information necessary to both classify and determine the necessary depth of recall, need for public notification, etc. and may coordinate with State officials to collect it. FDA may notify the firm of the classification and necessary changes in its recall strategy, including the need for press releases for those recalls conducted voluntarily.

8.4.2. State Roles: Communications and Press Releases

The State, working in conjunction with FDA, may notify firms within their jurisdiction of the classification and the need for press releases for those recalls conducted voluntarily. The State may assist the firm with composing the press release language, and may coordinate with FDA to ensure all parties have a clear understanding of the recall message and appropriate language has been incorporated. There are several ways that information is communicated during recall activities. Additionally the state may issue a press release announcing the recall of the product in their state.

8.4.3. Intra and Inter-Agency Information Sharing

Local, State and Federal authorities should have 24/7 contact information for their own and each other's staff. Contact lists should be updated at least annually to ensure the appropriate information is available. Open, accurate and rapid information sharing can be expedited between agencies that have entered into a Memorandum of Understanding with each other regarding commercially confidential information.

FDA also has the ability to share other investigatory and/or pre-decisional information with State and local officials who have signed 20.88 Confidentiality Commitment Agreements or are commissioned through the Federal commissioning procedure. The current FDA commissioning policies and procedures were developed and refined over the years by FDA to grant

specific authority in a specific program area in a designated state to state and local officials pursuant to the following laws: Section 702(a) of the Federal Food, Drug, and Cosmetic Act; Section 360 E(2) of the Public Health Service Act; and authority delegated to the Commissioner of Food and Drugs by the Secretary of Health and Human Services under 21 CFR 5.35.

Recommended practices:

- Key Information to share:
  - Any facts regarding epidemiological and/or lab information on health risk, product contamination and/or reported illnesses or injuries;
  - Preliminary product information linked to illnesses or injuries and any positive sample results or other problems warranting a recall; and
  - Information regarding the company or companies involved, their contact information and location and the scope of the proposed recall, if known.
- Establish routine meetings between Federal, State, and Local personnel who are involved in recall coordination activities to share informational updates and maintain lines of communication. This could be accomplished through Food Safety Task Force Meetings or other routine meetings.

8.5. Initial Investigation/Data Gathering

FDA and state agency representatives should consider collaboration for investigation and data gathering at the firm if there is shared regulatory jurisdiction, or alternatively, determine which agency is in the best position regarding available resources to investigate at the firm. FDA or States should use Attachment F of this chapter, "ALERT TO RECALL and ATTACHMENT B GUIDANCE", based on the instructions in Chapter 7 of the FDA's Regulatory Procedures Manual (RPM) and Chapter 7 of the FDA's Investigations Operations Manual (IOM) for collection of necessary recall data.

In most cases, an establishment inspection should be conducted to determine the root cause(s) of the problem and document violations for possible regulatory action if appropriate corrective action is not being implemented, and evaluate overall compliance. See the IOM Chapter 7: Recall Activities for more procedures on recall related inspections.

Prior to initiating an establishment inspection, regulatory authorities should determine whether similar complaints have been entered into the FDA's Field Accomplishments and Compliance Tracking System (FACTS) or a State database or record.

The establishment inspection should, in addition to other activities:

- Obtain the recalling firm's proposed recall strategy [21 CFR 7.46(a)], if not previously submitted by the firm.
- Collect copies of all labeling associated with the product.
- Obtain complete distribution of all shipments of the suspect lot(s), including complete names and addresses of all foreign consignees.
- Obtain supporting documentation that will assist the agency in identifying and evaluating the problem such as product complaints, product specifications and test results, including the methods used to obtain the results.
- Assess the root causes of the problem. Determine how and when the problem occurred and how and when it was discovered. Obtain the firm's corrective action to prevent future occurrences.
- Verbally apprise the firm's management that the FDA Recall Coordinator and/or State regulatory authority should be consulted prior to the reconditioning or destruction of any returned product. Management should also be advised that FDA or the State or local regulatory authority should witness or otherwise verify product disposition.

8.6. Recall Enterprise System (RES) Data Needs

The FDA DRC should submit this Recall Alert through RES by completing, at a minimum, the following fields:

- Product(s) Description
- Codes
- Recalling Firm
- Short Reason for Recall
- Division Awareness Date
- Recall Initiation Date, with Type of Initial Firm Notification
- Recall Status
- Voluntary or FDA Mandated Pick Lists, with Date

The DRC may submit any other information at the same time.

8.7. Industry Communication

A firm may identify a problem with a product and notify FDA or a State regulatory agency. If a State is notified of an industry-initiated recall directly by the firm, media, etc., it should immediately notify the FDA DRC and Division Compliance Branch Director via telephone, fax or email.

Registered Food Facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States under section 415(a) of the FD&C Act (21 U.S.C. 350d) are required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health

consequences or death to humans or animals. This information is submitted through an electronic portal called the Reportable Food Registry (RFR). The RFR applies to all FDA regulated categories of human and animal food, except dietary supplements and infant formula. It is important to note that a report filed through the RFR does not always result in a product recall.

8.8. Public Notification/Press Releases

The recalling firm has a responsibility to provide information when there is a need to alert the public to a serious hazard presented by exposure to the firm's product(s). Industry should work with FDA and/or State regulatory authorities to ensure that the public message clearly identifies the products, and the potential risk involved. Public notification is important, particularly in situations where the recalled product may pose a significant health hazard and may be in the hands of consumers. In such situations (often Class I and sometimes Class II recalls), prompt issuance of a press release should be high priority. Unique situations will be handled on a case-by-case basis. When public notification is necessary, state and FDA regulatory officials will work with firms initiating a recall to issue a press release as soon as the recall situations are identified. Alternative forms of communication, in addition to a press release, should be considered if feasible through licensees and other partners (e.g., to school licensees, hospitals, etc.). FDA, states, and locals may issue press release in addition to those issued by the recalling firm.

8.9. Press Releases

Essential elements of a press release include the following:

- Establishment – The name and address of the firm with points of contact for recall information, as appropriate (e.g., Compliance/Recall Coordinator, Recall Management, Media Inquiries, Consumer Inquiries, website) and phone or fax number(s) including the days and times (with time zone) when the consumer information phones are answered;
- Product Recalled – Exact and complete description of the specific product(s) recalled including type of packaging and sizes;
- Production Dates/ID Codes – Specific identifying codes or marks on the packages; specific dates of production including plant codes, sell-by dates, expiration dates and location of codes on the package;
- Quantity Recalled – The quantity of product recalled;
- Recall Classification – Class I, II, or III if information is available; Note: Typically press releases are issued before the recall has been classified, so this information is unavailable.
- Recall Notification Level – Wholesale, retail, consumer;
- Problem/Reason for Recall – The problem with the product or the reason for the recall;
- Specific Nature of Potential Hazard – Examples: allergic reaction, infection;
- How and When Discovered – Details regarding the discovery of the hazard;

- Distribution – Geographic (international, nationwide, statewide, specific counties, and if possible, names of retail chains that carried the product);
- Media and Consumer Contacts and Instructions – Two different contacts are often given. Instructions to the public regarding typical symptoms of illness and what to do with the recalled product if they have it, including the name and telephone number of a company contact for consumers with any questions including the days and times (with time zone) when the consumer information phones are answered. Indicate if there have been any illnesses associated with the recalled product;
- Risk Information – Succinct information about specific steps consumers can take to reduce their risk of illness. An explanation of the risk involved in consuming the product including typical signs and symptoms of adverse health effects caused by the agent;
- Follow-up Activities – A statement regarding the status of the investigation and agencies involved, as appropriate (e.g., "the firm is cooperating with the investigation by state and federal officials to identify the source of contamination").

See the following:

- Example Press Release (Attachment B)
- Example Customer Notification Letter (Attachment C)
- Examples of contamination or hazard warning language (Attachment D)

8.10. Recall Effectiveness

It is the recalling firm's responsibility to determine whether its recall is progressing satisfactorily. The firm has an obligation to conduct effectiveness checks as part of its recall strategy. Effectiveness checks assist in the verification that all known, affected consignees have received notification about a recall and have taken appropriate action.

In some instances, a recalling firm may be unable to check the effectiveness of its recall. This could occur when a recall extends to the consumer-user level, the confidential business records of a firm's customers are not accessible, wholesalers, distributors, or retailers do not cooperate, or, because the urgency of the situation requires an all-out effort. In such cases, FDA or state regulatory authorities may assist in this activity and, where necessary, seek assistance from cooperating state and local agencies.

8.10.1. Recall Audit Checks:

A recall audit check conducted by FDA, state or local agency is a personal visit, telephone call, letter, e-mail, or a combination thereof, to a consignee of a recalling firm, or a user or consumer in the chain of distribution. It is made to verify all consignees at the recall depth specified by the strategy

have received notification about the recall and have taken appropriate action.

8.10.2. Level of Audit Checks (IOM 7.3.2.2)

- Level A – 100% of the total number of consignees to be contacted.
- Level B – Greater than 10% but less than 100% of the total number of consignees to be contacted.
- Level C – 10% of the total number of consignees to be contacted.
- Level D – 2% of the total number of consignees to be contacted.
- Level E – No audit checks.

Information that may be used to determine the level of audit check required can include:

- Recall Classification Level (I, II, or III)
- Width of product distribution
- Likelihood that product is still in commerce
- Reports of confirmed illness linked to the product
- Target population group likely to consume product

8.10.3. Conducting a Recall Audit Check

Recall audit checks may be conducted in various ways including in-person visits, phone calls, e-mails, record checks, etc. The information that should be obtained during an audit check includes:

- Name and title of person interviewed
- Verification that notification was received, understood, and followed
- Date and method of notification
- Amount of recalled product on hand at time of notification
- Amount returned and the method of return
- Amount destroyed and method of destruction
- Amount presently on hand and its status (held for sale, awaiting return, etc.)
- Date of anticipated return or destruction, and planned method (if applicable)
- Was sub-recall conducted? (If so, obtain a list of consignees from which to select your sub-recall check locations)
- Have injury reports or complaints been received? If so, report details.
- See: FDA Recall Audit Check Form 3177 (Attachment E)

Normally within 10 days of issuance of the firm's recall communication, the monitoring FDA Division office will issue audit check assignments at the appropriate level in the FDA audit program. FDA may request State assistance in conducting these audits, depending on available resources,

severity of risk to the public or volume of distribution of the recalled products. A state may also determine the necessity of conducting its own recall audit checks and/or requesting assistance from local agencies based on distribution information it receives from FDA or the firm. It is strongly suggested that the State coordinate any independent audit check efforts with its FDA Division counterpart to avoid duplication of effort.

Exceptions to the ten-day time frame would be made for Class I situations when the recall is to the consumer/user level and it is critical that the agency be certain that the products are off the market or that consumer/users have been notified of the recall action.

Upon receipt of completed audit check assignments from FDA, the DRC reviews the FDA 3177 for completeness and determines whether the recall was effective or not. States having conducted independent audits using the FDA 3177 form should submit their completed, signed forms to the FDA DRC within an agreed-upon time frame. Local agencies should submit completed forms through their State partners to insure coordination of audit responses with Federal authorities.

If a State uses its own recall audit data gathering mechanism, such as a web-based tool or spreadsheet, the data should be shared with the FDA DRC as soon as possible and a summary of how the data was gathered and how to interpret it should be provided.

8.10.4. Ineffective Recalls

If an audit check discloses recalled product being held for sale, or a requested sub-recall has not been initiated, the responsibility for failure to follow recall instructions should be documented. This is particularly important if the account received the recall notice and ignored it or the consignee (downstream) failed to receive notification altogether. In these instances, product should always be removed from sale before the audit check is completed.

8.10.5. Termination of Recall

Recall Terminated: A recall can be terminated when a State or Federal regulatory authority determines that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. For recalls that FDA is coordinating, written notification that a

recall is terminated will be issued by the appropriate FDA Division Office to the recalling firm.

Recall Completed: For monitoring purposes, the FDA classifies a recall action "Completed" when all outstanding product, which could reasonably be expected to be, is recovered, impounded, or corrected.

Documenting Recall Procedure Effectiveness: For large scale events, it may be helpful to include recall activities and issues in the After Action Report. This would provide a mechanism for documenting issues encountered with the recall procedure and provide opportunity to review and revise the procedures as needed.

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

Level	Description
1	Single Agency Basic – The Agency* has conducted a review of recall resources and guidance to identify applicable legal requirements/recommended practices and has basic procedures and contact lists for communicating recall information to consumers, other agencies and relevant stakeholders.
2	Multi-Agency Basic – Appropriate individuals within the Agency have either signed a 20.88 Confidentiality Agreement with FDA or are commissioned so the agency can receive commercial confidential information from FDA to expedite removal of recalled product from commerce.
3	Single Agency Comprehensive – The Agency has developed and implemented comprehensive written recall procedures, which include 1) procedures for sharing of recall information; 2) procedures for prompt removal of recalled products; 3) procedures for audit checks; 4) adequate recordkeeping and a periodic review and revision process for the procedures.
4	Multi-Agency Comrehensive– The Agency regularly maintains and has implemented a communication and coordination process with recall partner agencies during emergency and non-emergency events to ensure recall procedures are revised as needed to increase the effectiveness of multi-agency recall activities. Routine communication could include incorporating recall activity discussions in Food Safety Task Force Meetings or other regularly scheduled meetings. Including recall activity discussion into After Action Reports would provide a mechanism for documenting recall issues and provide an opportunity for revision of procedures as needed.

*Agency is defined as any agency participating in the Rapid Response Team

10. RELATED DOCUMENTS

10.1. Food Recall References, Regulatory Authorities, and Guidance

10.1.1. State: Regulatory authority to mandate recalls varies from state to state. States may use their own or Federal food recall references and regulations for guidance or procedures on how to monitor recalls effectively. If a state cannot mandate food recalls within their jurisdiction, they may have other

authorities outlined in their respective state statutes that allow them to regulate foods that may be adulterated.

10.1.2. **Federal:** This chapter is focused on food that is subject to FDA recall authority.

10.2. Related RRT Best Practices Manual Chapters, Topics, and References

10.2.1. Traceback: If source of product or ingredients is unknown

10.2.2. Environmental Assessment: To identify the root cause of the contamination

10.2.3. Joint investigations

11. REFERENCES AND OTHER RESOURCES

11.1. 21 CFR Part 7, Subpart C – Recalls (7.41 to 7.59) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7

11.2. 21 CFR Part 107, Subpart E – Infant Formula Recalls (107.200 to 107.280) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=107

11.3. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm

11.4. FDA Investigations Operations Manual, Chapter 7 – Recall Activities https://www.fda.gov/iceci/inspections/iom/default.htm

11.5. FDA Regulatory Procedures Manual, Chapter 7 – Recall Activities https://www.fda.gov/ICECI/compliancemanuals/regulatoryproceduresmanual/default.htm

11.6. United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) Recall information https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts

11.7. Food Safety Modernization Act (FSMA) Mandatory Recall Authority https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm#SEC206

12. ATTACHMENTS

12.1. Attachment A – Examples of Recall Situations

12.2. Attachment B – Example Press Releases

12.3. Attachment C – Example of a Customer Notification Letter

12.4. Attachment D – Recommended Wording for Specific Contaminants

12.5. Attachment E – Recall Audit Check Form 3177

12.6. Attachment F – Alert to Recall and Attachment B Guidance

12.7. Attachment G – Example of a Recall Flow Diagram

13. DOCUMENT HISTORY

Version #	Status*	Date	Author

Version #	Status*	Date	Author
1.0	I	10/26/12	RRT Recalls WG (ATL-DO**, FDA OO/OEIO/DE, MA, MI, NC)
1.1	R	5/26/17	ORA/OP

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)
**Workgroup Lead

Change History

1.1 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.

Attachment A – Examples of Recall Situations

Examples of Class I, II, and III Recall Situations
Recall classifications often occur on a case-by-case basis. Certain hazards may be classified as Class I, II, or III depending on circumstances and risk. Each unique situation cannot be captured in list format, therefore the following list is meant as a guide only. When the state is assisting with a recall, the FDA is consulted as appropriate to assure proper recall classification.

Note: *The following list represents the most common classifications for the hazards listed. Many factors are considered when assessing hazards associated with products such as the level of an adulterant in a product or the population most likely to use a product. Consult with your local FDA District RC regarding the specific circumstances involved with the product being considered for recall.*

Class I
Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Examples
Listeria monocytogenes in certain types of ready-to-eat food

Clostridium botulinum toxin

Shiga toxin producing Escherichia coli including E. coli O157:H7 and non-O157 Shiga toxin producing strains (STECs)

Salmonella sp. in ready-to-eat food

Salmonella sp. in pet food or pet treats

Uneviscerated salt-cured, dried, or smoked fish products greater than 5" in length (FDA Compliance Policy Guide 540.650 http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm124048.htm)

Foods containing undeclared sulfites at a level greater than 10 mg per serving

Foods containing an undeclared ingredient that contains protein derived from one of the following:

- milk
- egg
- fish
- Crustacean shellfish

- tree nuts
- wheat
- peanuts
- soybeans

Note: *The hazard posed by these allergens in food may be mitigated in ways such as the presence of another labeled ingredient in the food derived from the same allergen, the obvious presence of the allergen in the food or further processing the ingredient to eliminate all or most of the allergenic protein. For more information on labeling of foods containing allergens, see the following guidance on FDA's website* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059116.

Class II

Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Examples

Certain undeclared coloring agents such as FD&C Yellow No. 5- See 31 CFR 101.22 (k) (3) for requirements specific to color declaration on butter, cheese and ice cream

Undeclared wheat

Certain situations where a pathogen risk in food is likely to be mitigated by a heat-kill/processing step performed by the consumer/user (for example, *Salmonella* in tea intended to be prepared using boiling water)

Norovirus

Adulteration with hard/sharp foreign objects such as glass or metal pieces

Histamine in seafood

Class III

A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences

Examples

Undeclared certified colors other than yellow 5. Refer to CFSAN and FDA Federal Food, Drug and Cosmetic Act, section 721 (a).

Decomposition (which does not result in health hazard such as histamine)

Filth (which does not result in health hazard)

Products which are unfit for food based on off-odor or off-taste but do not pose a hazard to health

Minor labeling problems (e.g., format, undeclared ingredients that are not allergens)

Attachment B – Examples and Links to General and Commodity-Specific Questionnaires
For Various Food Operations

<COMPANY NAME>
<COMPANY ADDRESS>
<COMPANY CITY, STATE, ZIP>

FOR IMMEDIATE RELEASE <**TODAY'S DATE**>
COMPANY OFFICIAL NAME, TITLE, PHONE
DESCRIPTIVE TITLE OF RECALL
CITY <COMPANY NAME, ADDRESS>, is recalling its <SPECIFIC PRODUCT(S)> because they <SPECIFIC REASON FOR RECALL>.
INSERT PATHOGEN OR OTHER REASON FOR RECALL DESCRIPTION – HAZARD STATEMENT
(***Note: The phrase "potentially harmful" is not adequate to express the nature of a hazard for a Class I recall.)***

The recalled <PRODUCT> was distributed <DISTRIBUTION DESCRIPTION>.

SPECIFIC PRODUCT DESCRIPTION (UPC/ Lot Code, Packaging, location of coding on package)

Illnesses <HAVE/HAVE NOT> been reported to date in connection with this problem.

The contamination was noted after testing by <STATE/FEDERAL AGENCY NAME> revealed the presence of <PATHOGEN NAME> in some <DESCRIPTION OF PRODUCT>.
Production of the product has been suspended while <THE COMPANY, STATE AND FEDERAL OFFICIALS> continue their investigation as to the source of the problem.
Consumers who have purchased <DESCRIPTION OF PRODUCT> are urged to return them to the place of purchase for a full refund. Consumers with questions may contact <THE COMPANY and COMPANY CONTACT NUMBER>.

Pathogen Contamination Recall Press Release Example

ABC Produce
43234 Test Drive
Lansing, MI 48912
August 20, 2007
FOR IMMEDIATE RELEASE
John Smith, Communications Director, 517-444-2333
ABC Produce Announces the Recall of Cantaloupe Melons Due to Potential Salmonella Contamination
LANSING– ABC Produce, a wholesale importer of fresh fruit and vegetables, announced the recall of cantaloupes due to potential Salmonella contamination. The recalled product has been linked with a multi-state outbreak of Salmonella.
Healthy persons infected with Salmonella often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstance, infection with Salmonella can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (infected aneurysms), endocarditis and arthritis. The very young, the elderly, and persons with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention.

Approximately 3,430 cantaloupes were distributed to retail stores in Ohio, Michigan, Indiana, and Wisconsin. The cantaloupes have a light green color skin on the exterior with orange flesh. The cantaloupes were distributed for sale in bulk in cardboard cartons, with 10-12 cantaloupes per carton. The recalled cartons are a natural brown color, with “Tropi-loupes de Costa Rica” printed on the side in green and white lettering.

On the bottom of each carton is a 10-digit code; the first three digits are between 099 and 135. Cantaloupes bear a “Tropi-loupe de Costa Rica” sticker, with a code of 09879. The recalled product has been epidemiologically linked with a multi-state outbreak of Salmonella. Investigation is ongoing.

Consumers who have purchased the recalled cantaloupes are urged to return them to the place of purchase for a full refund. Consumers with questions may contact ABC Produce Monday – Saturday from 8 AM to 6 PM EST at 517-444-2333.

Allergen Recall Press Release Example

XYZ Company
P.O. Box 123
Lansing, MI 48912
August 20, 2007
FOR IMMEDIATE RELEASE
Mary Smith, Communications, 877-111-2222, ext. 12
XYZ COMPANY ISSUES ALLERGY ALERT ON UNDECLARED MILK AND EGG IN "XYZ CHOCOLATE CHIPPERS, CHOCOLATE CHIP COOKIES"

LANSING – XYZ Company of Lansing, MI is recalling 16-ounce packages of "XYZ Chocolate Chippers, Chocolate Chip Cookies" because they may contain undeclared milk. People who have allergies to milk run the risk of serious or life-threatening reactions if they consume this product. The recalled "XYZ Chocolate Chippers, Chocolate Chip Cookies" were distributed nationwide through retail stores.

The recalled product comes in a 16-ounce red package with gold writing, UPC code of 33333-49393. All date codes are included in this recall. The codes are located on the back label.

No illnesses have been reported to date in connection with the recalled product.

The recall was initiated after it was discovered that the milk containing product was distributed in packaging that did not reveal the presence of milk. Subsequent investigation indicates a malfunction in the labeling equipment. This has been corrected.

Consumers who have purchased 16-ounce packages of "XYZ Chocolate Chippers, Chocolate Chip Cookies" are urged to return them to the place of purchase for a full refund. Consumers with question may contact the company Monday – Saturday from 8 AM to 6 PM EST at 877-111-2222, ext. 12.

Attachment C – Example of a Customer Notification Letter

Recalling firm:
NAME
ADDRESS
TELEPHONE NUMBER
TODAYS DATE

CUSTOMER FIRM NAME & ADDRESS
Attention: <CONTACT PERSON NAME & TITLE>
Re: Recall of <TYPE OF PRODUCT>

Dear Sir or Madam:
This letter is to confirm that <COMPANY NAME> is recalling the following product(s) because <SPECIFY REASON FOR RECALL>: <DESCRIBE THE PRODUCT(S), INCLUDING NAME, BRAND, CODE, PACKAGE SIZE AND TYPE, ESTABLISHMENT NUMBER, ETC.>

We request that you review your inventory records, and discontinue selling your existing stock of this product. Please segregate the <PRODUCT(S)> and <INDICATE PROPER DISPOSITION> as soon as possible. We will credit your account for product returned.

We are undertaking this action in cooperation with the <REGULATORY AGENCY/AGENCIES>. State and federal officials may contact you to confirm that you have received this notice and are cooperating in this action.

Your prompt action will greatly assist <COMPANY NAME> in this action. If you have any questions, please do not hesitate to contact <COMPANY RECALL COORDINATOR at PHONE NUMBER>.

Thank you for your cooperation.

Sincerely,

<COMPANY OFFICIAL NAME AND TITLE>

Additional Content For Class I Recalls
In order to advise the <REGULATORY AUTHORITY> about the effectiveness of this recall, please inform us of the quantity of the above product on hand immediately after you received this recall letter.
Please sign and send or fax to <FAX NUMBER> this letter back to us as soon as possible.
Quantity on Hand: _____ Cases/Cans/Packages (Circle One)

_____ _____

(Store Owners Name) (Signature)

Example of In-Store Notification
Voluntary Recall Notice
We were notified on <DATE> that traces of <ADULTERANT> were present in <PRODUCT> produced on <DATE(S)> in our store. We believe this to be an isolated occurrence in this one batch. We have had no other reports of <ADULTERANT> to date and are cooperating fully with federal and state officials investigating this event.

If you have any <PRODUCT> at all with a packed on date of <DATE> and sell by date of <DATE>, please return it for a full refund.

We appreciate your business and if you have any further questions, please feel free to call the store manager <NAME> at <PHONE NUMBER> or contact the store director <NAME> at <PHONE NUMBER>.

Thank You,

_____
(Store Owner's Name)

Attachment D – Recommended Wording for Specific Contaminants

Common Signs and Symptoms

***E. coli* 0157:H7**
E. coli 0157:H7 infections can cause watery diarrhea (bloody or non-bloody), dehydration, abdominal cramps, vomiting, and in severe cases a serious condition involving kidney failure called *hemolytic uremic syndrome* (HUS). The very young, the elderly, and persons with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention. Onset time after ingesting = 1-3 days.

Listeria monocytogenes
Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Listeriosis can cause high fever, severe headache, muscle aches, diarrhea, and nausea. Listeriosis can also cause miscarriages and stillbirths. The very young, the pregnant, the elderly, and persons with compromised immune systems are the most susceptible to infection. People experiencing these problems should seek immediate medical attention. The onset time to serious forms of listeriosis is unknown but may range from a few days to three weeks.

Clostridium botulinum
Botulism, a potentially fatal form of food poisoning, can cause the following symptoms: general weakness, vomiting, diarrhea, dizziness, descending flaccid paralysis, double vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of muscles, abdominal distension and constipation may also be common symptoms. The very young, the elderly, and persons with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention. Onset time after ingesting = 12-72 hours.

Salmonella
Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstance, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (infected aneurysms), endocarditis and arthritis. The very young, the elderly, and persons with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention. Onset time after ingesting = 6-48 hours.

Allergens
People who have an allergy or severe sensitivity to specific type of allergen (e.g., peanuts, tree nuts {chestnuts, Brazil nuts, walnuts, hazelnuts, pecans, pine nuts, cashews}, eggs, sulfites) run the risk of serious or life-threatening allergic reaction if they consume these products. Onset -

Most severe allergic reactions occur within seconds or minutes after exposure to the allergen. However, some reactions can occur after several hours, particularly if the allergen causes a reaction after it has been eaten. In very rare cases, reactions develop after 24 hours.

Attachment E – FDA Recall Audit Check Report Form 3177

1. RECALL INFORMATION

a. RES/RECALL NUMBER(S)	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)

2. PROGRAM DATA

a. HOME DISTRICT	b. FEI NUMBER OF RECALLING FIRM

c. PAC CODE	d. HOURS

3. AUDIT ACCOUNTS

a. DIRECT	b. SUB-ACCOUNT (SECONDARY)
PHONE NO.:	PHONE NO.:

c. SUB-ACCOUNT (TERTIARY)	PHONE NO.

4. CONSIGNEE DATA

Contacted by: ☐ Phone ☐ Visit ☐ Other

a. NAME OF PERSON CONTACTED & TITLE

b. TYPE CONSIGNEE

☐ Distributor ☐ Consumer ☐ Pharmacy
☐ Retailer ☐ Physician ☐ Restaurant
☐ Processor ☐ Hospital ☐ School
☐ Other:

c. DOES (DID) THE CONSIGNEE HANDLE RECALLED PRODUCT?

☐ Yes ☐ No

5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED? *(If "No", skip to item 6c.)*

☐ Yes ☐ No ☐ Cannot be determined

(If answer is other than "No", explain in remarks.)

b. RECALL NOTIFICATION RECEIVED FROM

☐ Recalling Firm ☐ Other *(Specify below)*
☐ Direct Account
☐ Sub-Account

c. DATE NOTIFIED *(mm/dd/yyyy)*

d. TYPE OF NOTICE RECEIVED *(e.g., letter, phone)*

6. ACTION AND STATUS DATA

a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? *(If "No", discuss in "Remarks" action taken upon FDA contact.)* ☐ Yes ☐ No

b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION

c. CURRENT STATUS OF RECALLED ITEMS

☐ Returned ☐ None on Hand
☐ Corrected ☐ Was Still Held for Sale/Use*
☐ Destroyed ☐ Held for Return/Correction*

* = Ensure Proper Quarantine/Action

d. DATE AND METHOD OF DISPOSITION

7. SUB-RECALL NEEDED? *Did consignee distribute to any other accounts? (If "Yes", collect information and/or provide details in "Remarks" or Memo.)* ☐ Yes ☐ No

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND

9. INJURIES/COMPLAINTS

a. IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS?

☐ Injury ☐ Complaint
☐ Illness ☐ None

If answer is other than "None", report details in a separate memo to monitoring district and copy to OEO (HFA-615).

10. REMARKS *(Include action taken if product was still available for sale or use.)*

CHECK		ENDORSEMENT
INVESTIGATOR	SCSO OR R&E COORDINATOR	☐ Effective ☐ Does Not Carry Product
Signature	Signature	☐ Ineffective *(Indicate level)* ☐ Out of Business
Printed Name	Printed Name	☐ Recalling Firm ☐ Consignee
Date of Check *(mm/dd/yyyy)* / District	Date of Endorsement *(mm/dd/yyyy)*	☐ Other *(Specify)*:

FORM FDA 3177 (2/10) RECALL AUDIT CHECK REPORT PSC Graphics (301) 443-1090 EF

Instructions:

1. **Recall Information:**
   a. **RES/Recall Number** – Assigned by FDA--If available, enter the recall number assigned by the Center. If not available, leave blank. If more than one number is involved, enter the lead number.

   b. **Recalling Establishment** – Provide the name and address of the firm responsible for issuing the recall notification. This must be filled in or audit will not be credited to appropriate recall

   c. **Recalled Codes –** Provide the lot, batch, or serial number under recall. **Product** - Provide the name of the product under recall. If numerous products are involved, use generic term, e.g., ice cream, dried fruit, etc.

2. **Program Data**: Only complete those items listed below. Most of the other fields in this section will be filled in by FDA
   a. **Hours** – record the on-site hours spent on-site conducting the audit check.

3. **Audit Accounts**: Note that not all audits will go all the way down to the tertiary level, based on distribution. Complete address and contact information for each account identified as part of the distribution to the consignee. As shown on the example below.
   a. ***Direct Account –*** This should the information for the company that received the recalled product directly from the recalling company. (In the example above, it would be Sizzle Distributors, who received it from the recalling company, Bixby Darling Corporation)

   b. ***Secondary Account –*** The company receiving recalled product directly from the Direct Account listed in 3a. (e.g Wilson Grocery Distribution Center, who received from Sizzle Distributors

   c. ***Tertiary Account –*** The company receiving recalled product directly from the Secondary Account in 3b. (e.g., Wilson Grocery #445, who received from Wilson Grocery Distribution Center)

1. RECALL INFORMATION

a. RES/RECALL NUMBER(S)	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)
(this is assigned by FDA)	Bixby Darling Corporation 12234 Ninth Street Anytown, WI 59999	CsUPC 48859 49953; Lot 11123A (best if used by date 2/29/2012) UPC 48859 49950; Lot 11134B (best if used by date 2/29/2012)	Darling peanut butter, 10oz plastic jar Darling peanut butter, 32 oz plastic jar

2. PROGRAM DATA
(This whole section is COMPLETED BY FDA)

a. HOME DISTRICT: MIN
b. FEI NUMBER OF RECALLING FIRM:
c. PAC CODE:
d. HOURS:

3. AUDIT ACCOUNTS

a. DIRECT
Sizzle Distributors
33454 Johnson
Mason, MI 48554
PHONE NO.: 517-676-5555

b. SUB-ACCOUNT (SECONDARY)
Wilson Grocery distribution center
32 Wilson Street
Lansing, MI 48909
PHONE NO.: 517-992-5555

c. SUB-ACCOUNT (TERTIARY)
Wilson Grocery #445
423 Miner Rd
Lansing, MI 48990
PHONE NO.
517-997-5111

4. CONSIGNEE DATA

Contacted by: ☐ Phone ■ Visit ☐ Other

a. NAME OF PERSON CONTACTED & TITLE
Owen James, store manager

b. TYPE CONSIGNEE
☐ Distributor ☐ Consumer ☐ Pharmacy
■ Retailer ☐ Physician ☐ Restaurant
☐ Processor ☐ Hospital ☐ School
☐ Other:

c. DOES (DID) THE CONSIGNEE HANDLE RECALLED PRODUCT?
■ Yes ☐ No

4. **Consignee Data**: "Consignee" is the account at which the audit check is being conducted.
- A consignee may be a retail facility, distributor, food bank, etc.
- The consignee would be the last facility in the distribution chain listed on the audit.

In the example above, the Consignee would be the Tertiary Account, Wilson Grocery #445". The audit information being collected on the form would be for the Wilson Grocery #445.

If the audit check was being conducted at the Secondary Account facility, the Secondary Account facility would be considered the Consignee, and both the Direct Account and Secondary Account address and contact information should be shown on the audit form.

1. RECALL INFORMATION

a. RES/RECALL NUMBER(S)	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)
(this is assigned by FDA)	Bixby Darling Corporation 12234 Ninth Street Anytown, WI 59999	CsUPC 48859 49953; Lot 11123A (best if used by date 2/29/2012) UPC 48859 49950; Lot 11134B (best if used by date 2/29/2012)	Darling peanut butter, 10oz plastic jar Darling peanut butter, 32 oz plastic jar

2. PROGRAM DATA
(This whole section is COMPLETED BY FDA)

a. HOME DISTRICT: MIN
b. FEI NUMBER OF RECALLING FIRM:
c. PAC CODE:
d. HOURS:

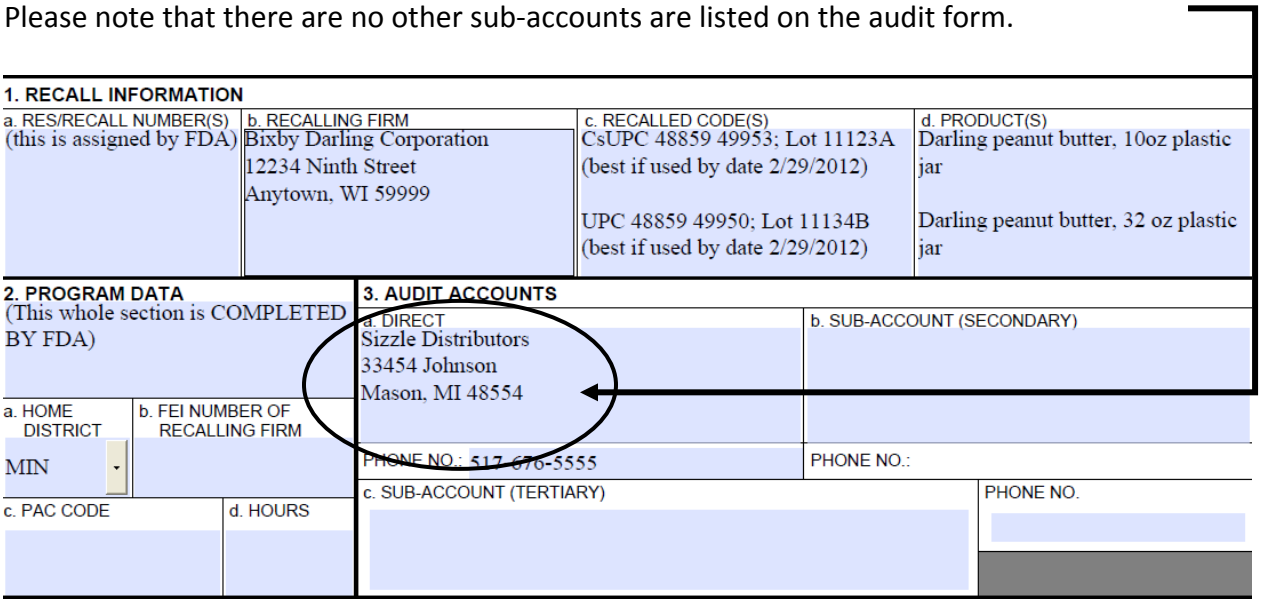
3. AUDIT ACCOUNTS

a. DIRECT
Sizzle Distributors
33454 Johnson
Mason, MI 48554
PHONE NO.: 517-676-5555

b. SUB-ACCOUNT (SECONDARY)
Wilson Grocery distribution center
32 Wilson Street
Lansing, MI 48909
PHONE NO.: 517-992-5555

c. SUB-ACCOUNT (TERTIARY)
PHONE NO.

In the example below, the Consignee being audited is the Direct account, Sizzle Distributors. Please note that there are no other sub-accounts are listed on the audit form.



1. RECALL INFORMATION

a. RES/RECALL NUMBER(S)	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)
(this is assigned by FDA)	Bixby Darling Corporation 12234 Ninth Street Anytown, WI 59999	CsUPC 48859 49953; Lot 11123A (best if used by date 2/29/2012) UPC 48859 49950; Lot 11134B (best if used by date 2/29/2012)	Darling peanut butter, 10oz plastic jar Darling peanut butter, 32 oz plastic jar

2. PROGRAM DATA
(This whole section is COMPLETED BY FDA)

a. HOME DISTRICT	b. FEI NUMBER OF RECALLING FIRM
MIN	

c. PAC CODE	d. HOURS

3. AUDIT ACCOUNTS

a. DIRECT	b. SUB-ACCOUNT (SECONDARY)
Sizzle Distributors 33454 Johnson Mason, MI 48554	
PHONE NO.: 517-676-5555	PHONE NO.:

c. SUB-ACCOUNT (TERTIARY)	PHONE NO.

- The data requested is self explanatory.
- If the consignee typically has/had the product in stock during the time frame covered by the recall (carried the product six months ago, and the recall is for product in commerce at that time), 4c would be marked 'yes'.
- If the consignee has further distributed product and a sub-recall is needed to reach the appropriate recall depth, obtain a copy of their distribution list for the recalled product.

5. **Notification Data**: Box 5, a-d, each section box must have a checkbox completed and the detail of how the firm was notified.

- Did consignee receive a specific written, verbal, or personal contact providing recall notification?
- From whom and when was notice received?
- If they only heard about it from the media, include this information

6. **Action and Status Data**:

a. Did the consignee follow the directions they received from their supplier/recalling company regarding what to do with the product? If 'no', record the consignee explanation for not following the directions along with other findings in Block 10.

b. Record the amount the consignee said they had when they received notification of the recall, NOT the amount they have when you contact them.

NOTE: If firm does not remember how much they had, document 'not available'. If they didn't have any when they were notified, enter 'none'

c. Record information for product both on-site at time of audit as well as product they may have disposed of or sent back to the supplier.

d. Document what firm did to the best of their recollection.

7. **Sub-Recall Needed**: If consignee supplies/supplied product to other accounts, then they may need to do a sub-recall in order to meet the appropriate recall depth. The inspector should mark item 7 with "YES"

- If the firm needs to do a sub-recall, obtain a copy of the distribution list for all of the recalled products and describe firm's sub-recall procedures in Block 10 REMARKS
- The inspector may also be asked to complete Attachment B information if directed by the Regional supervisor, and submit all information collected.
- If firm has refused to sub-recall properly without justification, include your agency follow-up actions in Block 10 and give reason why firm states they refuse to conduct a sub-recall. Mark INEFFECTIVE in the Endorsement block in the lower right hand corner.

8. **Amount of Recalled Product Now on hand:** If none on hand at time of audit, document 'none', do not leave blank.

9. **Injuries/Complaints:** Self-explanatory.

10. **Remarks:** Provide all information not covered in 1-9 which aids in the evaluation of recall effectiveness at this consignee.

CHECK section (lower left corner of document):

- Signature of CSO/CSI: Inspector's name goes here, preferable to physically sign and scan document to send electronically, if possible.
- Date of Check needs to be completed
- District will be provided to inspector

ENDORSEMENT Section of Form (lower center and right corner of document):

- This section is left blank by the Consumer Safety Officer (CSO), Consumer Safety Inspector (CSI), or field inspector for completion by the supervisor.
- The endorsement box needs to be completed by the supervisor with their name, statement "effective" or "not effective", and date of endorsement.

Examples:
"Not Effective": The audit check discloses recalled product being held for sale or a requested sub-recall has not been initiated, Document the responsibility for failure to follow recall instructions. This is particularly important if the account received the recall notice and ignored it. The audit

check is also considered ineffective if the consignee did not receive notification from the firm (recalling firm or distributor) that sold the recalled product to the consignee.

"Effective" Recall notice was received from the firm (recalling firm or distributor) that sold the recalled product to the consignee and the consignee followed the instructions in the recall notification.

Attachment F – Alert to Recall and Attachment B Guidance

RECALL REPORTING INSTRUCTIONS
(Not intended for blood, blood products or tissue recalls)

The following instructions may be used to assist in gathering recall information and documents from a recalling firm. It is based on the instructions in Chapter 7 of the RPM and Chapter 7 of the IOM and is intended to be a more descriptive, easier to use format.

ALERT TO RECALL (also known as "24 Hour Alert"):

Provide to the District Recall Coordinator (RC) within 24 hours of learning the recall is planned or underway.

When you encounter a voluntary recall situation at a firm that has not yet notified the FDA of the recall, contact the FDA District Recall Coordinator at your home District to report the recall as soon as possible, preferably the day you discover the recall.

(1) PRODUCT (brand name and product name of the product(s) being recalled)
(2) CODE (all production and manufacturing code(s) involved)
(3) RECALLING FIRM/MANUFACTURER (name and address, FEI/CFN)
(4) REASON FOR RECALL (briefly explain reason(s) product is being recalled)
(5) AWARENESS DATE/ RECALL START DATE (date any FDA District personnel first became aware of the recall, date firm sent notice to consignees, and date firm issued press release**, if any)**

ATTACHMENT B INFORMATION (PLEASE Do **NOT** hold this form until you complete your inspection report):

This information is due to the RC within 4 working days of when the Alert information was submitted (within 10 working days for a closed recall).
Please be sure to collect copies of the "Recall Documents":
Recall Documents:

(1) Product label(s): Labels and labeling for each product/size, if product is unlabeled, collect any other record that shows the name of the product. Digital pictures are excellent.
(2) Recall Letter(s): letters/faxes/bulletins/emails that communicate recall information to consignees, customers and consumers.
(3) Distribution List: list of consignees with FULL ADDRESSES and phone number
(4) Product Catalog: if any
(5) Test Results: analytical work sheet, methodology used, if available. If done by contract lab, obtain full name and address of lab

(6) Press Release**:** news release, or allergy alert, if any
(7) Health Hazard Documents: health hazard evaluation, risk analysis, etc.
(8) Other Documents**:** documents that reflect corrective actions, such as SOP changes

Please provide an **electronic** copy of the following information with the Recall Documents

Date(s) of establishment inspection:
Date CSO/inspector became aware of firm's recall:

Provide detailed information regarding the recall **(please follow the number format below)**:

1. PRODUCT(S):

IF THE PRODUCT IS A **FOOD**, BEVERAGE, ETC., INCLUDE:

a. Name of product:
b. Brand name:
c. Unit size (1/2 gallon, 18 ounce, 2 lb. pkgs.):
d. Container description (in paper cartons, in glass jars):
e. Total package size (12 packages per case):
f. Distributed by and/or Manufactured by (name & address—quote from label):
g. Storage instructions, if any (frozen, refrigerate after opening etc.):
h. Shelf life and/or expiration date:

2. CODE(S):

List all batch numbers, lot numbers, UPCs, product numbers, packer or manufacturer or plant numbers, etc.

3. RECALLING FIRM/MANUFACTURER:

Provide complete name and address of the recalling firm, including FEI/CFN. Provide complete name and address of manufacturer, if different from recalling firm.

4. REASON FOR RECALL RECOMMENDATION:

a. State simply **WHY** the firm has decided to recall the product.
b. How did the firm **DISCOVER THE REASON** for recall?
c. What is the **ROOT CAUSE** for the reason for recall? Include any analytical finding in qualitative and/or quantitative terms, indicating whether firm's analysis or private laboratory was involved. Provide copies of test results/lab results analytical work sheets, and methodology used, copy of FDA-483, report narrative and coversheet (483, EIR and C/S may be forwarded when completed).

d. What type of ILLNESS **or INJURY** may be caused by the problem?
e. What is the TOTAL number of reports of **ILLNESS or INJURY COMPLAINTS** received regarding recall product? Collect copies of all complaints and complaint investigations. If that is too voluminous, collect summary documents and a few representative complaints.
f. What is the TOTAL number of reports of **PRODUCT DEFECT COMPLAINTS** received regarding recall product? Collect copies of all complaints and complaint investigations. If that is too voluminous, collect summary documents and a few representative complaints.
g. Has the firm done any **HEALTH HAZARD EVALUATIONS** and/or Health Risk Assessments associated with the recall product? Is so, summarize and include copies.
h. What action is the firm taking to **PREVENT A SIMILAR OCCURRENCE** of the problem? Collect verification of training or SOP changes, documents pertaining to product QA, design control, specifications, validation of software, etc., as appropriate to support firm's actions.

5. VOLUME OF PRODUCT IN COMMERCE:

a. What is the total amount of product that was manufactured?
b. What is the total amount of product distributed in commerce?
c. What is the amount of recalled product remaining at the firm?
d. What are the dates of distribution? (e.g., 12/3/10 to 4/14/12)
e. Provide an estimate (%) of the amount of product that may be recovered.

6. DISTRIBUTION PATTERN:

a. What is the TOTAL number of **consignees** (all customers) that received the recall product? (6b+6c+6d+6e, see below)
b. What is the TOTAL number of **wholesaler dealers** that received the recall product?
c. What is the TOTAL number of **distributors** that received the recall product?
d. What is the TOTAL number of **retailers** that received the recall product?
e. What is the TOTAL number of **consumers/users** that received the recall product?
f. Where is the recall product **distributed**? Indicate whether worldwide, nationwide, statewide. If foreign distribution, name the countries. Also **name the U.S. States,** e.g., MI, IN or provide a list of the **U.S consignees** with their FULL ADDRESSES with PHONE NUMBERS. For recalls with Class I potential we will usually need a complete list of consignees, foreign and domestic.
g. Were there any recalled products distributed to the Defense Supply Center, Veteran's Administration or other Federal Government sales/distribution centers? For all recalls, regardless of class, provide List of **foreign/military/government consignees** with full addresses.

7. FIRM'S RECALL STRATEGY:

a. Include the **DATE** the decision was made to recall and the **DATE** of the first recall communication to consignees.
b. How does the firm plan to **NOTIFY** all consignees affected by this recall? By letter, press release, fax, telephone, e-mail, visit, etc.?
c. Does the recall strategy include a **SUB-RECALL (recall beyond direct accounts)**? If yes, provide details on how this will be accomplished. Will the direct accounts handle the sub-recall or will the recalling firm obtain distribution from the direct account and contact the sub-account themselves? Collect any additional letters, faxes, e-mails, etc. that are generated.
d. How does the firm plan to monitor the number of **CONSIGNEES NON-RESPONDING** to the recall communication? By response form mailed, certified mailing with return receipt, etc.?
e. How does the firm plan to do **EFFECTIVENESS CHECKS** of all the consignees? By response form mailed, certified mailing with return receipt, fax, telephone, e-mail, visit, follow-up letters, etc.?
f. How does the firm plan to **STORE** the recalled product?
NOTE: It is equally important to assure that all returned merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped. Our past experience in similar situations has shown that the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse.
g. How does the firm plan to **DISPOSE** of the recalled products? (destroy, recondition, correct label, field correct by firm's personnel, etc.)
h. Comment on whether you consider the procedures to be used in the recall strategy are adequate.

The firm should be reminded that any destruction, reconditioning or diversion to alternate use of recalled items may require FDA supervision and therefore the firm must inform the FDA prior to undertaking such action.

8. FIRM'S OFFICIAL:

List name, title, business address, direct business phone of the primary contact at the firm responsible for overseeing the recall (include phone number, fax number and email address).

9. FIRM'S MOST RESPONSIBLE INDIVIDUAL

List name, title, business address, direct business phone of the most responsible individual of the firm. Include phone number, fax number and email address.

10. STATUS: State whether the recall is ongoing, completed or terminated:

A recall is ongoing when the goods are still being retrieved from the market, still being field corrected, etc.

A recall completed when the recall action reaches the point at which the firm has actually retrieved and impounded all outstanding product that could reasonably be expected to be recovered, or has completed all product corrections.

A recall will be terminated when the FDA determines that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and when it is
reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate FDA District office to the recalling firm.

Collect destruction certificates or other documentation of destruction.

11. SAMPLE(s) COLLECTED (if any)**:**

State the sample number(s), if collected and product name. Indicate if documentary or physical sample was collected and the date collected.

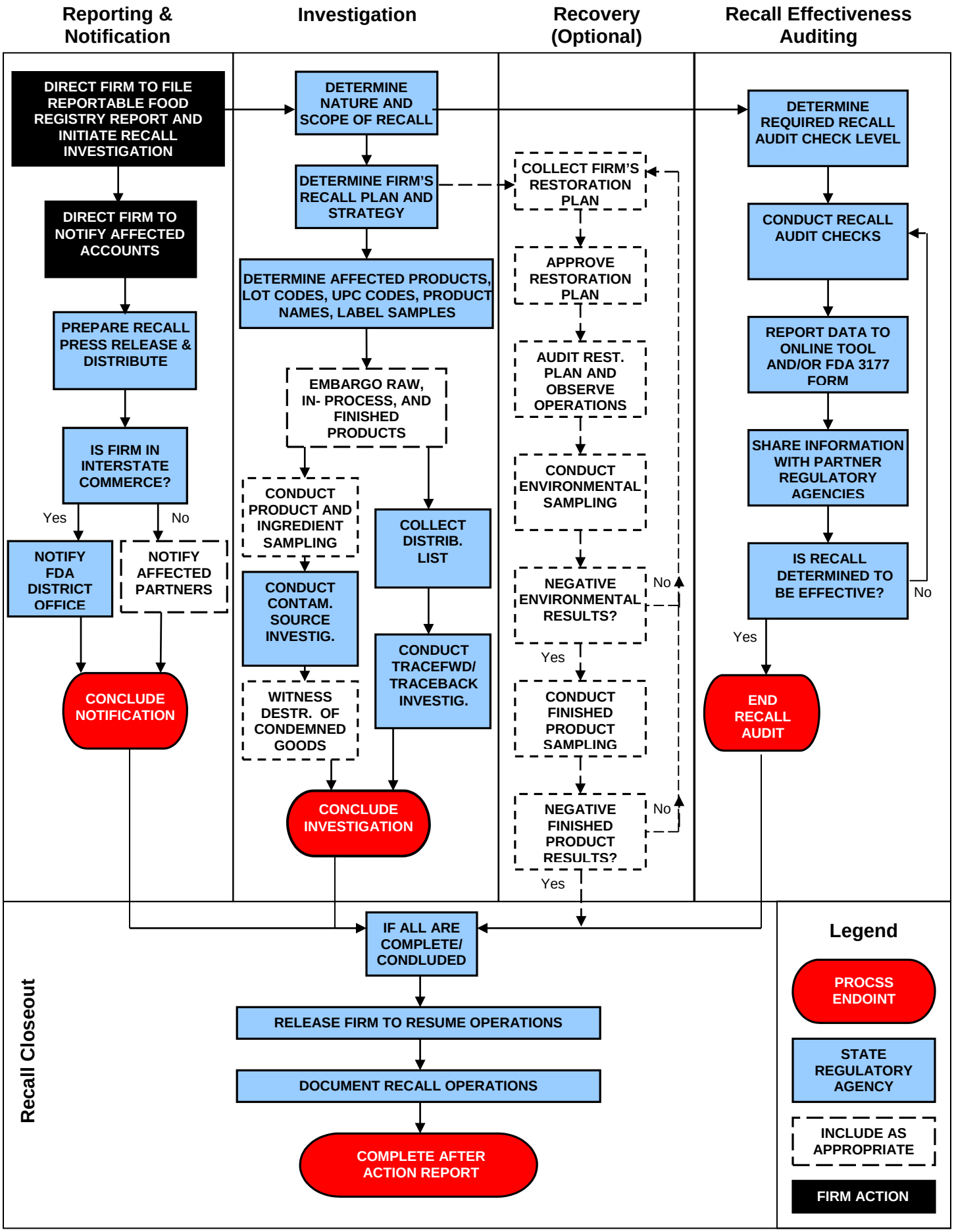
12. FDA PRODUCT CODE: **http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.cfm**

Some examples:
Ginger Ale in glass: 29BCG04
Carmel coated popcorn: 33SGG03
Maple Syrup in cans: 36BEG05
Ice Cream: 13AFGO1

13. LEGAL ACTION (if any)**:**

State any legal action planned/recommended/underway by State or Federal Regulatory Agency.

Attachment G – Example of a Recall Flow Diagram



Post Response and Prevention

Chapter 14. After Action Reviews

TABLE OF CONTENTS

1. PURPOSE

This document describes the procedures for completing an effective After Action Report/Improvement Plan (AAR/IP). This process will assess and evaluate actions taken during an event/incident/special investigation, etc., with input from all involved parties, to allow for continuous improvements to be implemented in future responses/events.

2. SCOPE

This applies to any agency response activity, whether to an emergency event, human or animal food related incident, special investigation, or other activity, such as an exercise, as a method to assess response performance and suggest improvements for future responses with all involved entities.

3. RESPONSIBILITY

3.1. Agency/Organization Leadership

Leadership of federal, state, and local agencies involved in responses to human and animal food incidents will (jointly) work to make any customizations needed to this template to develop and adopt an After Action Review process/SOP (Standard Operating Procedures) that is appropriate for their jurisdictions.

3.2. RRT Leadership (or investigatory team leadership, in states without an RRT)
RRT leadership is responsible for ensuring that the personnel assigned to respond to human or animal food incident have been provided with the Incident Command System (ICS) and investigation related training necessary for them to successfully complete the tasks they are assigned.

3.3. RRT Members (or investigatory team, in states without an RRT)
RRT members are each responsible for playing an active role in maintaining both their subject matter expertise and ability to work effectively in multi-disciplinary and multi-agency response teams.

4. DEFINITIONS

4.1. After Action Report (AAR) – The purpose of an AAR is to analyze results, identify strengths to be maintained and built upon, identify potential areas for further improvement, and support development of corrective actions. The report includes a summary of the incident, review of the response process, timeline of the events, strengths and areas for improvement observed during the response, and an improvement plan (IP). The IP should include a clear description of recommendations for improvement, who the responsible part(ies) will be for implementing each recommendation or each corrective action, and a timeframe for completion. If the AAR includes recommendations related to improving communications, it may be beneficial to include a flowchart or method of communications between the participating agencies that occurred during the incident, e.g., the communication process such as in regards to communication to the correct persons, information communicated clearly and in a timely manner, etc.

4.2. After Action Review – A no-fault process or meeting whereby everyone involved in the response/event collectively evaluates the response. The emphasis should be on identifying strengths and weaknesses of the jurisdiction's or multi-agencies plans, protocols, procedures, etc., and the tactics utilized to achieve the strategic goals.

4.3. Improvement Plan (IP) – A formal document that lists responsible entities to be accountable for agreed upon improvements to a response process within a designated time frame.

5. BACKGROUND

Outbreak and other special investigations typically require coordination among multiple regulatory agencies and/or programs. Effective communication and coordination are required for successful investigations of foodborne disease outbreaks, special investigations, and significant incidents. A review of the response to the incident provides

the opportunity to identify areas for improvement. *Continuous improvement* is a vital part of sustaining an integrated local, state, and federal food safety system. Over time, trends can also be identified across multiple reviews to determine the effectiveness of changes to the response network as well as the applicable regulatory programs.

Due to the demand on resources and frequency of incident/events (which will vary for each agency), many agencies will find it resource efficient/effective to prioritize resources for post response activities (such as after action reviews and reports) based on the significance of a given incident/event. As a general rule, a significant incident will warrant a review and report to detail successes, lessons learned, and develop a list of what actions are required to address specific needs and improve future responses. Suggested criteria for determining if an incident is 'significant' include: 1) complexity (multiple jurisdictions, multiple products); 2) impact (public health, industry, infrastructure); and 3) available resources (personnel, current workload/other demands).

While the actual determination of 'significant' may vary from agency to agency, it should be clearly defined in agency SOPs to allow for consistent implementation of After Action Reviews. Agencies may also determine that more rigorous After Action Review is appropriate for different levels of incident significance. For instance, incidents of low significance might warrant only a brief incident summary (addressing size, scope and distribution) and a 'lessons learned' summary (addressing challenges, recommendations and action items). This should also be clearly defined in agency SOPs. Any action items resulting from incidents, regardless of significance, should be tracked to ensure follow up action. Use of HSEEP compliant AAR/IP templates is encouraged for high profile or high significance incidents.

Because after action reviews include the review of how policies and procedures were implemented, involving representatives from agencies' legal counsel in the review process can be helpful if clarification or interpretation of law is needed.

6. SAFETY

N/A

7. EQUIPMENT/MATERIALS

N/A

8. PROCESS DESCRIPTION

The following sections were developed with the intention of taking recommendations for improvement from rapid response incidents, both those identified as issues within specific products, facilities or systems and those identified as coordination/collaboration issues, and applying them to improve the rapid response system and the regulatory programs.

8.1. Roles & Responsibilities

Responsibilities will vary depending on the management structure established for the response. Frequently used roles and responsibilities are identified below for your convenience.

8.1.1. **Administrators/Management –** should participate in all After Action Reviews in relation to their involvement in the response.

8.1.2. **Planning Section Chief –** The Planning Section Chief will draft the Summary of the Incident to be included in the AAR. If the Planning Section Chief position was not created for a response, this responsibility would default to the Incident Commander (IC).

8.1.3. **Facilitator –** It is often helpful to use a facilitator to conduct an after action review survey or meeting to gather feedback about strengths and areas for improvement; a person to lead the process. It is recommended that the facilitator be a person who was not involved in the day-to-day management of the response, but was familiar with the event. It is recommended that the facilitator be familiar with ICS structure and the protocols/procedures of participating agencies. The facilitator often begins with the objectives of the response as a starting point. Were the objectives met? What actions/responses caused them to be met or not met? The facilitator is responsible for ensuring completion and distribution of the AAR, but may not be responsible for creating the report; just ensuring its completion.

8.1.4. **Participants –** Ideally, everyone involved in the day-to-day management of the response, including command staff, general staff, and field staff will participate in the after action review. Any participant, internal or external to the jurisdiction, at any level, can and should contribute to the after action review; this could include inspectors, epidemiologist, subject matter experts, liaisons, public information officers, laboratorians, etc.

8.2. AAR Preparation

The preparation for the AAR is to be addressed at the beginning of the response whenever possible. All participants are to be reminded that they will be asked to provide feedback at the end of the response regarding significant strengths and areas for improvement for possible inclusion in an AAR. It is suggested that the AAR be completed within 45 days of the response.

The following information should be prepared in advance of the After Action Review:

8.2.1. **Establish Points of Contacts –** Solicit input and/or participation in the after action review from contributing agency leads that are available and others as needed.

8.2.2. **Summary of the Incident –** This written summary should begin with the first notification and finish with the final outcome or current status of the incident. The major response concerns should be identified along with the commodity and suspected/confirmed agent. The summary will

identify the findings and/or outcome of the incident. Include what agencies participated in the response, what type of incident command structure(s) was used to facilitate interagency work, key tasks involved and state what the objectives were. Describe possible root cause and possible mitigation steps; why/how did the situation occur. This summary should be clear and concise.

8.2.3. **Timeline of the Events –** This can be developed in multiple formats depending on the complexity of the incident and should help others to understand the sequence of events/actions.

8.2.4. **Legal Issues –** Determine if any information listed in the AAR/IP is considered sensitive for any agency. Consider this issue before public distribution of the report or limit its distribution. Consulting with legal counsel may be appropriate.

8.3. After Action Review

8.3.1. Whenever possible, at the beginning of the event, inform response participants that there will be an after action review and recommend they record on a daily basis for later compilation the strengths and areas for improvement that they observe along with recommended ways to improve. Agree on how the after action review process will work. The review can be conducted through a written survey, an in-person interview or through a group meeting/conference call. For example, each supervisor could inform their staff to be on the lookout for issues that arise, to make note of them, and to offer up possible solutions/remedies. The supervisor in turn reports these items up the chain to be included in the AAR. If possible, identify one person (or one from each participating agency) who will be responsible for collecting the information that will be used in the AAR.

8.3.2. **Recommendations for Improvement/Corrective Actions –** Create an IP on what can be done to improve policies, procedures and resources for future responses. Focus on items that can be improved and suggest solutions to identified problems. Limit areas of improvement to 3-4 items unless it was a large, complex incident. List top 3 strengths as well to ensure those are repeated during future responses. Assign a specific person responsible for implementing the suggested recommendation or corrective action with a designated timeline for completion.

8.3.3. **Facilitator** – It is imperative to allow the participants to be able to speak freely or anonymously in writing through a survey or some other form of written feedback. Emphasize that the overall goal is to make future responses. A “field meeting” with ground staff may be warranted in addition to the after action review with management. Remind participants that the discussion is to be focused on activities/actions (system problems) and not on people. The facilitator will follow-up with the designated agencies/individuals responsible for implementing the

suggested improvements within the time frame specified and report back to the participating agencies of the AAR/IP the status and outcome regarding the recommendations.

8.3.4. **NOTE:** The length of an AAR/IP is scalable, based on the event and number and types of agencies involved. The AAR/IP for a simple incident could be one page in length.

8.4. Flowchart of Communication Among the Various Agencies

If communications between the response agencies is identified in the AAR as a strength or an area for improvement, a chart showing how communication flowed during the response could help in describing what worked well or what should be improved upon for future responses. (Please see Appendix A, Listeria Contamination by MN for an example of a Flowchart of Communication.)

8.5. Full Summary (After Action Report – AAR/IP)

8.5.1. This is comprised of the incident summary, process review, timeline, flowchart and improvement plan and should be presented in a concise manner whenever possible. The report should be distributed to all involved parties, (e.g., Participant Agencies, Inspectors, Local Health Department personnel, Epidemiologists, Sanitarians or anyone else who contributed information or had a need to know during the incident). It is important to conduct the after action review as soon as possible and to generate your AAR/IP while the incident and issue is fresh in everyone's mind. It is recommended that an AAR/IP be completed within 45 days of the event/exercise.

8.5.2. Keep in mind that a thorough AAR/IP may also require modifications of existing protocols/procedures/training. Ensure your IP will capture this, and identify who is responsible for these revisions and are completed within a specified timeframe. A process for final approval is recommended such as a committee that reviews the final AAR/IP for management sign off for agency commitment.

8.5.3. Before making an AAR/IP public (e.g., posting on a public website), legal counsel for each affected agency should be given the opportunity to review the report and provide concurrence before releasing/posting.

8.6. Records to be maintained

8.6.1. **After Action Report (AAR)**

8.6.2. **Improvement Plan – (IP)**

8.6.3. **Follow-up** - The facilitator will provide a follow-up report detailing the status and outcome regarding the recommendations listed in the IP.

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

Full achievement of this best practice requires implementation of sufficient infrastructure to complete an After Action Review with state, local and federal partners (as appropriate)

that participated in a multi-agency response within 45 days of completion of the response. The outcome of the review would be an AAR/IP that is implemented by the participating agencies to improve future responses. This may include revisions to procedures, policy, training, etc.

Level	Description
1	Single Agency Basic – The agency* identifies criteria to determine for which responses an AAR will be completed and evaluates their own response to those incidents. Discussions focus on items/procedures they wish to change internally to improve their processes. Informal documentation may be generated.
2	Multi-Agency Basic – Principal response agencies agree on criteria to determine which multi-agency responses warrant an AAR. The principal agencies involved in these responses meet as needed to collectively discuss strengths and weaknesses identified during these responses. Recommendations and/or action items to improve multi-agency processes and coordination are identified. Informal documentation may be generated.
3	Single Agency Comprehensive – The agency implements a SOP based on the After Action Review Chapter, or other national guidance, which is reviewed on a yearly basis. For multi-agency responses, resulting AARs seek input from all participating agencies. In the absence of actual incidents, at least one exercise is conducted per year and an AAR is generated and recommended action items are tracked as part of the agency's continuous program improvement process.
4	Multi-Agency Comprehensive – Principal response agencies have agreed to and implemented a single SOP based on the After Action Review Chapter, or other national guidance, which is reviewed on a yearly basis. As a result, a joint AAR is generated for the response and recommended action items are tracked within each agency's continuous program improvement process. In the absence of actual incidents, at least one exercise is conducted per year and an AAR/IP is generated.

*Agency is defined as any Agency participating in the Rapid Response Team

10. RELATED DOCUMENTS

Examples of AARs from events of varying size and complexity are included as attachments in this chapter.

11. REFERENCES AND OTHER RESOURCES

11.1. Homeland Security Exercise and Evaluation Program Templates (https://hseep.dhs.gov/pages/1001_HSEEP7.aspx)

11.2. FDA After Action Procedures – Final Draft 3

12. ATTACHMENTS/TEMPLATES

12.1. Attachment A – Examples of After Action Reports (Simple)

12.2. Attachment B – Examples of After Action Reports (Medium)

12.3. Attachment C – Examples of After Action Reports (Complex)

12.4. Attachment D – After Action Report Template

12.5. Attachment E – After Action Report Template Homeland Security Exercise and Evaluation Program (HSEEP)

12.6. Attachment F – Lessons Learned/Recommendations Report Template

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	10/30/12	RRT AAR WG (FL**, MI, MN, WA) Other Contributors: FDA CORE
1.1	R	6/5/13	FDA ORA/OP
1.2	R	5/26/17	ORA/OP

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)

**Workgroup Lead

Change History

1.1 – Editorial revision by ORA to support document concurrence.

1.2 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.

Attachment A – Examples of After Action Reports (Simple)

- Attachment A-1: North Carolina Department of Agriculture and Consumer Services ESF 11 Hurricane Irene Response and Recovery After Action Report (AAR) Input Form
- Attachment A-2: Mad Minute AAR Template
- Attachment A-3: Minnesota RRT After Action Review Example: *Listeria* Contamination in Facility
- Attachment A-4: Texas RRT Example: *Salmonella* Agona Outbreak 2011 – After Action Report
- Attachment A-5: Missouri Severe Storms, Tornadoes & Flooding (2011), ESF 11 After Action Report (AAR)

NCDA&CS ESF 11
Hurricane Irene 08222011 Response and Recovery
After Action Report (AAR) Input Form

AAR Observation: *Briefly Describe the general area of activity whether a strength or an area for improvement concerning the NCDA&CS ESF 11 Hurricane Irene response and recovery efforts.*	1. Coordination between the supervisors/field and Raleigh Office	☒Noted Strength ☐Area for Improvement	☐Equipment ☒Organization ☐Personnel ☐Planning ☐Process ☐Training
	2. Lack of directions as to how to fill out NCFDEM database	☐Noted Strength ☒Area for Improvement	☐Equipment ☐Organization ☐Personnel ☐Planning ☐Process ☒Training
	3. Refinement of input page in NCFDEM database	☐Noted Strength ☒Area for Improvement	☒Equipment ☐Organization ☐Personnel ☐Planning ☒Process ☐Training
	4. During phone calls – some firms refused to provide information unless NCDA personnel showed up in person with credentials	☐Noted Strength ☒Area for Improvement	☐Equipment ☐Organization ☐Personnel ☐Planning ☒Process ☐Training
Recommendations- *Please make any recommendations to address identified areas for improvement, based on judgment and experience here as applicable.*	1. Process already in place		
	2. Provide “how-to” training or web instructions		
	3. Make an event-specific option, rather than utilize the “recall” response option		
	4. Case-by-case situation; information via phone calls utilized to reduce response time in the field. Corporate companies need to be made aware of reasons.		

NCDA&CS ESF 11
Hurricane Irene 08222011 Response and Recovery
After Action Report (AAR) Input Form

AAR Observation: *Briefly Describe the general area of activity whether a strength or an area for improvement concerning the NCDA&CS ESF 11 Hurricane Irene response and recovery efforts.*	5. Slow response to questions regarding assistance related to computer/database problems	☐ Noted Strength ☒ Area for Improvement	☐ Equipment ☒ Organization ☐ Personnel ☐ Planning ☒ Process ☐ Training
	6. Computer issues: entries showed up twice on daily log	☐ Noted Strength ☒ Area for Improvement	☐ Equipment ☐ Organization ☐ Personnel ☐ Planning ☒ Process ☐ Training
	7. Duplicate information entry in both Food Firm database and NCFDEM	☐ Noted Strength ☒ Area for Improvement	☐ Equipment ☐ Organization ☐ Personnel ☐ Planning ☒ Process ☐ Training
	8. Unable to change the lead inspector for cross region inspection	☐ Noted Strength ☒ Area for Improvement	☐ Equipment ☐ Organization ☐ Personnel ☒ Planning ☐ Process ☐ Training
Recommendations- *Please make any recommendations to address identified areas for improvement, based on judgment and experience here as applicable.*	5. Administrative personnel and backups with access to databases needed available during event		
	6. At the time, was the only way to have entries logged; will find a way around duplication.		
	7. Porting information between the two programs is on Daniel's work list		
	8. After communicating with Daniel, changing the name of lead inspector should not be a problem. That should only be an individual event.		

NCDA&CS ESF 11
Hurricane Irene 08222011 Response and Recovery
After Action Report (AAR) Input Form

AAR Observation: *Briefly Describe the general area of activity whether a strength or an area for improvement concerning the NCDA&CS ESF 11 Hurricane Irene response and recovery efforts.*	9. Firm information on the database is incorrect	☐Noted Strength ☒Area for Improvement	☐Equipment ☐Organization ☐Personnel ☐Planning ☒Process ☐Training
	10. Having a firm list every evening for next day's planning	☒Noted Strength ☐Area for Improvement	☐Equipment ☒Organization ☐Personnel ☒Planning ☐Process ☐Training
	11. Having backup/ buddy system when needed and for daily findings	☒Noted Strength ☐Area for Improvement	☐Equipment ☒Organization ☐Personnel ☒Planning ☒Process ☐Training
	12. Calling (instead of visiting) the firm when a generator is present (when power outage occurs)	☐Noted Strength ☒Area for Improvement	☐Equipment ☐Organization ☐Personnel ☐Planning ☐Process ☒Training
Recommendations- *Please make any recommendations to address identified areas for improvement, based on judgment and experience here as applicable.*	9. Attention to detail. Correct or flag any mistakes or questionable firms for further processing. Issue that needs to be owned and corrected by specialists in their territories during routine inspections, not during an event (if correctly input, no issues).		
	10.		
	11.		
	12. During routine inspections, make notes when a firm has a backup power source		

NCDA&CS ESF 11
Hurricane Irene 08222011 Response and Recovery
After Action Report (AAR) Input Form

AAR Observation: *Briefly Describe the general area of activity whether a strength or an area for improvement concerning the NCDA&CS ESF 11 Hurricane Irene response and recovery efforts.*	13. Duplication in the NOI and Hurricane Irene 2011 Field Response was unnecessary	☐Noted Strength ☒Area for Improvement	☐Equipment ☐Organization ☐Personnel ☐Planning ☒Process ☐Training
	14. Having more freedom to conduct visits based on the inspector's understanding to the area (instead of following the list only)	☐Noted Strength ☒Area for Improvement	☐Equipment ☐Organization ☐Personnel ☐Planning ☒Process ☐Training
	15. Personnel should visit the stores and verify the information provided by the cooperate office	☐Noted Strength ☒Area for Improvement	☐Equipment ☐Organization ☐Personnel ☐Planning ☒Process ☐Training
	16. Focus attention on severely damaged firms	☐Noted Strength ☒Area for Improvement	☐Equipment ☐Organization ☐Personnel ☒Planning ☐Process ☐Training
Recommendations- *Please make any recommendations to address identified areas for improvement, based on judgment and experience here as applicable.*	13. Completion of the short form at the time of the visit and attach it to the NOI; the observation sheet was only required if regulatory action taken. Short form was an attempt to prevent duplication with observation sheet		
	14. Utilize field experience and knowledge of assigned territories.		
	15. That should not be necessary; goal was to gain effective information without creation of more field work		
	Attempted to identify severely affected areas via the electrical companies and NCDA EP prior to sending field on "fishing" expeditions. For the future, categorize assignments if possible into the NCFDEM system according to the seriousness of damage		

Discussion Draft: April 13, 2011

After Action Report Template

Incident Title: _____
Incident Date(s):_____
Report Date: _____
Participants: _____

Ground Rules (Review as needed)

The facilitator reviews ground rules at the onset of an AAR

- All participants have equal status
- Plain speaking is essential
- Tact and civility are required
- This is a "No-Fault" evaluation. Focus on "what" and not "who". Avoid finding fault or assigning blame. During the discussion, mistakes are not held against those who admit them. However, this does not grant immunity outside of the AAR for malfeasance or gross negligence.
- Discussion details stay "in house". Relevant information from lessons learned will be incorporated into the after action report.

Executive Summary Key Points - Address what was planned vs. what actually happened

-

Incident Timeline of key dates and events (if available)

-

Areas That Worked Well

-

Suggestions For Further Improvements

-

Other comments

-

xxxxxxxx – *Listeria* contamination in xxxx facility
After Action Review
xx/xx/xxxx

Attendance:

Minnesota Department of Agriculture:
Jan Kelly, Ben Miller, Jim Topie, Erin Ryan, Holly Blais, Carrie Rigdon

FDA MPLS District Office:
Darlene Krieger, Amy McIntyre

Facilitator/Note Taker:
Jan Kelly/Carrie Rigdon

Reason/Purpose for HOT WASH:

- To discuss value of MDA and FDA staff experiences regarding the Rapid Response Team (RRT) involved with a just concluded response activity
- What Worked, what didn't work
- What can be changed/improved upon

Specific areas discussed:

1) Communication/Information sharing
   a. Went well:
      i. Sharing of information went well between field staff and rest of ICS response team.
      ii. Firm had a white board where the field team wrote down what they would be doing in the firm that day, along with other significant dates like lab result reporting. That really helped in communication with employees/management at the firm that everyone could see the plan for that day. Overall, communication with the firm was very good (but see Tennessen Warning note below).
   b. Needs improvement:
      i. The agency lead for the investigation and lead for the field team (particularly in the shift from sampling team to GMP inspection team) were not well defined or there was some confusion.
         - Set advance definition of what 'lead agency' responsibility roles are; likewise for the supporting agency
         - Future initial planning calls:
           - Explicitly discuss management of event and define lead and other roles (by filling out ICS org chart, for example)
           - Clearly define field team lead and for what duration or aspect of the response (will that change with different team duties?)
           - Explicitly discuss and determine if this response will include a contract inspection and/or contract sampling (part of initial notification form?) and what the implications of this is for actions and management of the response

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ii. Even though the field team explained the joint FDA-MDA investigation to the firm and that some actions were being taken on MDA authority vs. FDA authority (like issuing orders or discussing Corrective Action Plan) and there we no difficult conflicts of authority in this instance, it did raise the question of what we do if there are conflicts. For example, if MDA issues corrective actions and they feel they have been complied with, but later FDA compliance still feels there are problems, that could be very confusing to the firm.

iii. After issuing the MDA Tennessen Warnings, there was a noticeable communication difference with the firm.

- Replace with Notice of Inspection (NOI)?

2) Use of ICS structure during an investigation

a. Needs Improvement:

i. There were conflicting assumptions on using ICS in the instance: MDA assumed that ICS encompassed responders from both agencies; FDA assumed that ICS was only being used internally by MDA.

ii. As stated above, there needs to be explicit discussion on how the response will be managed. It is MDA's belief that all joint responses to incidents should operate under an ICS structure.

iii. Not all FDA staff have had ICS training – don't have clear understanding of use/meaning. MDA staff have had the training, but not clear about use during a food related incident.

3) Field Investigation

a. General issues

i. Safety concerns: Is there a health risk or safety concern for pregnant women when sampling in a firm where Listeria (or Salmonella) are present? Both agencies would allow personnel to opt out of being part of the field team (FDA requires documentation).

- Draw up document that explains the risks to personnel
- Response management team should assess whether this may limit availability for creating a field team

b. Records review

i. Went well: a representative from each agency reviewed all records – split by date

- Create list of types of records to include in review as reference for future responses

c. GMP inspection

i. Agency differences: FDA included the warehouse in their inspection but MDA did not (because inspector assigned to firm was part of team and easily go back after investigation)

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- Document rules or guidance for investigation focus (highlight any differences between FDA and MDA)
- Scheduling for after hours or overnight staffing: an MDA inspector was staying near the firm and was available to be on site during late evening/early morning cleaning and sanitation. This was agreed upon by the team, but in retrospect it would have been better to plan for more members of the team to be there to witness it or have a different team cover this because of the longer hours/scheduling it takes. All agreed on the value that after hours observation can bring to an investigation.
- Include overnight coverage as part of the planning meeting.

4) Sample Collection and Submission
   a. Needs improvement:
      i. Differences in protocol: the field team was acting under DFID sampling protocol that was based on an FDA protocol that had since been updated without DFID being aware of the changes.
         - Update DFID protocol (consider applying it for all manufacturing samples – investigation and routine)
         - Ensure updates are disseminated in a timely manner
         - Recommendation for team to practice in advance
      ii. Sampling equipment:
         - Need disposable lab coats so inspectors can have a fresh garment every day (concerns with safety, cross-contamination, and logistics of laundering the current coats)
         - Need to pare down existing sampling tote to just include necessary items and make it lighter and use smaller empty tote to take necessary items into the facility.
5) Laboratory Analysis/Reporting
   a. Worked well: quick turn-around time

Outcomes:

- ❖ Lessons Learned – Knowledge and experience, positive or negative, derived from actual incidents as well as from observations and historical study of operations, training and exercises
- ❖ Best Practices Identified – Exemplary, peer-validated techniques, procedures, good ideas, or solutions that work and are solidly grounded in actual operations, training, and exercise experience.

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Improvement Plan

This improvement plan has been developed specifically for the MN RRT as a result of the Roma/Vistar Listeria Investigation from 11/8 – 11/29/2010.

Tasks	Improvement Recommendations	Responsible Party/Agency	Completion Date
Update Environmental sampling SOP (MDA)	Adopt current guidance in DFI Bulletin	MDA: Jan Kelly, Sarah Schabert, Jim Topie	1/3/2011
Retraining of field staff on environmental sampling (MDA)	Dependent on updated SOP (above)	MDA: Kristin Viger	2/1/2011
Communications SOP – draft for joint response	(a) Better clarifications during initial planning (b) Deciding on Contract vs. Not Contract (c) Define roles and responsibilities of "lead" agency.	**1st Draft:** MDA: Jan Kelly and Carrie Rigdon FDA: Darlene Krieger and ?	**1st Draft:** Prior to Quarterly Meeting **2nd Draft:** 3/1/2011 **Final approval:** 4/1/2011
Initial Planning: Checklist and Discussion as part of Communications SOP	(a) Use of ICS structure in joint response (b) Will joint response include contract inspection or contract sampling? And implications of this. (c) Who is lead agency? And implications of this. (d) Coverage for after hours inspections (e) Designing Initial Notification form	**1st Draft:** MDA: Jan Kelly and Carrie Rigdon FDA: Darlene Krieger and ?	**1st Draft:** Prior to Quarterly Meeting **2nd Draft:** 3/1/2011 **Final approval:** 4/1/2011

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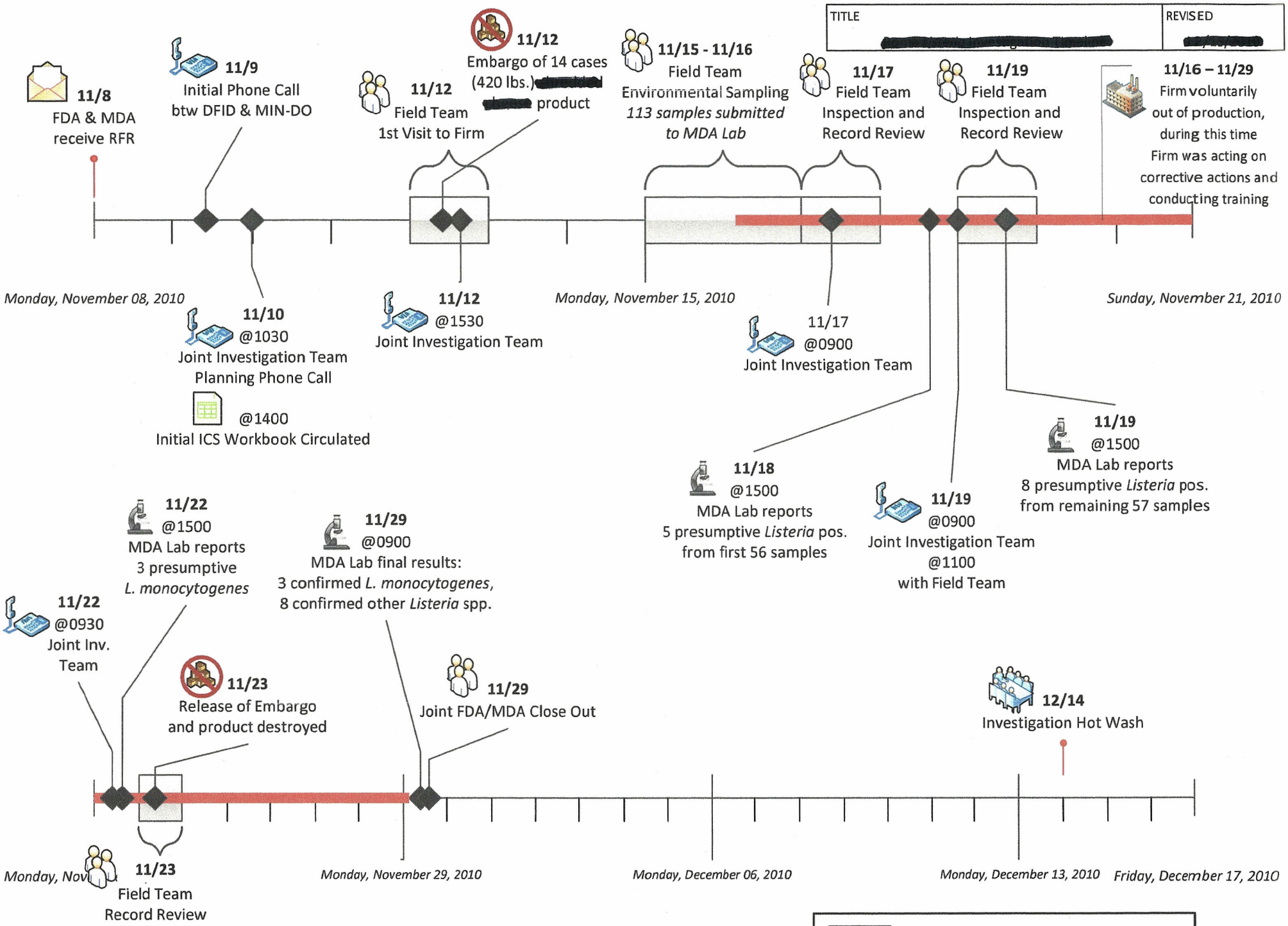
Tasks	Improvement Recommendations	Responsible Party/Agency	Completion Date
ICS training	Formal ICS training	FDA: ?	[to be filled in by FDA]
	Training with inspectors on ICS during incident response	MDA: Jan Kelly, Kristin Viger	6/1/2011
Communication to **firm** on what Joint Response means and roles of each agency during investigation	Create document or hand-out for firm	MDA: Jim Topie, Heidi Kassenborg FDA: ??	**1st Draft:** 4/1/2011 **Final Approval:** 6/1/2011

Tracking progress of Improvement Plan:

- MDA will use SharePoint for tracking progress


TITLE
[redacted]
REVISED
[redacted]
11/8
FDA & MDA receive RFR
11/9
Initial Phone Call btw DFID & MIN-DO
11/10
@1030
Joint Investigation Team Planning Phone Call
@1400
Initial ICS Workbook Circulated
11/12
Field Team
1st Visit to Firm
11/12
Embargo of 14 cases (420 lbs.) [redacted] product
11/12
@1530
Joint Investigation Team
11/15 - 11/16
Field Team
Environmental Sampling
113 samples submitted to MDA Lab
11/17
Field Team
Inspection and Record Review
11/17
@0900
Joint Investigation Team
11/19
Field Team
Inspection and Record Review
11/16 – 11/29
Firm voluntarily out of production, during this time Firm was acting on corrective actions and conducting training
Monday, November 08, 2010
Monday, November 15, 2010
Sunday, November 21, 2010
11/18
@1500
MDA Lab reports
5 presumptive Listeria pos. from first 56 samples
11/19
@0900
Joint Investigation Team
@1100
with Field Team
11/19
@1500
MDA Lab reports
8 presumptive Listeria pos. from remaining 57 samples
11/22
@1500
MDA Lab reports
3 presumptive L. monocytogenes
11/29
@0900
MDA Lab final results:
3 confirmed L. monocytogenes,
8 confirmed other Listeria spp.
11/22
@0930
Joint Inv. Team
11/23
Release of Embargo and product destroyed
11/29
Joint FDA/MDA Close Out
12/14
Investigation Hot Wash
11/23
Field Team
Record Review
Monday, Nov
Monday, November 29, 2010
Monday, December 06, 2010
Monday, December 13, 2010
Friday, December 17, 2010
Field Team on site at firm
Firm voluntarily out of production

Salmonella Agona Outbreak 2011 – After Action Report – First Draft – 9-28-2011

Meeting: Thursday, September 8, 2011
Location: Exchange Bldg., - N-218
Time: 2:00 PM to 4:00 PM

Attendees:

Jeff Taylor	RRT – Incident Commander
L. B. Booty	Incident Commander
Tyson Chapman	Incident Commander
Julie Loera	Planning Chief
Claire Perkins	Planning Chief
Susan Tennyson	Other Agency Representative
Frank Borden	Operations Chief
Jane Broussard	Operations Chief
Davonna Koebrick	Operations Chief
David Sueltenfuss	Operations Chief
Debbra Callan	Liaison Officer
Dr. Linda Gaul	Epidemiology
Liz Delamater	Laboratory
Lewis Ressler	Records Documentation
Catherine Thibodaux	Records Documentation
Kevin Veal	Other Agency Representative
Susan Tennyson	Other Agency Representative
Ricky Rodriquez	Other Agency Representative
Charlotte Dokes	Other Agency Representative
Tyson Chapman	Other Agency Representative
Ricky Rodriguez	Other Agency Representative
Shari Shambaugh	Other Agency Representative
Susan Turcovski	Other Agency Representative
Ben Jones	Other Agency Representative/Operations Field Team
Homero Garza	Operations Field Team
Alberto Cornezo	Operations Field Team
Manuel Lopez	Operations Field Team
Jose Martinez	Operations Field Team
Tamara Hurt	Operations Field Team
Stacey Belore	Operations Field Team
Tricia Martinez	Operations Field Team
Ryan Pope	Operations Field Team
Julio Salozar	Operations Field Team
Emilio Escobar	Operations Field Team
David Pitman	Operations Field Team
Silina Mata	Operations Field Team
Rene Ramirez	Operations Field Team
Alvaro Dominguez	Operations Field Team
Connie Lucero	Operations Field Team
Sandra Jacquez	Operations Field Team
Francisco Mendoza	Operations Field Team

Note: We are uncertain that all on call are listed. If you see anyone missing, please advise.

Agenda:

Distribution and review of the timeline as presented by and Julie Lorea
AAR:

- Section I - What went well
- Section II - What needs improvement
- Section III - Lessons Learned - what steps do we take to make the improvements

Section I - What went well?

1. Early activation of relatively small outbreak:

- Early activation of the Texas Rapid Response Team (TRRT), using the Scope and Trigger document instructions, had a great deal to do with getting a jump on this situation for both DSHS and DALDO, which led to a very early determination of source of contamination;
- The first call for the TRRT Steering Committee happened in less than 24 hours;
- The laboratories were also engaged early on;
- Communication maintained among all agencies throughout the event.

2. Records analysis:

- A new program was developed in one day and coordinated the records throughout the activation;
- The collection, data entry, and all coordination of records led to the success of this activation.

See Section III - #7 and #8

3. Use of Traction website:

- Experts on the Traction system provided valuable assistance by posting instructions, making assignments, etc., on the new Traction website;
- The Traction website was set up and running with one day of activation;
- Once learned, Traction was easy to use. It was found that it was easy to share information and documents for both DSHS and FDA.

See Section III - #6

4. EPI involvement:

- The Epidemiology notification to Regulatory partners was timely;
- The food history work done at Epi showed a lot of work done during the initial stages and behind the scenes to capture where the products were purchased; the detail in the food history on cases that helped limit the focus of the investigation. This excellent Epi work is critical to assisting the regulatory traceback process.

See Section III, #3.

5. DSHS and FDA Field Teams:

   - The field teams did an excellent job of using Traction, accepting assignments and instructions under ICS structure, and working well together. This was the first event where the field RRT teams have been staffed with both DSHS and FDA employees;
   - Further, the FDA Rockville offices were able to share some analysis of import data. There was great coordination between agencies, i.e., DSHS, SWID, and Dallas District.

6. Time:

   - All staff, from all agencies, were willing to put in the long hours of work needed to solve this outbreak.

   See Section III - #4

Section II – What Needs Improvement:

1. Depth of resources:

   - There is a lack of depth of resources; not enough back-up for employees and equipment;
   - This led to the record keeping duties being somewhat overwhelmed with the records flowing in;
   - Only two employees could do the flow charting due to Visio program being available only on one desktop computer and one laptop. The laptop happened to be out of order with a virus during the mist of the activation;
   - Need more resources available during activation and more IT assistance both for Traction and to enable better sharing of programs/records between DSHS and DALDO. More Visio software is needed;

   See Section III - #9-b, 9-d, 9-e and #10-d

2. Stakeholders:

   - RRT did not involve all stakeholders; TDA was not notified of activation and ensuing activities.

   See Section III - #1.

3. Communication:

   - At the beginning of the activation there was a bleeding over of roles. This may have been exacerbated by the fact that Command and General staff were scattered across state. Further, there was no notification of changes in Command staff when they occurred. However, as this will always be the case, the problem must be addressed in further ICS training;
   - It was noted that the field investigators were not always kept informed of details of the situations which led to some confusion, i.e., picking up traceforward rather than traceback information. Notification was either poor and/or slow.

   See Section III - #2, #8, and #9-a, 9-c and 9-g

4. Identification of lab resources:

   - It was noted that the labs should, in the future, give special instructions for RRT samples rather than going through regular channels to ensure that the RRT samples get handled and results distributed on the most timely basis as possible.

5. Transition process

   - It was determined that there is a need to improve the transition process; hand-offs to new, or second team, i.e, better communications between the current Command Staff and the transitioning staff.

   See Section III - #10-a, 10-b, 10-c and 10-e

6. Epi concerns:

   - Concerns were expressed from EPI about further contamination and continuing surveillance and the potential impact this should have on consideration to demobilize at this time.

7. Activities Outside of RRT:

   - Comments were made about an emergency created due to lack of communication and coordination by parties outside of the control of the RRT;
   - It was difficult to scramble to initiate a domestic recall based on import sample results;
   - There is a need to establish sampling processes parameters for communication of possible samples results.

Section III – Lesson Learned - What steps do we take to make the improvements:

1. Develop list of stakeholders and put at ready for notifications of any future situations in which they may be involved. It was felt that communicating with industry should be on an ongoing basis. This would be almost like a mini after action with industry.

2. It was also suggested that DSHS needs to develop a communication system to include DALDO earlier on in CDC calls, as these can be the precursor to an outbreak situation.

3. Need to ensure the Epi food history is the RRT activation process is captured in the time line. This information also needs to be captured in an SOP to ensure that if staff changes they have this great source of information provided every time an incident occurs.

4. Due to the lack of depth in personnel, it is most important that a dedicated room for the Command and General staff be used in order to have all members physically present and working together and away from their normal day-to-day activities to enable them to concentrate on the activation only and not be interrupted by co-workers on usual daily activities.

5. It was suggested that the TRRT observe other activations to see how they handle some of the "need to improve" areas; DSHS radiation group was one suggestion.

6. There should be basic instructions for use of Traction; SOP or Procedures Manual. Furthermore, the Traction website did not capture operational oversight, such as a resource request. Also, a few assignments were lost. A system is needed to keep people outside of the actual operation up-to-date on the event.

7. Continue training efforts on traceback and traceforward for all staff.

8. Order test scanners for field staff to enable them to scan documents while at facilities directly to the Traction website. During this activation there was only one scanner available in one area.

9. The following comments all relate to field staff and their supervisors:

    a) DSHS must establish policies for notification to supervisors when staff have been activated on the RRT. This is extremely important for two reasons; a) when a staff member is activated in the field, they are relieved of their every-day duties until demobilization of their team/group so the supervisor must be aware of this and ready to either fill their vacancy on the every-day work or construct delays as necessary, and b) a staff member must realize that they no longer have to respond or check in with their day-to-day supervisor when working on an RRT activation due to the ICS structure guidelines. Accordingly, the activation process needs to be reviewed.

    b) It would be helpful to identify team members that might be needed down the road in an activation who may be pulled into an investigation up-to-date on activities so they are aware of what is going on and they may potentially be needed to do. Also, there needs to be a procedure in making assignments within the teams in order that roles are established, as it was not always clear who was going to perform each activity needed.

    c) Notification went to field teams that additional firms had been identified but there was a lag in when the firm names arrived. The timeline was set the previous week but the names of the firms where they needed to go to collect records did not arrive until a few days later. The timeline was not adjusted and staff had to work very hard to make the timeline. Field teams felt the notification was poor and slow. Furthermore, the sheer number of records coming in to process was overwhelming and they felt that getting assignments on a timelier manner would have helped this situation.

    d) The tight time-frame for sampling made it difficult to ensure supplies were appropriate for task. The supply issues should be addressed in SOP's/Procedure Manual so that everyone is prepared in the event of an activation/incident.

e) When sampling teams are assembled, they should be briefed on the potential for action such as a recall on the sample results, i.e., what evidence is needed and how paper work needs to be filled out properly. Also, instruction should be provided as to how the collection of labels for any products produced during the inspection can be used as part of documentation.

f) Response to request for additional resources was slow in coming. This should be included in an SOP or Procedures Manual.

g) There should be better definitions provided of records be collected during the activation process.

h) Wireless equipment, laptops with wireless capabilities are needed in field to upload and access Traction.

10. The following comments pertained to the ICS structure and it's proper usage during an event:

a) Planning P – At the beginning of the operation period there was not a lot of structure to the operational calls. Learning more about the Plan P would help overcome this problem as the operations, planning and incident command calls were being combined.

b) Transitional periods went badly and there was no transitional time between members. There was no rotation of staff on and off activation. As stated above, this problem must be addressed in further ICS training.

c) More people should be included in the initial meeting for operations, i.e., SWID, State, IB.

d) Resource issues must be discussed and solutions undertaken to alleviate this problem and provide a continuity of operations during an activation. This applies both for members of the RRT while activated and their unit to cover the individual's day-to-day work. Command staff should have other duties re-assigned in order to dedicate full time on the incident. Duties for Command staff are very time consuming.

e) Procedures should be established as to how we transition from an outbreak investigation to a regulatory action with regard to documentation collection and evidence collection. This should provide clarification on what was collected during the outbreak investigation and what was still needed. Again, how do we communicate to a larger group and keep them informed of what is going on with the team investigation?

NOTE:
Upon review of all attendees and amendments/suggested provided to Debbra Callan and a final draft approved, the corrective action plan will developed from the last section of this report.

1980DR-Missouri
Severe Storms, Tornadoes & Flooding
May 24 - June 28 2011
ESF 11 After Action Report (AAR)

Incident Summary

On 25 May, FEMA Region VII mission assigned ESF11 to support FEMA and the State of Missouri for Severe Storms, Tornadoes and Flooding along the Missouri and Mississippi River. ESF11 was activated and requested to deploy Desk Officers to cover the RRCC in Kansas City, MO and other locations as requested, under the Federal Operations Support Mission Assignment. The ESF11 Coordinator advised partner agencies, state, and federal stakeholders of the activation and requested information related to the disaster response efforts. USDA FSIS reported impacted facilities, but none that required additional assistance. Department of Interior (DOI) was put in contact with the FEMA Environment and Historic Preservation Officer, in case assessments revealed a need for further DOI assistance. USDA FNS provided USDA Foods data to ESF11 and ESF6, and assisted Missouri with the Disaster Supplemental Nutrition Assistance Program (D-SNAP). ESF11 held daily coordination calls with USDA APHIS, FSIS, and FNS, DOI, representatives from Iowa, Kansas, Missouri, and Nebraska, and non governmental agencies.

Assessment of the 5 focus areas of ESF 11 discovered Emerald Ash Borer (a plant pest) quarantine was active in an impacted county. ESF 11 notified the State Plant Health Director (Missouri) and hosted a conference call to allow information sharing and guidance from PPQ to be shared with FEMA, other federal ESFs and multiple state stakeholders. Site assessments were conducted by PPQ and measures to reduce spread of the pest were taken. A desk officer was deployed to the IOF in Joplin, MO to conduct an assessment of the safety and well being of household pets. The assessment was shared with FEMA and on 28 May FEMA issued a Mission Assignment Task Order to “provide one APHIS ESF11 representative to the Joplin Division Office in Joplin Missouri to support FEMA in the coordination of Pet Sheltering Mission.” The ESF11 Desk Officer (DO) held the position of ESF11 Liaison Officer (LNO) on the FEMA Incident Management Assistance Team in Joplin. The desk officer provided technical assistance in several areas to include: trapping displaced pets so they would not become feral and pose a future public health and safety risk, resource ordering, and monitoring heat concerns at shelters. Information from the media that an elephant was being utilized to move debris was relayed to APHIS Animal Care. Pet calls were held to address needs and ensure communication with all relevant parties. Over 1300 pets received assistance by the Joplin sheltering process. After a month of sheltering, 745 displaced pets still needed homes. A pet adoption event was hosted by the Joplin community and the remaining pets were successfully adopted. ESF 11 mission was completed 28 June.

Lessons Learned

Things that worked well:

1. Support from APHIS Western Region (programs and dispatch) and headquarters (national coordinator and mission assignment manager) regarding questions and concerns related to ESF11 support to Missouri for Severe Storms, Tornadoes, deployment of employees, and obtaining APHIS accounting codes to track reimbursable expenses.
2. Successful coordination between Missouri and FEMA of Emerald Ash Borer Quarantine in a county approved for FEMA Public Assistance. Plant Protection and Quarantine (PPQ) provided guidance for handling infected wood/tree material to reduce spread of plant pest in a timely manner.
3. Staff Integrated into the FEMA Incident Management Assistance Team (IMAT). Unique situation, but one well suited for ESF11 desk officer with veterinary expertise. The ESF11 DO was able to provide communication linkage and situational awareness between USDA and

FEMA and the various state and local government and nongovernmental entities assisting in the Joplin Pet Sheltering operations. The Animal Welfare Act expertise was beneficial in identifying an item of concern that was raised about an animal being used to assist in debris removal. That information was quickly relayed to appropriate entities to address or investigate.

4. Open communication and situational awareness exchange between the State Emergency Boards (SEBs) and ESF11 within Iowa, Kansas, Missouri, and Nebraska.

Things that could use improvement:

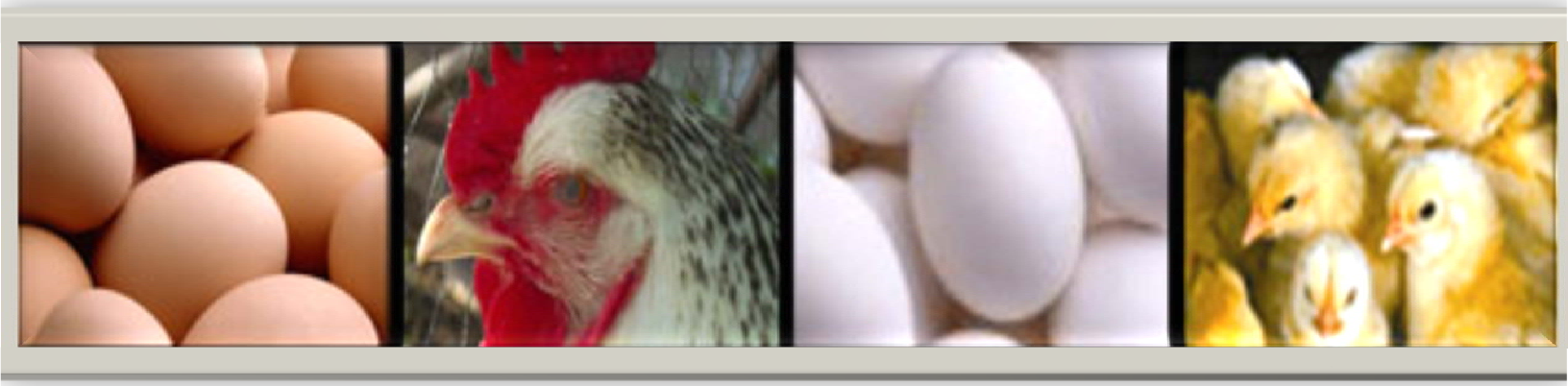
1. It is critical for APHIS employees to have IT support after-hours and on weekends.
2. Resource Management: Support is needed from region and headquarters regarding the role of the ESF 11 coordinator as the responsible party for mission assignments and the resources assigned to them. Without this clarity, resources may have conflicting input from FEMA, APHIS programs, and ESF 11. The goal of integrating resources into an ESF 11 team culture is challenged when home agencies provide guidance independent of the ESF 11 coordinator. It is recommended that during ESF 11 activations and deployments, employees put home-program discussions on-hold to the extent possible. The following resource management questions are recommended for discussion with programs: Who determines how long a resource is deployed? Who leads communication with FEMA or state IMTs regarding resource needs and decisions?
3. Resource Request Workbooks: requesting resources by position (rather than name-requests) provides APHIS programs flexibility and latitude as they decide which program and employees will be dispatched. Specifying under the “Special Needs” column any critical IT or skill needs (e.g. Blackberry, laptop with wireless capability, proficient with ICS-215’s, etc) and specifying desired length of deployment are also helpful to identify appropriate resources and ensuring they arrive prepared.
4. ESF 11 Daily Report: guidance may be needed on the acquiring and reporting of pet numbers.

Attachment B – Examples of After Action Reports (Medium)

- Attachment B-1: Shell-Shocked AAR – FLIRRT

After Action Report

Exercise “Shell Shocked”



August 5, 2011

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Handling Instructions

1. The title of this document is the "2011 Exercise Shell Shocked After Action Report" (AAR).
2. Information gathered in this AAR is designated as For Official Use Only (FOUO) and should be handled as sensitive information that is not to be disclosed. This document should be safeguarded, handled, transmitted, and stored in accordance with appropriate security directives. Reproduction of this document, in whole or in part, without prior approval from the Florida Department of Agriculture and Consumer Services is prohibited.
3. At a minimum, the attached materials will be disseminated strictly on a need-to-know basis and, when unattended, will be stored in a locked container or area that offers sufficient protection against theft, compromise, inadvertent access, and unauthorized disclosure.
4. For more information about the exercise, please consult the following point of contact (POC):

   Denise Imbler
   Apalachee Regional Planning Council
   20776 Central Avenue East
   Blountstown, FL 32424
   (850) 488-6211 (office)
   Denise.Imbler@thearpc.com

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Contents

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After Action Report **2011 Exercise Shell Shocked**

Executive Summary

The Florida Integrated Rapid Response Team (FLIRRT) was formed to support Florida's capability to respond immediately following a disaster incident. The team includes members from the Florida Department of Agriculture and Consumer Services, Florida Department of Health, Florida Department of Business and Professional Regulation, U.S. Food and Drug Administration and U.S. Department of Agriculture. All agencies were involved in the design of the exercise and Pasco County Emergency Management and the Florida Department of Law Enforcement also collaborated, bringing both local government and intelligence gathering components to the design of the scenario.

The purpose of this exercise was to practice a multi-jurisdictional and multi-agency response to a catastrophic food/feed incident and to examine the Incident Command System (ICS) and communication capabilities of the FLIRRT in anticipation of and preparation for such a response. The exercise was designed to emphasize information sharing, coordination, collaboration, integration of capabilities and resolution in a condensed timeline format. All of the exercise participants had completed ICS training prior to the exercise and were familiar with basic concepts of the communication tools available for use during an emergency incident.

This tabletop exercise allowed for the design team and players alike, to discuss their ICS roles and communication protocols in a stress free environment. It provided an opportunity for review and enhancement of activation and notification procedures. It also proved invaluable as a place for the Steering Committee members to come together to discuss and resolve specific issues within the context of a real world scenario.

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Section 1: Exercise Overview

Exercise Details

Exercise Name:	Exercise "Shell Shocked"
Type of Exercise:	Tabletop Exercise
Exercise Start Date:	June 2, 2011, 8:300 a.m.
Exercise End Date:	June 2, 2011, 3:30 p.m.
Duration:	One Day
Location:	Tallahassee, Florida
Sponsor:	Florida Department of Agriculture and Consumer Services
Mission:	Respond
Capabilities:	Animal Disease Emergency Support
	Food and Agriculture Safety and Defense
Scenario Type:	Table-top Exercise

Exercise Planning Team

Rita Johnson, Florida Department of Agriculture and Consumer Services

Michael Turner, Florida Department of Agriculture and Consumer Services

John Burkette, Florida Department of Agriculture and Consumer Services

Art Johnstone, Florida Department of Agriculture and Consumer Services

George Hayslip, Florida Department of Agriculture and Consumer Services

Mike Whitehead, Florida Department of Business and Professional Regulations

Michael Wydotis, Florida Department of Health

Hilary Rios, Florida Department of Law Enforcement

Annette Doying, Pasco County Emergency Management

Kimberly Livsey, U.S. Food and Drug Administration

Kendra Stauffer, U.S. Department of Agriculture

Denise Imbler, Apalachee Regional Planning Council

Chris Rietow, Apalachee Regional Planning Counil

Participating Organizations

Florida Department of Agriculture and Consumer Services

Florida Department of Business and Professional Regulations

After Action Report **2011 Exercise Shell Shocked**

Florida Department of Health

Florida Department of Law Enforcement

Pasco County Emergency Management

U.S. Food and Drug Administration

U.S. Department of Agriculture

Apalachee Regional Planning Council

Number of Participants

- Players - 42
- Controllers/Facilitators - 2
- Evaluators - 5

Section 2: Exercise Design Summary

Exercise Purpose and Design

The Florida Integrated Rapid Response Team (FLIRRT) was formed to support Florida's capability to respond immediately following a disaster incident. The team includes members from FDACS, FDOH, FDBPR, FDA and USDA and can be mobilized within hours to respond to agriculture emergencies anywhere in the state. The purpose of this exercise is to practice a multi-jurisdictional and multi-agency response to a catastrophic food/feed incident and to examine the Incident Command System (ICS) and communication capabilities of the FLIRRT in anticipation of and preparation for such a response.

This table-top exercise was a single-state, multi-agency, full-day exercise that focused on the use of ICS, communications and information sharing between State and Federal agencies. The exercise was designed to emphasize information sharing, coordination, collaboration, integration of capabilities and resolution in a condensed timeline format.

Exercise Objectives, Capabilities and Activities

The National Planning Scenarios and establishment of the National Preparedness Priorities have steered the focus of homeland security toward a capabilities-based planning approach. Capabilities-based planning focuses on planning under uncertainty because the next danger or disaster can never be forecast with complete accuracy. The capabilities listed here were selected by the Exercise Planning Team and provide the foundation for development of the exercise design objectives and scenario. The purpose of this exercise was to measure and validate performance of these capabilities and their associated critical tasks. The selected target capabilities were:

- Animal Disease Emergency Support
- Food and Agriculture Safety and Defense

Exercise design objectives focus on improving the participants' understanding of the response concept and identifying opportunities or problems. The exercise focused on the following objectives selected by the Exercise Planning Team:

Objective 1:

Exercise and develop procedures for the FLIRRT including communication plans between responding state agencies (FDACS ,FDOH, FDBPR) and federal agencies (FDA, USDA) that insure all concerned parties are kept informed in a timely manner.

Objective 2:

Exercise ICS roles and responsibilities of the FLIRRT.

Scenario Summary

The scenario developed by the Exercise Planning Team involved contamination of a feed source for egg laying chickens which caused a widespread bacterial infection in the human population. The scenario included seven activities which occurred over a several month period and gradually escalated resulting in the activation of the FLIRRT. Due to time constraints, only five activities were completed. The entire scenario is available in the Situation Manual. The five

activities which were completed during the exercise, along with the findings of the participants, are listed in Section 3. The exercise participants were divided into five groups and addressed the activities as a unit. Scribes for each group provided notes of the group discussion. For the purposes of the AAR, the notes provided by each group have been condensed into the "Findings" listed beneath the "Activity" in Section 3.

Section 3: Analysis of Capabilities

Activity 1

March – May 18, 2011

Scenario
Over the last few months, increasing incidents of salmonella have been reported from hospitals and county health departments statewide.

Activity
Discuss the actions that would have already taken place, including all notifications to various local, state and federal agencies and the methodologies of these communications.
What communications notifications would you make at this time?

Findings
All groups agreed that FDOH would be the lead agency for the scenario at this point. Other agencies which may have been contacted include FDACS and U.S. FDA. It was agreed by all groups that the State Fusion Center would not have been notified at this point. FDOH uses a communication tool called "Epi-Com" for alerts which is embedded within the Florida Department of Health's Emergency Notification System (FDENS). This is an information system used by FDOH to notify the public health emergency response system of any events which may have a public health consequence. This system will be used to issue daily updates on the progress of the outbreak. However, if there is nothing suspicious about the incidents, it was stated that an alert would probably not be issued at this point. Also, there is not a designated threshold (number of cases) that would trigger a FDENS alert. However, there are a number of variables that can trigger an alert and response leaders will make the decision based on the incident, on when to issue a FDENS alert.

Activity 2

Thursday, May 19, 2011

Scenario
Seventy-five Jacksonville Elementary School students have become sick from gastrointestinal illness. Additionally, thirty-five senior citizens with similar symptoms throughout the central and northern parts of the state are hospitalized and several are in critical condition. Thirteen of these senior citizens reside in nursing homes.

Activity
Discuss the actions that are now taking place, including all notifications to various local, state and federal agencies and the methodologies of these communications.

Findings
All groups agreed that FDOH would remain the lead agency, but now other agencies would be notified and start to stand-up their response process. Agencies notified included FDACS, Center for Disease Control, U.S. FDA, USDA, FDBPR, Agency for Healthcare Administration and

Department of Children and Families. FDENS, Epi-Com and EpiX were communication systems that were discussed by the groups as being used to notify local, state and federal agencies. EpiX is a robust CDC managed communications tool with a thorough screening process to utilize. It was noted that FDBPR does not use FDENS and would not have been notified through this system, but may be notified via regular email.

Activity
Would the FLIRRT be activated at this point? If so, what would they be doing? Would ICS be stood up? If not, discuss what level of emergency the FLIRRT would be stood up. What would trigger the initiation of ICS?

Findings
There was disagreement amongst the groups as to whether or not the FLIRRT would activate, some groups said yes, while others stated no. The groups which stated that the FLIRRT would be activated also said that the Steering Committee would be notified and start to initiate ICS during the planning stage. The groups that stated that the FLIRRT would not be activated said that there would need to be an identified source for the salmonella before the FLIRRT would activate.

Activity
What Epi activities are taking place throughout the state?

Findings
All groups stating that Epi teams, under authority of FDOH, would be conducting interviews and investigations at this point in the scenario.

Activity
Is the State Fusion Center involved? And if so how were they notified?

Findings
All groups agreed that the Fusion Center would not be involved at this point.

General Notes:
Two of the groups mentioned the role of the media at this point in the scenario and that they may play an integral role in ramping up the response and public awareness of the incidents.

Activity 3

Sunday, May 22, 2011

Scenario
Ten of the Jacksonville cases have been confirmed to be salmonella related. One hundred and twenty (120) additional salmonella-related illnesses have been reported throughout central and northern Florida. Two nursing home residents have died from salmonella related complications and an additional 15 senior citizens are in intensive care in critical condition. Of the 120 cases, 40 of them are elementary school children from different North Florida schools and 20 are preschool-aged children in central Florida counties. The remaining cases are adults.

Activity
Discuss the actions that are now taking place, including all notifications to various local, state and federal agencies and the methodologies of these communications. What agencies (federal, state, local) are involved in the response and who is leading the response?

Findings
FDOH remains the lead agency and Epi investigations continue. It was determined that FDOH would still have available resources and not yet need outside assistance. CDC and FDACS could provide laboratory assistance to speed up the investigation process if needed. FDOH would also be coordinating all communications with the media. Epi-Com would be the main communication tool across agencies for the investigation process and would be continuously updated.

Recommendation:
It was recommended that a daily update be provided through Epi-Com even if no new developments have occurred.

Activity
Would the FLIRRT be activated at this point? If so, what would they be doing? Who activated the FLIRRT? Would ICS be stood up? Who is in charge?

Findings
There remained disagreement on this point, some groups thought that FLIRRT would be activated. Others groups believed that the FLIRRT Steering Committee would now be coordinating with FDOH, but that the full FLIRRT would not yet be activated. It was commented that only a large-scale, multi-jurisdictional incident would initiate the need for the FLIRRT. There remains uncertainty about when and who activates the FLIRRT.

Activity
What Epi activities are taking place throughout the state? What information would be reported and to whom? How does the FLIRRT interact with the Epi investigation? Who manages this information?

Findings
FDOH continues to coordinate all Epi investigations; however ICS is used by some but not all local health departments. FDOH does not routinely use ICS to manage Epi investigations, but if the situation escalates, ICS may be implemented. Both CDC and FDACS are on standby. This remains a situation that is still within the response capabilities of FDOH.

Recommendation
It was discussed by several groups that there needs to be a set protocol on how the information from the investigation is shared with other agencies.

Activity
What is the role of the State Fusion Center at this stage in the incident?

Findings

All groups agreed that the State Fusion Center would not be involved at this stage of the incident.

Activity 4

Tuesday, May 24, 2011

Scenario
751 salmonella type cases to date have now been reported ranging from Orlando to Jacksonville to Chipley. Lab tests indicate that the same strain of salmonella is present in the majority of the samples collected. Epi interviews have implicated eggs as the likely source of the outbreak.

Activity
Discuss the actions that are now taking place, including all notifications to various local, state and federal agencies and the methodologies of these communications. What additional agencies have been contacted now that eggs are implicated as the source of the salmonella?

Findings
Most groups agreed that FDACS would now be the lead agency coordinating the investigation efforts, although one group maintained that FDOH would remain the lead agency for the duration of the exercise. It was suggested by one group that the Steering Committee would now decide which agency was the lead. All groups identified that U.S. FDA and USDA would now be involved in the response and that U.S. FDA may have jurisdiction because the source of the infection is eggs. There were some differences of opinion on how communications would be managed at this point. One group identified that communications would be by telephone rather than email and that communications would now be managed by the FLIRRT. Several groups mentioned the formation of a JIC by FDOH to manage the press inquiries and public notifications.

Activity
Would the FLIRRT be activated at this point? If so, what would they be doing? Who activated the FLIRRT? Who is in charge? List the FLIRRT members for this incident. Would ICS be used?

Findings
Only one group did not activate the FLIRRT at this point, but all groups stated that the FLIRRT would be using ICS to set up either their own operations or to work within the multi-agency response. There was definite confusion as to exactly when to activate the FLIRRT, what it meant to activate the FLIRRT and the precise definition of a FLIRRT and who had responsibilities for logistics. It was stated by several groups that the Steering Committee or any member of the Steering Committee could activate the FLIRRT.

Notes:

The more the outbreak increased in severity and geographic area, the more uncertain the group became about when and how FLIRRT response would occur.

Activity
What Epi activities are taking place throughout the state? What information would be reported and to whom? How does the FLIRRT interact with FDOH and the Epi investigation? Who manages this information?

Findings
All groups agreed that traceback investigations by FDACS and or FLIRRT would now start to take place. It was also stated that communications would take place through a designated person within the FLIRRT ICS structure, however that position/person was not specifically identified. It was suggested that communications should be by phone rather than email due to the sensitivity of the information and the potential economic impact on the industry if mis-information was released.

Activity
What is the role of the State Fusion center at this stage in the incident?

Findings
It was the general consensus that the State Fusion Center would be asked to focus intelligence gathering on any information regarding intentional or unintentional food related outbreak activity.

Summary
During this activity there was a comprehensive discussion by several groups about ICS structure in the field and the role of the Steering Committee as a Multi-Agency Coordination (MAC) Group; but, there remained confusion in roles as Incident Commander versus Operations Section Chief and what role the Agency Administrator serves. It was evident by this point in the exercise that agencies were comfortable with their job in the field but unclear on how coordination and communication through the FLIRRT would take place, especially when involving agencies such as the Department of Education, who are not members of the Steering Committee or the FLIRRT. It was also evident that specific triggers for the activation of the FLIRRT need to be identified and written down in a set or procedures.

Activity 5

Wednesday, May 25, 2011

Scenario
There are approximately 13 layer facilities in this region and over 50 layer facilities statewide, none of which have been investigated yet.

Activity
Based on this information what is the next step and which agency(ies) are involved? Which agency leads the investigation? Identify each agency's Incident Commander. Are these Commanders working in a Unified Command? If so, which IC will act as the IC Spokesperson?

Findings
The groups had different approaches at this point in the exercise. One group formed unified command with FDACS as the lead agency, but then listed a person from each agency to act as

IC. Two other groups formed a MAC, but did not list an IC or Unified Commander. While there was general knowledge amongst the groups of ICS, actual practical application of the system was not fully understood. FDENS is listed as the primary tool for communication, although concerns remain over the security of information and there was uncertainty over the communications plan. Some groups have all of the information going back to the Steering Committee while others do not.

Activity
Describe how Public Information Officers from all agencies involved work together to develop one public message. Have the PIOs from the agencies write a Press Release with a Public Safety component.

Findings
All groups agreed that having a unified message was essential and that a JIC would be used for that purpose.

Activity
What is the role of the State Fusion Center at this stage in the incident?

Findings
The consensus was that the State Fusion Center would be notified and be in a monitoring and information gathering mode.

Section 4: Conclusion

The purpose of Exercise "Shell Shocked" was to practice a multi-jurisdictional and multi-agency response to a catastrophic food/feed incident and to examine the Incident Command System (ICS) and communication capabilities of the FLIRRT in anticipation of and preparation for such a response. It allowed for the design team and players alike, to discuss their ICS roles and communication protocols in a stress free environment. It also provided an opportunity for review and enhancement of activation and notification procedures. In addition, It proved invaluable as a place for the Steering Committee members to come together to discuss and resolve specific issues within the context of a real world scenario.

The exercise was a success in identifying planning and training needs for the FLIRRT and the agencies that comprise the FLIRRT network. The recommendations listed in the Improvement Plan are a summary of the exercise participant's findings captured during the exercise. They are meant to serve as an opportunity to improve the coordination, communication and response capabilities of the FLIRRT.

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After Action Report
Shocked

2011 Exercise Shell

Appendix A: Improvement Plan

Objective	Observation Title	Recommendation	Capability Element	Primary Responsible Agency	Agency POC	Start Date	Completion Date
Objective 1: Exercise FLIRRT Communications Plans	Observation 1 – Participants understood some communication methodologies, but need further understanding of communications tools and protocols.	1.1 Develop specific Communications Procedures for the FLIRRT listing all communications tools and roles responsibilities. Work with FDOH about using EpiCom as the primary communications system for the FLIRRT throughout an incident	Planning	FDACS	FLIRRT Coordinator & Steering Committee	7/28/2011	
		1.2 Conduct a TTX and drills on these procedures once complete	Training/Exercise	FDACS	FLIRRT Coordinator & Steering Committee	7/28/2011	
Objective 2: Exercise ICS Roles &	2. Observation 1 – Participants	2.1 Develop a SOG for the FLIRRT, listing	Planning	FDACS	FLIRRT Coordinator & Steering	7/28/2011	

After Action Report **2011 Exercise Shell**
Shocked

Responsibilities	had a general knowledge of ICS, but did not fully understand how it would be practically applied.	Org Charts, Activation Protocols etc 2.2 Once complete, conduct drills and exercise of the SOG			Committee		
			Training/Exercise	FDACS	FLIRRT Coordinator & Steering Committee	7/28/2011	
		The FERP needs to address command designation during multi-agency response incidents.		FERP Work Group	John Burkette	7/28/2011	

Appendix B: Acronyms

Acronym	Term
DHS	Department of Homeland Security
FDOH	Florida Department of Health
FDBPR	Florida Department of Business and Professional Regulation
U.S. FDA	Food and Drug Administration
FDACS	Florida Department of Agriculture and Consumer Service
FDLE	Florida Department of Law Enforcement
FLIRRT	Florida Integrated Rapid Response Team
HSEEP	Homeland Security Exercise and Evaluation Program
IC	Incident Commander
ICS	Incident Command System
NIMS	National Incident Management System
TTX	Tabletop Exercise
USDA	United States Department of Agriculture

Attachment C – Examples of After Action Reports (Complex)

- Attachment C-1: Florida Biological Chemical Agent Full Scale Exercise AAR

2012 Florida Biological Chemical Agent Full Scale Exercise

AFTER ACTION REPORT

IMPROVEMENT PLAN

MARCH 15, 2012

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HANDLING INSTRUCTIONS

1. The title of this document is *2012 Florida Biological Chemical Agent Full Scale Exercise After Action Report/Improvement Plan*.

2. The information gathered in this AAR/IP is classified as **Controlled with Specified Dissemination** and should be handled as sensitive information not to be disclosed. This document should be safeguarded, handled, transmitted, and stored in accordance with appropriate security directives. Reproduction of this document, in whole or in part, without prior approval from the *Florida Department of Health, Bureau of Laboratories* is prohibited.

3. At a minimum, the attached materials will be disseminated only on a need-to-know basis and when unattended, will be stored in a locked container or area offering sufficient protection against theft, compromise, inadvertent access, and unauthorized disclosure.

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CONTENTS

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EXECUTIVE SUMMARY

Homeland security preparedness involves a cycle of outreach, planning, capability development, training, exercising, evaluation, and improvement. Successful exercises lead to an ongoing program of process improvements. This After-Action Report/Improvement Plan (AAR/IP) is intended to assist agencies striving for preparedness excellence by analyzing exercise results and achieving the following:

- Identifying strengths to be maintained and built upon
- Identifying potential areas for further improvement
- Recommending exercise follow up actions

The suggested actions in this AAR/IP should be viewed as recommendations only. In some cases, agencies may determine that the benefits of implementation are insufficient to outweigh the costs. In other cases, agencies may identify alternative solutions that are more effective. Each agency should review the recommendations and determine the most appropriate action and time needed for implementation.

The Florida Department of Health, Bureau of Laboratories is a part of the Laboratory Response Network (LRN). In an All Hazards approach to public health preparedness, the LRN's role is to collaborate with local, state and federal agencies and to provide a response to address potential biological or chemical exposure. The LRN laboratories are prepared to analyze samples for biological agents or patient clinical specimens for a number of chemical agents. The LRN laboratories routinely prepare for actual incidents with proficiency testing and surge capacity exercises.

The *2012 Florida Biological Chemical Agent Full Scale Exercise* was conducted from February 13-17, 2012, throughout the state of Florida. The scenario was based on intentional food poisoning with exposure to a biological toxin, ricin, which was also considered a chemical agent. The Exercise Planning Team selected objectives that focused on evaluating the combined biological and chemical exposure response procedures including Information Sharing; Public Health Laboratory Testing; Public Health Surveillance and Epidemiological Investigation and achieving a collaborative attitude with participating agencies. This Full Scale Exercise allowed participating local, state and federal agencies to determine how effectively intra and inter agency communications succeeded and how their current standard operating procedures (SOPs) addressed responding to a biological or chemical exposure event.

Overall this Full Scale Exercise proved to be very successful. All partner agencies were able to work together to provide an effective response to the biological-chemical exposure event. Moreover, this Exercise presented a practical learning environment for agencies to become familiar with the issues and concepts that may arise during a separate or combined biological chemical exposure incident. Participating agencies and staff were able to partner and respond to meet the Exercise objectives. As a result of this Exercise, not only are local, state and federal agencies more aware of the scope of response involved in a biological or chemical exposure event, but they also were able to determine where gaps existed in planning, procedures and inter/intra agency communication.

MAJOR STRENGTHS

The major strengths identified during this exercise include the following:

- The Exercise was able to bring together multiple local, state and federal agencies that would respond to a biological or chemical public health emergency. The Exercise Planning Conferences allowed everyone to participate and to learn how a multi agency response to a biological or chemical agent incident would be coordinated.
- The State of Florida Comprehensive Laboratory Response Plan for Chemical, Biological and Radiological Incidents (CLRP) describes how the use of Florida's laboratory resources will be coordinated to respond to public health emergencies of all types.
- Transporting either the patient specimens from the hospital laboratories or the pseudo food samples from the county health departments to the Bureau of Laboratories in a timely fashion was successfully demonstrated.
- Coordination for public health investigation between the epidemiologists, the Florida Poison Information Center Network, the hospital laboratories and the Bureau of Laboratories was very good.

PRIMARY AREAS FOR IMPROVEMENT

Throughout the exercise opportunities for improvement were identified. The primary areas for improvement, including recommendations, are as follows:

AREA FOR IMPROVEMENT

The Exercise needs to include additional participation from partner agencies. At the hospitals this would include Emergency Department personnel and Infection Control Practitioners (ICPs) and at the County Health Department level this would include Preparedness Planners and Public Information Officers.

KEY RECOMMENDATION: The Exercise Planning Team needs to include additional participation from partner agencies. It was stated that the CHD Epidemiologists can provide contact information for the hospital ICPs who, in turn, can encourage participation from the Emergency Department staff. It was also noted that the Bureau of Preparedness and Response would be a good source for contact information at the CHD level for Preparedness Planners and PIOs.

SECTION 1: EXERCISE OVERVIEW

Exercise Name

2012 Florida Biological Chemical Agent Full Scale Exercise

Exercise Start Date

February 13, 2012

Exercise End Date

February 17, 2012

Type of Exercise

Full Scale Exercise

Duration

5 days

Location

Florida

Sponsor and Program

Public Health Emergency Preparedness (PHEP) Cooperative Agreement

Funding Recipient

Florida Department of Health, Bureau of Laboratories

Mission

Response

Capabilities

- Capability 6: Information Sharing
- Capability 12: Public Health Laboratory Testing
- Capability 13: Public Health Surveillance and Epidemiological Investigation

Classification

Controlled with Specified Dissemination

Scenario

Intentional food contamination with a combined biological and chemical agent - ricin

Exercise Planning Team

All of the Exercise Players (listed below) were an integral part of the Exercise Planning Team. Their participation in the Exercise Planning Conferences was instrumental in coordinating the large number of agencies that were part of the Exercise. Each agency was involved in planning for the details of both the inter- and intra-agency actions and events that was specific for their response. Their input was a valuable part of the learning process.

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Exercise Players

Federal
Centers for Disease Control and Prevention (CDC)
Federal Bureau of Investigation (FBI)

State
Bureau of Emergency Preparedness and Response
Bureau of Epidemiology
Bureau of Food Laboratories
Bureau of Laboratories
Division of Disease Control
Division of Emergency Medical Operations
Division of Environmental Health
Florida Department of Law Enforcement
Florida Poison Information Center
Food and Waterborne Disease Program
FDOH Office of Communications

Local
(**County Health Departments**)
Broward County Health Department
Clay County Health Department
Duval County Health Department
Flagler County Health Department
Hillsborough County Health Department
Manatee County Health Department
Martin County Health Department
Miami-Dade County Health Department
Polk County Health Department
Seminole County Health Department
Volusia County Health Department

(**Hospitals**)
All Children's Hospital
Bayfront Medical Center
Cape Canaveral Hospital
Delray Medical Center
Florida Hospital Laboratory
Holmes Regional Medical Center
Indian River Medical Center
Metropolitan Hospital of Miami
Miami VA Health Care System
Mount Sinai Medical Center
Munroe Regional Medical Center
Orange Park Medical Center Inc
Putnam Community Medical Center City
South Miami Hospital
St. Cloud Regional Medical Center

Number of Participants

Players/Observers: 157

Evaluators: 38

Controllers: 38

SECTION 2: EXERCISE DESIGN SUMMARY

The *2012 Florida Biological Chemical Agent Full Scale Exercise* was crafted as a five day exercise to involve local, state and federal agencies who would be part of a response to a biological or chemical exposure incident. The exercise was designed to evaluate communication and coordination between the local, state and federal agencies and the state laboratory and to evaluate public health laboratory testing capabilities.

This exercise was also able to fulfill the Public Health Emergency Preparedness (PHEP) Cooperative Agreement requirements for the Bureau of Laboratories as an annual exercise.

Exercise Objectives and Activities

Capabilities-based planning allows for exercise planning teams to develop exercise objectives and observe exercise outcomes through a framework of specific action items. The capabilities for this exercise were derived from the Centers for Disease Control and Prevention (CDC) *Public Health Preparedness Capabilities: National Standards for State and Local Planning*. The capabilities listed below and stated in the ExPlan have been selected by the 2012 Florida Biological Chemical Agent Full Scale Exercise Planning Team and form the foundation for the organization of all activities and tasks in this exercise. The purpose of this exercise is to measure and validate performance of these capabilities and their associated critical tasks.

Capability 6: Information Sharing

Objective 1.
Identify stakeholders to be incorporated into information flow. (Function 1)

Prior to and as necessary during an incident, identify inter-jurisdictional public health stakeholders to determine information sharing needs. (Task 2)

Objective 2.
Identify and develop rules and data elements for sharing. (Function 2)

Prior to and as necessary during an incident, identify, through public health agency legal counsel (and counsel to other agencies and jurisdictions as appropriate), current jurisdictional and federal regulatory, statutory, privacy-related and other provisions, laws, and policies that authorize and limit sharing of information relevant to emergency situational awareness. Such laws and policies may include Health Insurance Portability and Accountability Act (HIPAA), Office of the National Coordinator Health IT Information Technology Policy, HHS Information Management Policy, and specific requirements of current memoranda of understanding and memoranda of agreements; these laws may address privacy, civil liberties, intellectual property, and other substantive issues. (Task 1)

Prior to and as necessary during an incident, identify routine or incident-specific data requirements for each stakeholder. (Task 2)

Prior to and as necessary during an incident, identify public health events and incidents that, when observed, will necessitate information exchange. (Task 3)

Prior to, during, and after an incident, utilize continuous quality improvement or have a processes and a corrective action system to identify and correct unintended legal and policy barriers to sharing of situational awareness information that are within the jurisdictional public health agency's control (e.g., legal and policy barriers, opportunities to shorten the amount of time to share data). (Task 4)

Objective 3.
Exchange information to determine a common operating picture. (Function 3)

Prior to and during an incident, collaborate with and participate in jurisdictional health information exchange. (Task 1)

Capability 12: Public Health Laboratory Testing

Objective 4.
Manage laboratory activities. (Function 1)

Exchange information and data with laboratories and laboratory networks within the jurisdiction. (Task 1)

Objective 5.
Perform sample management. (Function 2)

Handle, package, and transport samples following established IATA/DOT and laboratory-specific protocols. (Task 1)

Maintain forensic chain-of-custody throughout the sample-management process. (Task 2)

Objective 6.
Conduct testing and analysis for routine and surge capacity. (Function 3)

Conduct chemical laboratory testing following LRN-C testing methods. (Task 2)

Objective 7.
Support public health investigations (Function 4)

Establish and maintain the ability to provide analytical support for investigations with first responders and other health investigation community partners. (Task 1)

Objective 8.
Report Results (Function 5)

Notify appropriate public health, public safety, and law enforcement officials (24/7) of presumptive and/or confirmed laboratory results from clinical, food, or environmental samples that involve a chemical, radiological, or biological threat agent. (Task 1)

Send presumptive and confirmed chemical, radiological, or biological laboratory results to CDC and all submitters. (Task 2)

Capability 13: Public Health Surveillance and Epidemiological Investigation

Objective 9.
Conduct public health surveillance and detection. (Function 1)

Engage and retain stakeholders, which are defined by the jurisdiction, who can provide health data to support routine surveillance, including daily activities outside of an incident, and to support response to an identified public health threat or incident. (Task 1)

Maintain surveillance systems that can identify health problems, threats, and environmental hazards and receive and respond to (or investigate) reports 24/7. (Task 4)

Objective 10.
Conduct public health and epidemiological investigations. (Function 2)

Conduct investigations of disease, injury or exposure in response to natural or man-made threats or incidents and ensure coordination of investigation with jurisdictional partner agencies. Partners include law enforcement, environmental health practitioners, public health nurses, maternal and child health, and other regulatory agencies if illegal activity is suspected. (Task 1)

Provide epidemiological and environmental public health consultation, technical assistance, and information to local health departments regarding disease, injury, or exposure and methods of surveillance, investigation, and response. (Task 2)

Objective 11.
Improve public health surveillance and epidemiological investigation systems. (Function 4)

Identify issues and outcomes during and after the incident. (Task 1)

Conduct post-incident/post-exercise agency evaluation meeting(s) including all active participants (e.g., law enforcement, volunteer agencies, clinical partners or environmental regulatory agency) to identify internal protocols and deficiencies that require corrective actions in areas such as programs, personnel, training, equipment, and organizational structure. (Task 2)

Develop an After Action Report/Improvement Plan. (Task 3)

Communicate recommended After Action Report Improvement Plan corrective actions to public health leadership. (Task 4)

SCENARIO SUMMARY

This scenario was designed to specifically involve the local, state and federal agencies, all of which would be part of a response to a biological or chemical exposure incident. The purpose of the scenario was to "paint the picture" for players. Only a limited number of activities were planned for this exercise and some of the events described in the scenario were simulated.

The Big Moose Lodge hosted their annual Fund Drive and Fair the weekend before the Exercise. This was a large carnival event with games and food provided by vendors. During the weekend, a number of patients began presenting to local hospitals with symptoms of nausea, vomiting, diarrhea (some bloody), with weakness and abdominal pain (1). One of the hospitals consulted with the Florida Poison Information Center on the patient symptoms.

An ESSENCE (Electronic Surveillance System for the Early Notification of Community-based Epidemics) Alert was triggered. This informed the Epidemiologists of a food related outbreak. This prompted the surveillance Epidemiologists to carry out their notification procedures which varied by region, county and specific epidemiology assignments. A query was also performed on the event and indicated that various patients were also having additional complaints of dehydration and hypotension.

A foodborne outbreak investigation by Epidemiology revealed that some of the patients had eaten similar foods at the Big Moose Lodge Fund Drive and Fair. The Big Moose Lodge did not prepare their own food on site but purchased from a vendor (2). The patients reported that the symptoms appeared about 1-3 hours after eating. Additionally, some patients had reported a burning sensation of the mouth and throat. The Epidemiologists contacted the Florida Poison Information Center or the Food and Waterborne Disease Program with the updated information since this indicated that the outbreak could be related to a chemical exposure.

On Day 3 of the exercise, the Daily Grind Newspaper had received a letter from the anti-government group Concerned Citizens for the Constitution (3). The rambling manifesto stated that there is too much government regulation and emphasized that they will get a "taste of their own medicine". They indicated that they had poisoned the food supply to show they meant business. The letter was signed by Castor Bean. This brought the FBI and Florida Fusion Center into the picture.

A conference call was conducted with all of the stakeholders and the possible link between the foodborne outbreak and the credible threat was made. It was decided that food samples would be collected and then transported to the Bureau of Laboratories to be tested for ricin. Similarly, patient clinical specimens would be collected and then transported to the Bureau of Laboratories to be tested for ricinine, a biomarker for ricin exposure. The laboratory results were then reported to the county epidemiologists, hospitals, Poison Information Center, law enforcement and other need to know partners.

Reference:

1. These symptoms are related to ricin but could also be the result of campylobacter, Shigella or E. coli infection.

2. By using a fraternal organization to host the fair, which was specifically catered by an outside vendor, the Exercise was able to have the Bureau of Laboratories as the primary public health laboratory to respond.

   Generally, the Department of Health regulates food service establishments located in institutional settings (such as schools, assisted living facilities, adult day cares, and detention facilities), civic and fraternal organizations, bars and lounges that don't prepare foods, and theaters that limit their food service to items customarily served at theaters (such as beverages, pop corn, hot dogs and nachos). The codes and standards for food service establishments are found in Chapter 64E-11, Florida Administrative Code. For more information about the food hygiene program, please visit their websites at, http://www.doh.state.fl.us/environment/community/food/index.html or http://www.doh.state.fl.us/Environment/community/food/FoodFAQ.html

3. Concerned Citizens for the Constitution (CCC) - The CCC is a loosely organized group of individuals who have adopted a right-wing anarchist ideology. They believe that virtually all existing government in the United States is illegitimate and they seek to "restore" an idealized, minimalist government. To this end, the CCC plots against the government and other forms of authority and uses harassment and intimidation tactics, and occasionally resorts to violence.

SECTION 3: ANALYSIS OF CAPABILITIES

This section of the report reviews the performance of the exercised capabilities, activities, and tasks. The capabilities linked to the exercise objectives of the *2012 Florida Biological Chemical Agent Full Scale Exercise* are listed below. Each activity is followed by related observations, which includes an analysis, and recommendations.

CAPABILITY 6: INFORMATION SHARING

Objective 1: Identify stakeholders to be incorporated into information flow. (Function 1)

Activity 1: Prior to and as necessary during an incident, identify inter-jurisdictional public health stakeholders to determine information sharing needs. (Task 2)

Observation: During the planning conferences, the public health stakeholders were identified and the information for the primary contacts from the participating agencies were obtained, organized and distributed before the exercise was conducted.

Additionally, the hospital laboratory, county health department, and the Bureau of Laboratories (BOL) contacts were organized into a separate list for the agencies that would be participating in packaging and shipping activities.

Prior to the start of the exercise, the hospital laboratory and county health department players were directed to contact their regional BOL as needed for instructions on packaging and shipping of patient specimens or other pertinent information.

The participant feedback indicated that hospital laboratories and county health departments participating in packaging and shipping activities were able to contact the BOL to consult on procedures and notify of shipment of samples and specimens.

After completing the pseudo food sample testing or patient clinical specimen analysis the BOL was able to report the results back to the respective county health department contacts or submitting hospital laboratories. However, it was mentioned in the feedback that one of the county health departments was not contacted by the BOL regarding the results of the pseudo food sample testing.

In the Hot Wash, the Florida Poison Information Center (Tampa) mentioned that they didn't get the clinical patient specimen testing results back directly from the BOL. This was probably due to the oversight of the Exercise Planning Team and the way the Florida Poison Information Centers phone communication works. The patient results were reported from the Jacksonville BOL.

Therefore, the call would have been routed to the Jacksonville Poison Information Center.

During the planning conferences, the Office of Communications indicated that they would be able to provide information to the county health department Public Information Officers (PIOs). Prior to the Exercise, the Office of Communication drafted ricin messaging products which were provide to the CHD PIO representatives through the Crisis and Emergency Risk Communication (CERC) Portal for their use during the Exercise.

Analysis: Strength. It was indicated as a strength on the Participant Feedback form that the communication between the regional epidemiologist, the CHD epidemiologist, and the lab was very good.

The hospital laboratories and county health departments participating in packaging and shipping activities indicated that they were able to contact the BOL to consult on procedures and notify of shipment of samples and specimens.

Analysis: Area for Improvement. It was mentioned in the feedback that one of the county health departments was not contacted by the BOL regarding the results of the pseudo food sample testing.

The Florida Poison Information Center (Tampa) mentioned in the feedback that they didn't get the clinical patient testing results back directly from the BOL.

Both of these will be discussed below under Capability 12: Public Health Laboratory Testing; Objective 8: Report Results.

Recommendation: The Exercise Planning Team needs to consider the best way for information to be relayed to all participants including those who have specific routing procedures such as the Florida Poison Information Center.

It was suggested in the participant feedback that agencies have a Communication Plan.

Objective 2: Identify and develop rules and data elements for sharing. (Function 2)

Activity 1: Prior to and as necessary during an incident, identify, through public health agency legal counsel (and counsel to other agencies and jurisdictions as appropriate), current jurisdictional and federal regulatory, statutory, privacy-related and other provisions, laws, and policies that authorize and limit sharing of information relevant to emergency situational awareness. Such laws and policies may include Health Insurance Portability and Accountability Act (HIPAA), Office of the National Coordinator Health IT Information Technology Policy, HHS

Information Management Policy, and specific requirements of current memoranda of understanding and memoranda of agreements; these laws may address privacy, civil liberties, intellectual property, and other substantive issues. (Task 1)

Observation: The Florida Department of Health is required by law to maintain the privacy of protected health information. Protected health information contains specific information that identifies a person or can be used to identify a person. Protected health information includes demographic and medical information that concerns the past, present, or future physical or mental health of an individual. Demographic information could include name, address, telephone number, social security number and any other means of identifying a specific person. Protected health information may be used or disclosed by the Department of Health for purposes of treatment, payment, and health care operations.

The Florida Poison Information Centers were established as health care providers authorized to share protected patient information with health care providers providing direct patient care in HIPAA regulations in 45CFR parts 160 and 164 as published in the Federal Register on Dec 28, 2000. In addition, the CDC has provided the American Association of Poison Control Centers (AAPCC) with a grant of authority to conduct surveillance activity and function as a public health authority to which covered entities may disclose protected health information.

In addition, the Florida Poison Information Centers are a State of Florida, Department of Health program performing public health functions. As such they are exempt from HIPAA privacy regulations.

Analysis: Strength. The Florida Department of Health and the Florida Poison Information Center Network have provisions, laws, and policies that authorize and limit sharing of information relevant to emergency situational awareness.

Analysis: Area for Improvement. NONE

Recommendation: NONE

Activity 2: Prior to and as necessary during an incident, identify routine or incident-specific data requirements for each stakeholder. (Task 2)

Observation: The State of Florida Comprehensive Laboratory Response Plan for Chemical, Biological and Radiological Incidents (CLRP) establishes the framework to ensure that the State of Florida will be able to mount a laboratory response to these hazards. The CLRP outlines the roles and responsibilities of

the participating laboratories (government and non-government). The CLRP coordinates response and recovery activities across the full spectrum of responding entities. The CLRP unifies the efforts of these groups for a comprehensive approach to reducing the effects of an emergency and/or disaster. It is intended for use by emergency responders and government officials responsible for Public Health, Food Safety, Animal Health, Environmental Health, Law Enforcement, HazMat, Fire Rescue, and Emergency Medical Services.

The CLRP addresses the four phases of emergency management (preparedness, response, recovery, and mitigation), parallels the State of Florida Comprehensive Emergency Management Plan (SCEMP), as well as Federal activities set forth in the National Response Plan (NRP), and describes how the use of Florida's laboratory resources (government and non-government, including commercial laboratories) will be coordinated to respond to public health emergencies of all types. Laboratory capabilities reflected in this Plan are current as of the date of distribution. The CLRP is reviewed annually and updated whenever capabilities change.

During the Hot Wash, one of the County Health Departments (CHD) stated that their Epidemiology Program was able to keep everyone updated on the progress of the Exercise with their Monday "Surveillance" Meeting.

Additionally, one of the hospital laboratories indicated that they would like to see involvement from Emergency Department (ED) staff particularly in being able to recognize symptoms, especially if it was a chemical agent, and how they would process the information in treating patients.

Also regarding hospital participation, one of the Epidemiologists commented that, in general, the Exercise Planning Team needs to give more thought in who should be invited to participate to make sure these important partner agency stakeholders are not left out. As an example, the hospital Infection Control Practitioner (ICP) is the main communication medium for the County Health Department epidemiology. It was stated that "They are like the ambassadors to the hospital. They are the best, best contact at the hospital. They are critical for the public health hospital interaction. "

Additionally, it was mentioned that others were left off the Exercise invitation list in the CHD who would be very important stakeholders. This includes the Preparedness Planners and Public Information Officers (PIO). It was pointed out that "Since this scenario involved a response to a public health emergency, these people would be leading the response at the CHD level."

Analysis: Strength. The State of Florida Comprehensive Laboratory Response Plan for Chemical, Biological and Radiological Incidents (CLRP) describes how the use of Florida's laboratory resources (government and non-government, including commercial laboratories) will be coordinated to respond to public health emergencies of all types. Laboratory capabilities reflected in this CLRP are current as of the date of distribution. The CLRP is reviewed annually and updated whenever capabilities change.

It appears that at least one CHD Epidemiology Program has regular meetings with staff where current situations regarding public health are discussed.

One of the hospitals stated that they would encourage additional hospital staff to participate in future exercises.

Analysis: Area for Improvement. The Exercise Planning Team needs to reach out to include additional participation from partner agencies. At the hospitals this would include Emergency Department personnel and Infection Control Practitioners (ICPs) and at the County Health Department level this would include Preparedness Planners and Public Information Officers.

Recommendation: The Exercise Planning Team needs to include additional participation from partner agencies. It was stated that the CHD Epidemiologists can provide contact information for the hospital ICPs who, in turn, can encourage participation from the Emergency Department staff. It was also noted that the Bureau of Preparedness and Response would be a good source for contact information at the CHD level for Preparedness Planners and PIOs.

Although the initial email distribution list for the Exercise invitation was extensive, the list was pared to only those who responded back after the Mid Term Planning Conference Call. This was to avoid nuisance emailing. The strategy for contacting stakeholders should be reviewed for the next exercise.

Activity 3: Prior to and as necessary during an incident, identify public health events and incidents that, when observed, will necessitate information exchange. (Task 3)

Observation: The Exercise Planning Conferences (Concepts and Objectives, Initial Planning, Mid Term Planning and Final Planning) gave the participating agencies the opportunity to identify public health events and incidents in the Exercise that would necessitate information exchange. Based upon these discussions, the Exercise included an ESSENCE Alert; an EpiCom message; a SIMCELL Inject to stimulate Law

Enforcement Intelligence Sharing; and a Health Alert Message. All of which relied upon information exchange.

The participant feedback indicated that there could have been more opportunities for interaction between agencies in providing information exchange.

Analysis: Strength. The Exercise Planning Conferences provided the partner agencies to discuss and identify public health events and incidents would necessitate information exchange.

Analysis: Area for Improvement. Provide more opportunities for interaction between agencies in providing information exchange in the Exercise Design.

Recommendation: Expand the Exercise to provide more opportunities for interaction between agencies in providing information exchange. One recommendation was to have more than one hospital laboratory in each region call into the Poison Centers for practice. Similarly, more than one county health department epidemiologist could also interact with the regional Poison Centers.

Activity 4: Prior to, during, and after an incident, utilize continuous quality improvement or have a processes and a corrective action system to identify and correct unintended legal and policy barriers to sharing of situational awareness information that are within the jurisdictional public health agency's control (e.g., legal and policy barriers, opportunities to shorten the amount of time to share data). (Task 4)

Observation: The Exercise Planning Conferences (Concepts and Objectives, Initial Planning, Mid Term Planning and Final Planning) gave the participating agencies the opportunity to identify potential legal and policy barriers to sharing of situational awareness information.

During the Question and Answer (Q&A) Conference call the participants discussed the issue of law enforcement agencies sharing intelligence information with the public health partners. Specifically, it was asked that if there was a credible threat of intentional food poisoning, who would the Florida Fusion Center share the information with?

A participant from the FBI stated that they would be in touch with the FBI WMD at Headquarters and the Florida Fusion Center to see if they had supplementary information regarding the incident.

It was further stated that the FBI has a good working relationship with DOH in Tallahassee (Leon County Public Health Hospital and

EMS Preparedness Planner) whom they work with when investigating white powder incidents.

Also, the FBI would be in touch with local CHD (MOU's are in place for all CHDs) for awareness and to gather more information if available.

During the Q&A Conference call the Food and Waterborne Disease Program (FWDP) stated that they are working to get Secret level clearance to join Florida Fusion Center so that environmental epidemiology will be part of the fusion center.

Analysis: Strength. The Exercise provided partner agencies the opportunity to discuss and identify legal and policy barriers to sharing of situational awareness information.

The Food and Waterborne Disease Program (FWDP) is working to get Secret level clearance to join Florida Fusion Center so that environmental epidemiology will be part of the fusion center and provide a direct access for public health awareness.

Analysis: Area for Improvement. NONE

Recommendation: NONE

Objective 3: Exchange information to determine a common operating picture. (Function 3)

Activity 1: Prior to and during an incident, collaborate with and participate in jurisdictional health information exchange. (Task 1)

Observation: One of the comments from the Participant Feedback form indicated that communication between the regional epidemiologist, the CHD epidemiologist, and the Bureau of Laboratories was very good.

Also, one of the Epidemiologists commented that hospital participation was very committed. They had called to consult on the Exercise and had a good discussion of the hospital status, policies and procedures that would occur if the outlined scenario was a real event.

During the Hot Wash it was stated that only the Tampa Poison Information Center was notified by the hospital and CHD Epidemiology participants and that the Jacksonville and Miami Poison Information Centers were not. It was added that faxing or providing the same information to the other Centers would have been useful. It was suggested that a dual notification system might have helped.

Analysis: Strength. Communication between the regional epidemiologist, the CHD epidemiologist, the hospitals and the Bureau of Laboratories was very good.

It was commented that the players were committed to the Exercise.

Analysis: Area for Improvement. The Exercise Planning Team should be aware that some agencies, such as the Florida Poison Information Center, are networked and the Exercise should strive to provide a means to include the entire network in Exercise play.

Recommendation: The Exercise Planning Team should be aware that some agencies are networked and the Exercise should strive to provide a means to include the entire network in Exercise play. This may be accomplished by using faxing or providing the same information to the other parts of the network in other ways. It was suggested that a dual notification system might help.

CAPABILITY 12: PUBLIC HEALTH LABORATORY TESTING

Objective 4: Manage laboratory activities. (Function 1)

Activity 1: Exchange information and data with laboratories and laboratory networks within the jurisdiction. (Task 1)

Observation: The Exercise Packaging and Shipping Planning Conference Call allowed for the explanation of the specific requirements for the packaging and shipping of patient clinical specimens from the hospital laboratory to the regional Bureau of Laboratories for the Exercise. Also discussed were the specific instructions for the packaging and shipping the pseudo food samples from the county health departments to the regional Bureau of Laboratories for the Exercise. The procedures followed in the Exercise would be similar to those for a real event.

The clinical patient specimens are classified as Biological Substance, Category B based on IATA and DOT requirements for shipping. As part of the outreach to the health and medical community, the Bureau of Laboratories Chemical Threat Program had previously trained a number of the hospital laboratories that participated in the exercise on the CDC protocols for shipping urine specimens after a chemical exposure incident.

Additionally, the Bureau of Laboratories offers *Infectious Substances Packaging and Shipping Training* to the Hospital laboratories through the CDC Cooperative Agreement Grant for Public Health Emergency Preparedness.

A comment from a BT laboratorian was that they did not feel that the BT lab was adequately provided with the scope of what was going on. It was stated that "I think it is critical to let the BT labs know what is going on as soon as possible during an event. In other words, the first contact with the lab shouldn't be when samples are being prepared to be shipped to us."

It was further stated that this information could be critical in helping to analyze data and/or troubleshoot assays. This information would also help to prepare equipment, reagents, personnel, etc. for an above average period of testing. The information might also be pivotal in analysis decisions and therefore providing additional necessary information to the stakeholders.

Analysis: Strength. The Participant Feedback indicated that the Instructions for packaging and shipping both food samples and patient specimens were very helpful.

Analysis: Area for Improvement. Communication with the laboratorians could be improved. They should be included in the information exchange to better provide collaboration in obtaining a common operating picture.

Recommendation: Prior to and during an incident include the laboratorians to better obtain a common operating picture.

Objective 2: Perform sample management. (Function 2)

Activity 1: Handle, package, and transport samples following established IATA/DOT and laboratory-specific protocols. (Task 1)

Observation: About a week before the start of the Exercise, the Bureau of Laboratories sent the hospital laboratories the materials they needed for packaging and shipping. Overall, the Participant Feedback indicated that Instructions were complete and the provision of the return shipping materials was very helpful. However, one of the hospitals stated that they did not receive supplies by shipper. Instead they were physically delivered on the Friday before the start of the Exercise just making it in time.

Also, a week before the exercise the hospital laboratories had received spiked patient specimens from the CDC. On the first day of the exercise, the hospital laboratories sent the spiked

specimens to the regional LRN-C laboratory by either commercial shipper or local courier, using either dry ice or cold packs to maintain temperature. Eight participating hospital laboratories were able to have the specimens transported to the regional LRN-C laboratory by commercial shipper and seven by local courier. Of the 15 hospital laboratories participating in the exercise, seven shipped using dry ice while eight shipped using cold packs. A summary is shown in Table 1.

Table 1. Summary of Shipping Methods

	Cold Packs	Dry Ice	Total
Commercial Shipper	3	5	8
Local Courier	5	2	7

The hospital laboratories notified the Bureau of Laboratories when the specimens were shipped and the Bureau of Laboratories notified the hospital laboratories when the specimens were received. One participant indicated on the feedback that they hadn't received the notification of receipt. This might have been because only the primary contacts were notified upon receipt.

Upon arrival at the regional LRN-C laboratory the temperature of the specimens varied from -20℃ to 16℃ for those u sing dry ice and from -13℃ to 10℃ for those using cold packs. Of the eight specimen sets sent from the hospital laboratories on cold packs, one (12.5%) arrived frozen while seven (87.5%) arrived thawed and either cool or up to ambient temperature. Of the seven specimen sets sent from the hospital laboratories on dry ice, five (71%) arrived frozen while two (29%) arrived thawed and either cool or up to ambient temperature. The thawed specimen sets were due to not using enough dry ice for the time required to transport.

When the clinical specimens arrived, the packaging was evaluated based upon the Exercise Criteria for Packaging and Shipping (Table 2) to assess the strengths and areas for improvement in the packaging and shipping of specimens.

Table 2. 2011 Exercise Criteria for Packaging and Shipping

√	Advance notification of delivery
√	Sample Submission form included
√	Chain of Custody form included
√	Dry Ice with UN1845 Misc 9 Dry Ice Label or Cold Packs
√	UN3373 Biological Substance, Category B Label
√	Gridded Box For Urine Samples
√	Gridded Box placed in large 95kPa Bio-Pouch Bag
√	Absorbent sheets for packing
√	Two levels of Evidence Tape
√	Evidence Tape properly initialed

The Exercise also had pseudo food samples packaged and shipped to the regional Bureau of Laboratories by the county health department Epidemiologist or Environmental Health Scientist. The specific instructions for the packaging and shipping these samples from the county health departments to the regional Bureau of Laboratories for the Exercise were also discussed on the Packaging and Shipping Exercise Planning Conference Calls as mentioned above. The county health departments were provided with Biological Food Sample P&S Guidelines to follow and the Environmental Sample Submission Form and Chain of Custody Form to complete and send along with the samples. The county health departments used supplies that they had on hand for packaging.

On the day the pseudo food samples were to be transported the regional Bureau of Laboratories, the county health department Epidemiologist or Environmental Health Scientist consulted with the Biological Defense Coordinator to determine how best to transport the samples to the laboratory.

Through the feedback, it was noted that not all of the county health departments have someone who was IATA/DOT certified to package and ship.

Analysis: Strength. Transporting either the patient specimens from the hospital laboratories or the pseudo food samples from the county health departments to the Bureau of Laboratories in a timely fashion was successfully demonstrated.

The Participant Feedback indicated that the Instructions for packaging and shipping for the hospital laboratories were complete and the provision of the return shipping materials was very helpful.

Based upon the evaluation of the packaging of the patient clinical

specimens using the Exercise Criteria for Packaging and Shipping (Table 2), it is evident that the participating hospital laboratories were able to package and ship patient clinical specimens to the regional Bureau Laboratories following the CDC protocols and the IATA/DOT regulations for Biological Substances, Category B. Fourteen of the fifteen hospital laboratories were able to follow the packaging and shipping guidelines provided without any deficiencies whereas one did not use the labels as required.

The successful packaging and shipping we observed in this exercise for the patient clinical specimens may be the result of the fact that we sent the required packaging and shipping materials to the hospitals a week before the exercise. This would be similar to the way the Florida LRN-C laboratories would respond in an actual event.

One comment in the Participant Feedback was that each hospital should have packaging and shipping supplies on stock to ship patient specimens in the event of a real emergency. The Bureau of Laboratories had reviewed this issue thoroughly and decided against pre-staging of packaging and shipping materials at the hospitals or the assuming that the hospitals would have these materials on hand. This is based upon two disadvantages of pre-staging materials at the hospitals. First is that hospitals have a limited storage capacity and second; since these are items that are not used everyday, they could easily be misplaced and therefore would not be available when needed. Also, a strong advantage to delivering the supplies “just in time” or when needed is that this will allow accommodation for any changes in the packaging and shipping protocol by the CDC.

The county health departments also were successful in packaging and shipping the pseudo food samples to the Bureau of Laboratories. As one commented in the Participant Feedback “The CHD’s were great in transporting samples to us: two transported and one sent photos of their packaging and shipping step by step via email since they could not fed ex (sic) properly due to lack of training.”

The Participant Feedback indicated that the notification to the Bureau of Laboratories to expect the shipment was received for both the patient clinical specimens and the pseudo food samples.

Although only six of the 15 sets of specimens from the hospital laboratories arrived at the LRN-C regional laboratories frozen as required, based upon the specimen analysis, having the specimens arrive thawed and cool or up to ambient temperature did not affect the chemical testing and provided satisfactory analytical results (discussed below, Objective 6, Activity 1).

Although, as shown here, it appears that shipping on dry ice is not required for the consistent and reproducible detection of ricinine, hospital laboratories may want to consider using a dry ice vendor or local grocery store for obtaining dry ice for shipping patient specimens by commercial shipper.

Analysis: Area for Improvement. Not all of the participating hospital laboratories received the packaging and shipping supplies needed in a timely manner. Also, it was pointed out that the instructions for the packaging called using fiber strapping tape which was not included in the supplies and at least one hospital did not have in stock.

Regarding the pseudo food samples, it was noted in the feedback that the correct size coolers were not available at the CHD Epidemiology office for transporting larger samples. Similarly, it was noted that the CHD Epidemiologist had not had previous training or experience with packaging food samples.

This brings up an important issue in the Exercise design. There was an artificiality that was introduced into the Exercise which wasn't realistic. The Exercise called for the CHD Epidemiology involvement with the pseudo food sample collection and subsequent packaging and shipping. It was pointed out that it would have to be an overwhelming event (e.g. BT incident) for CHD Epidemiology to get involved with specimen/sample management. In a real foodborne outbreak, it is the Environmental Health people who would have the responsibility for collecting the food samples and then assuring that they are transported correctly to the state laboratory.

Along these same lines though, the feedback indicated that at least one county health departments has an Epidemiology Response Team composed of volunteers from the CHD who have training in epidemiology procedures. It was stated by the CHD Epidemiologist that this team was used during the 2009 H1N1 epidemic.

Regarding the transportation of the pseudo food samples, one commenter stated in their feedback that there are potential issues with relying on one specific agency, such as the RERAs (Regional Emergency Response Advisors), for transport if there is a large influx of samples in a short period of time. It was thought that it might be better to have the sample collectors bring the samples directly instead of waiting for law enforcement, a RERA, or overnight shipping them. It was added that this would depend upon the scale, scope, and other issues related to the event but that this might be able to free up key personnel to perform other tasks.

There was also feedback regarding the number of county health departments that were able to participate in the Exercise packaging and shipping of the pseudo food samples. One commenter stated that it "Would have been nice to have more than three counties participate" for their region.

Similarly, it was suggested that in the future it would be beneficial to simulate what it would be like to receive many samples all at once and spread out over the day to better assess surge capacity in an event like this. It was noted that "An event of that nature would require a completely different approach than the one we normally employ when responding to a white powder event."

There was a communication breakdown between one of the regional Bureau of Laboratories and the county health department. The feedback indicated this to be a result of mitigating issues not related to the exercise but prompted the comment stating that "…there should probably be a process for ensuring that samples do not get lost or overlooked during a real emergency."

As indicated above, of the 15 patient specimen sets sent from the hospital laboratories to the regional Bureau of Laboratories, nine of the specimen sets (60%) arrived thawed. Fortunately, based upon the specimen analysis, having the specimens arrive thawed and cool or up to ambient temperature didn't affect the chemical testing and provided satisfactory analytical results.

Recommendation: Not all of the participating hospital laboratories received the packaging and shipping supplies needed in a timely manner. In future exercises where there is a need to supply partner agencies with materials they may need for the exercise, the supplies should be received in a timely manner.

Also, it was pointed out that the instructions for the packaging called using fiber strapping tape which was not included in the supplies and at least hospital did not have in stock. In the future the fiber strapping tape should be included with the packaging and shipping supplies provided to the hospital laboratories for the shipping patient clinical specimens.

Although, as shown here, it appears that shipping on dry ice is not required for the consistent and reproducible detection of ricinine, hospital laboratories may want to consider using a dry ice vendor or local grocery store for obtaining dry ice for shipping patient specimens by commercial shipper.

It was suggested that it might be beneficial if the county health

departments (Environmental Health and maybe Epidemiology) have training in packaging and shipping of laboratory samples just in case a similar event really does happen. It also might be advantageous for the county health departments to keep the appropriate size shipping containers on hand for transporting the samples to the Bureau of Laboratories.

It is recommended that in future exercises the need to simulate what it would be like for the Bureau of Laboratories to receive many food samples "…all at once and spread out over the day" to truly assess the surge capacity in an event like this.

And finally, it is recommended that the notification of receipt of specimens and samples needs to go to more than one contact at the submitting facility if possible.

Activity 2: Maintain forensic chain-of-custody throughout the sample-management process. (Task 2)

Observation: Since, in a biological or chemical exposure incident, the sample/specimen analysis may be considered as admissible in court, we evaluated the Chain of Custody and evidence preservation procedures as part of the Exercise.

For the Exercise, the Bureau of Laboratories Chain of Custody forms were provided for transporting the samples/specimens to the regional laboratories. The chain of custody protocol requires that each person who has custody of the samples/specimen print and sign their name and enter the time and date of the change of custody on the Chain of Custody form that accompanies either the pseudo food samples or the patient clinical specimens.

The county health departments were able to maintain the Chain of Custody for transporting the pseudo food samples to the Bureau of Laboratories.

For the patient clinical specimens, the Chain of Custody was initiated at the hospital laboratory when the spiked specimens were received from the CDC. A copy of the hospital laboratory Chain of Custody then accompanied the packaged specimens when they were shipped or transported to the regional Bureau of Laboratories. Fourteen of the fifteen hospital laboratories were able to follow the guidelines provided without any deficiencies whereas one did not use evidence tape, which was the same hospital which did not use labels, as mentioned above.

Analysis: Strength. The Chain of Custody procedures were able to be maintained for both the pseudo food samples and the patient clinical specimens.

Analysis: Area for Improvement. NONE

Recommendation: As mentioned above, as part of the outreach to the health and medical community, the Bureau of Laboratories Chemical Threat Program had previously trained a number of the hospital laboratories that participated in the exercise on the CDC protocols for shipping urine specimens after a chemical exposure incident. This training includes evidentiary procedures. This outreach and training should be continued.

Objective 6: Conduct testing and analysis for routine and surge capacity. (Function 3)

Activity 1: Conduct chemical laboratory testing following LRN-C testing methods. (Task 2)

Observation: To evaluate chemical laboratory testing following LRN-C testing methods and how the temperature control of patient specimens affected the results of the chemical analysis, the Bureau of Laboratories, LRN-C Surge Capacity Laboratory analyzed spiked patient specimens under control and realistic conditions. The Hospital laboratories received spiked patient specimens from the CDC a week before the Exercise and then arranged to have the specimens transported to the Bureau of Laboratories for analysis. The specimens were provided by the CDC's National Center for Environmental Health (NCEH) and consisted of pooled, sets of ten patient urine specimens in cryovials. The specimen sets contained a mixture of low, medium, and high concentration spikes as well as an unspiked specimen.

A set of spiked specimens with low, medium and high concentrations of ricinine also was sent to the LRN-C surge capacity laboratory in Jacksonville, FL. The Jacksonville specimens were used as controls since they had been treated under the same conditions as the ones that the hospitals received (aliquoted, frozen, and air shipped) and "measured" under the same set of laboratory conditions (calibration curve, chemist, instruments, reagents, etc.). The low, medium, and high concentration controls were 17.1 ± 0.1, 103.3 ± 3.1, and 161 ± 1.0 ppb, respectively. This is comparable to the CDC concentrations of 15.8, 89.6, and 131 ppb calculated before sending the specimens out to the laboratories. The averaged mean error for all transportation methods were less than 7.9 % of the expected results of the corresponding control specimen values. When comparing each method, using a commercial shipper and cold packs ranged from 92.4% to 97.8%; using a commercial shipper and dry ice ranged from 90.6% to 94.3%; using a local courier and cold packs ranged from 92.4% to 97.7%; and using a local courier and dry ice ranged from 97.4% to 98.6% of the expected value.

The data represents the analysis of specimen sets from 14 hospital laboratories, since one hospital laboratory was unable to have the specimens transported to the regional LRN-C laboratory in time for analysis. The results are shown in Table 3, Table 4 and Chart 1.

Table 3. Average Ricinine Concentrations by Transportation

	Low Conc. ppb	Medium Conc. ppb	High Conc. ppb
Control	17.1 ± 0.1	103 ± 3.1	161 ± 1.0
CS-CP (n=2)	15.8 ± 0.7	101	149 ± 5.7
CS-DI (n=7)	15.5 ± 0.6	94.5 ± 6.4	152 ± 5.7
LC-CP (n=5)	16.3 ± 0.8	95.5 ± 3.8	157 ± 6.3
LC-DI (n=2)	16.8 ± 0.3	101 ± 2.7	159 ± 9.2

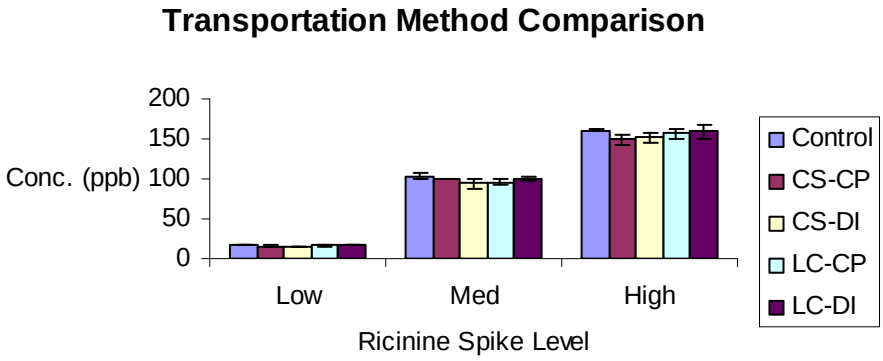
* CS-CP – Commercial Shipper with Cold Packs; CS-DI – Commercial Shipper with Dry Ice; LC-CP – Local Courier with Cold Packs; LC-DI – Local Courier with Dry Ice

Table 4. Range of Ricinine Concentrations by Transportation

	Low Conc. ppb	Medium Conc. ppb	High Conc. ppb
Control	17.0 - 17.1	100 – 106	160 - 162
CS-CP (n=2)	15.0 – 16.5	101	145 - 153
CS-DI (n=7)	15.0 – 17.1	83.9 - 106	146 - 162
LC-CP (n=5)	15.1 – 17.3	87.2 – 99.6	145 - 170
LC-DI (n=2)	16.6 – 17.3	97.2 - 103	150 - 169

* CS-CP – Commercial Shipper with Cold Packs; CS-DI – Commercial Shipper with Dry Ice; LC-CP – Local Courier with Cold Packs; LC-DI – Local Courier with Dry Ice

Chart 1. Effect of Transportation Method on Results



* CS-CP – Commercial Shipper with Cold Packs; CS-DI – Commercial Shipper with Dry Ice; LC-CP – Local Courier with Cold Packs; LC-DI – Local Courier with Dry Ice

When comparing how the specimens arrived at the regional LRN-C laboratory, those that arrived frozen were within ± 6.9% of the expected value; and those that arrived thawed and either cool or up to ambient temperature were within ± 4.8% of the expected value. The data is shown in Table 5, Table 6, and Chart 2.

Table 5. Average Ricinine Concentrations by Arrival Condition

	Low Conc. ppb	Medium Conc. ppb	High Conc. ppb
Control	17.1 ± 0.1	103 ± 3.1	161 ± 1.0
Frozen n=6	15.7 ± 0.8	96.1 ± 5.6	152 ± 5.2
*Thawed n=9	16.2 ± 0.7	96.4 ± 5.0	157 ± 7.3

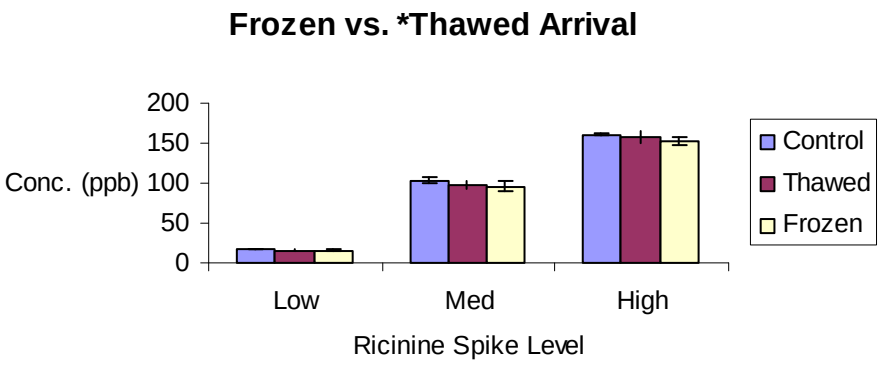
*Either cool or up to ambient temperature

Table 6. Range of Ricinine Concentrations by Arrival Condition

	Low Conc. ppb	Medium Conc. ppb	High Conc. ppb
Control	17.0 - 17.1	100 – 106	160 - 162
Frozen n=6	15.0 – 17.3	83.9 - 106	146 - 162
*Thawed n=9	15.0 – 17.3	87.2 - 103	145 - 170

*Either cool or up to ambient temperature

Chart 2. Comparison of Frozen vs. *Thawed Specimen Arrival



*Either cool or up to ambient temperature

Analysis: Strength. The Bureau of Laboratories LRN-C Surge Capacity laboratory was able to follow the CDC methods for the analysis of ricinine, a biomarker for ricin. Based upon the specimen analysis, having the specimens arrive thawed and cool or up to ambient temperature provided satisfactory analytical results. Although, as shown here, it appears that shipping on dry ice is not required for the consistent and reproducible detection of ricinine. Hospital laboratories may want to consider using a dry ice vendor or local grocery store for obtaining dry ice for shipping patient specimens by commercial shipper.

Analysis: Area for Improvement. One Hospital laboratory had the specimens received at the Hospital facility but due to a miscommunication they remained in the hospital laboratory for three days into the Exercise before they were shipped to the Bureau of Laboratories. Unfortunately, they arrived too late to be included in the chemical analysis.

Recommendation: The Bureau of Laboratories LRN-C Chemical Threat Program laboratory participation in the CDC Proficiency Testing; Surge Capacity Exercises; and Simulation Exercises, such as this, have prepared the analytical chemists well for the response to a chemical exposure event. Participation in these activities should continue to be funded by the Public Health Emergency Preparedness Grant.

Objective 7: Support public health investigations (Function 4)

Activity 1: Establish and maintain the ability to provide analytical support for investigations with first responders and other health investigation community partners. (Task 1)

Observation: Although not demonstrated in this Exercise, the Bureau of Laboratories Biological Defense Coordinators do have LRN methods in place to be able to analyze food samples for ricin.

The Bureau of Laboratories Chemical Threat program was able to demonstrate support for public health investigations for patients potentially exposed to ricin by providing the chemical analysis for the biomarker ricinine.

The results for the patient clinical specimens and the pseudo food samples results were reported back to the health investigation community partners including the submitting hospital laboratories, the FBI, the Florida Poison Information Center, and the submitting county health departments (See Objective 8: Results Reporting below).

Analysis: Strength. The Bureau of Laboratories has the capability to provide analytical support for a multitude of biological and chemical threat agents.

The results for both the patient clinical specimens and the pseudo food samples were reported back to other health investigation community partners during the exercise (See Objective 8: Results Reporting below).

Analysis: Area for Improvement. NONE

Recommendation: NONE

Objective 8: Report Results (Function 5)

Activity 1: Notify appropriate public health, public safety, and law enforcement officials (24/7) of presumptive and/or confirmed laboratory results from clinical, food, or environmental samples that involve a chemical, radiological, or biological threat agent. (Task 1)

Observation: The Bureau of Laboratories Biological Defense Coordinators notified most of the partner agencies of the results of the pseudo food sample testing. However, one county health department Epidemiologist stated that they were not notified.

The results from the patient clinical specimens were reported back to the hospital laboratories as well as the partner agencies. One of the commenter's feedback stated that they had received verbal results for the specimens their Lab had sent out but asked if written results could also be received via fax or email.

As mentioned above (Capability 6: Information Sharing, Obj. 1, Activity 1), only the Jacksonville Poison Information Center was notified of the chemical testing results. This was probably due to the oversight of the Exercise Planning Team and the way the Florida Poison Information Centers Network call routing works. The information was phoned in from the Jacksonville BOL and they were, therefore, connected with the Jacksonville Poison Information Center. Although the Florida Poison Information Centers in Tampa didn't get a call from Jacksonville they indicated during the Hot Wash that they had been emailing each other. Also, the Tampa Center reported that they did receive the SIMCELL inject of the results.

During the Hot Wash conference call the discussion turned to the contact lists between the agencies. It was stated by one of the CHD Epidemiologists that they had the Bureau of Laboratories contact information which included multiple Biological Defense

Coordinators and at least one Chemical Threat Laboratory Coordinator on hand.

Also in this discussion, one of the hospital Laboratory Directors mentioned that it would be beneficial to have a general contact (and a backup) for the hospital laboratory in case the primary contact was not available. This would make sure that there is someone available to receive emails and/or phone calls at all times.

Analysis: Strength. The Bureau of Laboratories was able to report results for both the patient clinical specimens and the pseudo food samples back to the other health investigation community partners.

Partner agencies who need to contact the Bureau of Laboratories Biological Defense Coordinators and Chemical Threat Laboratory Coordinator have the needed information on hand.

Analysis: Area for Improvement. Not all partner agencies received the results reports for the pseudo food samples submitted. This might have been due to “real world” events that interrupted Exercise play.

The Florida Poison Information Center (Tampa) mentioned in the feedback that they didn’t get the clinical patient testing results back directly from the BOL.

Recommendation: The Exercise Planning Team needs to consider the best way for information to be relayed to all participants including those who have specific routing procedures such as the Florida Poison Information Center.

It was suggested in the feedback that agencies have a Communication Plan.

In addition to verbal results reporting, the next Exercise should include sending the laboratory results by fax or email back to the submitting hospital laboratories or agencies.

Activity 2: Send presumptive and confirmed chemical, radiological, or biological laboratory results to CDC and all submitters. (Task 2)

Observation: This activity was included in the ExPlan, however for the exercise, special arrangements are required to send chemical testing results to the CDC through the LRN Messenger web application and these preparations were not completed.

Analysis: Strength. NA

Analysis: Area for Improvement. NA

Recommendation: The Bureau of Laboratories regularly sends presumptive and confirmed chemical or biological laboratory results to CDC during regular LRN testing and proficiency testing. The necessity to include this activity in future exercises will be reviewed.

CAPABILITY 13: PUBLIC HEALTH SURVEILLANCE AND EPIDEMIOLOGICAL INVESTIGATION

Objective 9: Conduct public health surveillance and detection. (Function 1)

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Activity 1: Engage and retain stakeholders, which are defined by the jurisdiction, who can provide health data to support routine surveillance, including daily activities outside of an incident, and to support response to an identified public health threat or incident. (Task 1)

Observation: Providing health data to support routine surveillance would be a responsibility of the state laboratories. As described previously, the State Comprehensive Laboratory Response Plan (CLRP) establishes the framework to ensure that the State of Florida will be able to mount a laboratory response to public health hazards. The CLRP outlines the roles and responsibilities of the participating laboratories (government and nongovernment) and coordinates response and recovery activities across the full spectrum of responding entities. The CLRP unifies the efforts of these groups for a comprehensive approach to reducing the effects of an emergency and/or disaster.

To support the laboratory response are partners who would provide the samples and clinical specimens to be tested. In this exercise, the support partners included 15 hospital laboratories representing 12 counties in five of the seven regional areas throughout Florida. The hospitals varied in patient capacity from 84 beds to 1,067 beds, including four Level II trauma centers and two Pediatric trauma centers. These hospital laboratories were able to provide the patient clinical specimens to be tested to the Bureau of Laboratories.

Additionally, eleven county health departments (Epidemiology and Environmental Health) participated in the simulated food sample collection and the transportation to the Bureau of Laboratories.

As mentioned above, there was an artificiality in the Exercise design which wasn't realistic. The Exercise called for the CHD

Epidemiology involvement with the pseudo food sample collection and subsequent packaging and shipping. It was pointed out that it would have to be an overwhelming event (e.g. BT incident) for CHD Epidemiology to get involved with specimen/sample management. In a real foodborne outbreak, it is the Environmental Health people who would have the responsibility for collecting the food samples and then assuring that they are transported to the correct state laboratory.

Analysis: Strength. The State Comprehensive Laboratory Response Plan (CLRP) establishes the framework to ensure that the State of Florida will be able to mount a laboratory response to public health hazards.

Support partners including the county health departments and the hospital laboratories were able to provide samples and patient clinical specimens for laboratory analysis.

Analysis: Area for Improvement. NONE

Recommendation: Continue to update the State of Florida Comprehensive Laboratory Response Plan (CLRP) and distribute to all of the partner agencies. Continue to maintain an up to date, contact information database for the partner agencies.

Continue outreach and training for the health and medical community on the packaging and shipping of laboratory samples and specimens.

Activity 2: Maintain surveillance systems that can identify health problems, threats, and environmental hazards and receive and respond to (or investigate) reports 24/7. (Task 4)

Observation: The Exercise included an ESSENCE Alert as a SIMCELL Inject to simulate the patients presenting to the hospitals with nausea, vomiting and diarrhea and indicate the start of the food borne outbreak.

The feedback from one of the Surveillance Epidemiologists was that in a real event of this size they would need to provide the regional Epidemiologists (both from the Bureau of Epidemiology and the Division of Environmental Health) with their updates. Additionally, it was stated that some counties might continue to need further assistance to interpret the updates even if Environmental Health is in the lead (and possibly overwhelmed). It was suggested that EpiCom would serve this function in a real incident.

During the Exercise Planning Conferences it was noted that the ESSENCE application is also monitored by the Florida Poison

Information Center Network. During the Hot Wash call they indicated that they are regularly in contact with the epidemiologists when they detect evidence of an outbreak. During the Exercise, the Florida Poison Information Center contacted the Food and Waterborne Disease Program after consulting with the hospital regarding the patient symptoms.

During the Exercise, the designated county health department epidemiologist was able to give updated information to the Florida Poison Information Center as planned. However, when they called the Poison Information Center, the initial response was that they had already been notified with this information. The Epidemiologist had to ask her to go over what had been reported and then was able to provide the new, updated information. In the Participant Feedback the Epidemiologist stated that the "…poison center also contacted the [X] CHD which I think confused them greatly since they weren't participating in the exercise."

One of the comments in the feedback stated that there seemed to be some confusion on the first day. They were getting SIMCEL notices providing information before the regional player was able to provide the information. "About 3pm on the first day I got a call from two surveillance epi's to see if they should be concerned with their ESSENCE data b/c they saw the 6 cases related to the exercise." This could have been due to either the Exercise Design or player inaction.

Analysis: Strength. The simulated ESSENCE Alert allowed the epidemiologists to evaluate communications between regional and local levels.

The Florida Poison Information Center also monitors the ESSENCE application.

The county health department epidemiologists regularly are in contact with the Florida Poison Information Center and were able to give updated information on the patients.

Analysis: Area for Improvement. There appears to have been some confusion in the planned Exercise activities regarding the simulated ESSENCE alert which caused some confusion on the first day. This might have led to a slight misunderstanding between Florida Poison Information Center and county health department epidemiologist when updating with new information.

Recommendation: The Exercise Planning Team will need to work further with the players who would be involved with the response to an ESSENCE alert for the next exercise design.

Objective 10: Conduct public health and epidemiological investigations. (Function 2)

Activity 1: Conduct investigations of disease, injury or exposure in response to natural or man-made threats or incidents and ensure coordination of investigation with jurisdictional partner agencies. Partners include law enforcement, environmental health practitioners, public health nurses, maternal and child health, and other regulatory agencies if illegal activity is suspected. (Task 1)

Observation: Although an actual epidemiological investigation was not included in the Exercise, there were several related activities.

The Florida Poison Information Center contacted the Food and Waterborne Disease Program after being consulting with the hospital regarding the patient symptoms. This was to inform them of a possible foodborne outbreak.

To simulate an epidemiological investigation, the county health department Epidemiologists contacted the participating hospital laboratory in there county, if there was one. This was an artificiality for the Exercise. It was pointed out that the Epidemiologists would normally contact the Infection Control Practitioner at the hospital for inquiries.

During the Hot Wash it was stated by one of the Epidemiologists that the Infection Control Practitioner (ICP) are the main communication point for the County Department of Health Epidemiology. It was added that the ICPs "…are like the ambassadors to the hospital. They are the best, best contact at the hospital. They are critical for the public health hospital interaction." It was mentioned that the county Epidemiologists can provide a list of ICPs for contacting to invite to the next exercise.

As mentioned before, the feedback indicated that some people were left off the invitation list in the CHD who would be very important public health and epidemiological investigations. This includes the Preparedness Planners and Public Information Officers (PIO). It was thought that the Bureau of Preparedness and Response could be a good source for encouraging these individuals to participate in the next exercise.

During the exercise the county health department Epidemiologists or Environmental Health Scientists consulted with the Biological Defense Coordinator at the regional Bureau of Laboratories to determine how best to transport the samples and specimens to the laboratory. The laboratory analysis would be essential in conducting investigations of disease, injury or exposure in response to natural or man-made threats or incidents.

One of the comments in the Participant Feedback mentioned that

it might be beneficial to assess if the Epidemiologist at the CHD may be called upon to collect and transport food specimens. If so, appropriate training on collecting the samples and having on hand the appropriate size shipping containers for transporting the sample to the state laboratories would be important in epidemiological investigations.

Analysis: Strength. The Florida Poison Centers and the Epidemiologists have an excellent working relationship. It was also stated in the Participant Feedback that the "…communication between the regional epidemiologist, the CHD epidemiologist, and the lab was very good."

Analysis: Area for Improvement. It may be beneficial to assess if the Epidemiologist at the CHD may be called upon to collect and transport food specimens. If so, appropriate training on collecting the samples and having on hand the appropriate size shipping containers for transporting the sample to the state laboratories would be important epidemiological investigations.

The Exercise Planning Team needs to be sure to include as many partner agencies as possible who would be involved with investigations of disease, injury or exposure in response to natural or man-made threats or incidents.

Recommendation: It may be beneficial for the county epidemiologists to consider having training on collecting the samples and having on hand the appropriate size shipping containers for transporting the sample to the state laboratories would be important epidemiological investigations.

The Exercise Planning Team needs to be sure to include as many partner agencies as possible who would be involved with investigations of disease, injury or exposure in response to natural or man-made threats or incidents.

Activity 2: Provide epidemiological and environmental public health consultation, technical assistance, and information to local health departments regarding disease, injury, or exposure and methods of surveillance, investigation, and response. (Task 2)

Observation: During the Exercise Planning conferences, the Office of Communications indicated that they would be able to provide information to the county health department Public Information Officers (PIOs) regarding risk communication in response to the incident. During the Exercise they were able to provide ricin messaging products to the CHD PIO representatives through the Crisis and Emergency Risk Communication (CERC) Portal for their use.

The Florida Poison Information Center stated on the Question and Answer conference call that they would be able to provide information to medical providers on the treatment of the patients. They would begin preparing this information as soon as they realized that this was a public health emergency, although they would not release the information until there was confirmation.

Analysis: Strength. The Office of Communications would be able to provide information to the county health department Public Information Officers (PIOs) on risk communication in an event like this. Additionally, the Florida Poison Information Center would be able to provide information to medical providers on the treatment of the patients and would begin preparing this information as soon as they realized that this was a public health emergency, although they would not release the information until there was confirmation.

Analysis: Area for Improvement. NONE

Recommendation: NONE

Objective 11: Improve public health surveillance and epidemiological investigation systems. (Function 4)

Activity 1: Identify issues and outcomes during and after the incident. (Task 1)

Observation: One of the Epidemiologist participant feedback comments mentioned that in the setting of a large epidemiology outbreak, it is probably important to include both the Bureau of Epidemiology and Environmental Health regional epidemiologists when disseminating updates. It was thought that some counties will likely continue to need assistance to interpret the updates. It was suggested that EpiCom would serve this function in a real incident.

Analysis: Strength. The Exercise included an ESSENCE Alert; an EpiCom message; and a Health Alert Message to provide an opportunity to identify issues in public health surveillance and epidemiological investigation.

Analysis: Area for Improvement. NONE

Recommendation: Partner agencies should review their activities during the Exercise to identify strengths and areas for improvement regarding public health surveillance and epidemiological investigation systems.

Activity 2: Conduct post-incident/post-exercise agency evaluation meeting(s) including all active participants (e.g., law enforcement, volunteer agencies, clinical partners or environmental regulatory agency) to identify internal protocols and deficiencies that require corrective actions in areas such as programs, personnel, training, equipment, and organizational structure. (Task 2)

Observation: The Exercise Planning Team provided for three Hot Wash conference calls for the participating agencies to provide feedback and observations on the Exercise.

Analysis: Strength. The Hot Wash conference calls were well attended an the players gave valuable input on both the Exercise activities and the Exercise design.

Analysis: Area for Improvement. NONE

Recommendation: Continue to provide multiple Hot Wash conference calls on different days and times for the convenience of the participating agencies. The input received is invaluable in constructing a meaningful After Action Report.

Activity 3: Develop an After Action Report/Improvement Plan. (Task 3)

Observation: This activity was included in the ExPlan. However, the Exercise Planning Team did not incorporate a means to evaluate the activity specifically for improving public health surveillance and epidemiological investigation systems. It is preserved here as a place holder.

However, the Hot Wash conference calls were well attended an the players gave valuable input on both the Exercise activities and the Exercise design. Additionally, the Participant Feedback forms provided a wealth of information.

Analysis: Strength. The Hot Wash conference calls were well attended an the players gave valuable input on both the Exercise activities and the Exercise design. Additionally, the Participant Feedback forms provided a wealth of information

Analysis: Area for Improvement. NA

Recommendation: NA

Activity 4: Communicate recommended After Action Report Improvement Plan corrective actions to public health leadership. (Task 4)

Observation: This activity was included in the ExPlan. However, the Exercise Planning Team did not incorporate a means to evaluate

the activity specifically for improving public health surveillance and epidemiological investigation systems. It is preserved here as a place holder.

However, the Hot Wash conference calls were well attended an the players gave valuable input on both the Exercise activities and the Exercise design. Additionally, the Participant Feedback forms provided a wealth of information.

Analysis: Strength. The Hot Wash conference calls were well attended an the players gave valuable input on both the Exercise activities and the Exercise design. Additionally, the Participant Feedback forms provided a wealth of information

Analysis: Area for Improvement. NA

Recommendation: NA

SECTION 4: CONCLUSION

The *2012 Florida Biological Chemical Agent Full Scale Exercise* was a state-wide exercise to evaluate the response to a biological or chemical exposure incident scenario. The exercise incorporated many local, state and federal agencies that would respond to this type of incident. Overall this Full Scale Exercise proved to be very successful. All partner agencies were able to work together to provide an effective response to the biological-chemical exposure event. Moreover, this Exercise presented a practical learning environment for agencies to become familiar with the issues and concepts that may arise during a separate or combined biological chemical exposure incident. Participating agencies and staff were able to partner and respond to meet the Exercise objectives. As a result of this Exercise, not only are local, state and federal agencies more aware of the scope of response involved in a biological or chemical exposure event, but they also were able to determine where gaps existed in planning, procedures and inter/intra agency communication.

MAJOR STRENGTHS

The major strengths identified during this exercise include the following:

- The Exercise was able to bring together multiple local, state and federal agencies that would respond to a biological or chemical public health emergency. The Exercise Planning Conferences allowed everyone to participate and to learn how a multi agency response to a biological or chemical agent incident would be coordinated.
- The State of Florida Comprehensive Laboratory Response Plan for Chemical, Biological and Radiological Incidents (CLRP) describes how the use of Florida's laboratory resources will be coordinated to respond to public health emergencies of all types.
- Transporting either the patient specimens from the hospital laboratories or the pseudo food samples from the county health departments to the Bureau of Laboratories in a timely fashion was successfully demonstrated.
- Coordination for public health investigation between the epidemiologists, the Florida Poison Information Center Network, the hospital laboratories and the Bureau of Laboratories was very good.

PRIMARY AREAS FOR IMPROVEMENT

Throughout the exercise opportunities for improvement were identified. The primary areas for improvement, including recommendations, are as follows:

AREA FOR IMPROVEMENT

The Exercise needs to include additional participation from partner agencies. At the hospitals this would include Emergency Department personnel and Infection Control Practitioners (ICPs) and at the County Health Department level this would include Preparedness Planners and Public Information Officers.

KEY RECOMMENDATION: The Exercise Planning Team needs to include additional participation from partner agencies. It was stated that the CHD Epidemiologists can provide contact information for the hospital ICPs who, in turn, can encourage participation from the Emergency Department staff. It was also noted that the Bureau of Preparedness and Response would be a good source for contact information at the CHD level for Preparedness Planners and PIOs.

APPENDIX A: IMPROVEMENT PLAN

This Improvement Plan (IP) has been developed specifically for the participating agencies as a result of the *2012 Florida Biological Chemical Agent Full Scale Exercise* conducted on June 13-17, 2011. These recommendations draw on both the After Action Report and the Participant Feedback.

Table A.1 *Improvement Plan Matrix*

Capability	Observation Title	Recommendation	Corrective Action Description	Primary Responsible Agency	Agency POC	Start Date	Completion Date
Information Sharing	Review Communication Plan	Each individual agency should review their communications plan.	Each individual agency should make updates as required to their communications plans.	Each individual agency	Agency Leadership	TBD	12/2012
Information Sharing	Include more partner agencies	Expand the outreach during the Exercise planning to include additional partner agencies.	Work with CHD Epidemiology and Bureau of Preparedness and Response to obtain hospital and CHD contact information.	Exercise Planning Team	Exercise Director	TBD	12/2012
Information Sharing	Increase interaction for information sharing	Expand the exercise to provide for more opportunities to exchange information.	Work with the Exercise Planning Team to provide for more opportunities to exchange information.	Exercise Planning Team	Exercise Director	TBD	12/2012
Information Sharing	Include entire networks in information sharing	The Exercise Planning Team needs to be aware of agencies that have networked information sharing.	Work with the Exercise Planning Team to provide for more opportunities for networked information sharing.	Exercise Planning Team	Exercise Director	TBD	12/2012
Public Health Laboratory Testing	Situational awareness	Include laboratorians early when it becomes apparent that there might be a public health emergency which will require their involvement.	Work laboratorians to discuss what needs they might have when responding to a public health emergency which will require their involvement.	Bureau of Laboraoties	Agency Leadership	TBD	12/2012

Capability	Observation Title	Recommendation	Corrective Action Description	Primary Responsible Agency	Agency POC	Start Date	Completion Date
Public Health Surveillance and Epidemiological Investigation	Packaging and shipping training	It may be beneficial for the county epidemiologists to consider having training on collecting the samples and having on hand the appropriate size shipping containers for transporting the sample to the state laboratories would be important epidemiological investigations.	1. Obtain training on packaging and shipping if the agency believes it will be needed. 2. Have packaging and shipping containers available.	County Health Department Environmental Health and Epidemiology Programs.	County Health Department Environmental Health and Epidemiology Program Leadership.	TBD	12/2012

APPENDIX B: MINUTES FROM QUESTION AND ANSWER CONFERENCE CALL

On Day 3 of the Exercise we had a general Question and Answer conference call. Since we had a large number of agencies involved in the Exercise, this gave us the opportunity to discuss the "what if's…" Agencies asked questions during the call regarding PPE for biological or chemical exposure, information sharing, and other issues they had.

Some of the questions were sent to the SIMCELL which was the facilitator for the conference call.

1. Would the Hospital Staff need to wear specific PPE (Personal Protective Equipment) for suspected ricin cases?

   The Florida Poison Information Center answered this question and they recommended that universal precautions be used. They further stated that there is no specific PPE used for ricin.

2. In a real Chemical event our hospital wouldn't have the shipping containers needed on hand. What is the best alternative method of shipping samples?

   The Bureau of Laboratories would work with the hospitals to be sure they had the necessary packaging and shipping supplies. These would be sent to the hospitals as they were during the Exercise.

3. This morning a SIMCELL Inject was sent indicating that there was a credible threat of intentional food poisoning. Who would the Florida Fusion Center share the information with about a credible threat of food poisoning or does this meet a criteria level yet? If so with who in the Department of Health?

   A participant from the FBI stated that they would be in touch with the Florida Fusion Center and FBI WMD at Headquarters to see if they have further information.

   It was further stated that the FBI has a good working relationship with DOH in Tallahassee (Leon County Public Health Hospital and EMS Preparedness Planner) whom they work with when investigating white powder incidents.

   Also, the FBI would be in touch with local CHD (MOU's in place all CHDs) for awareness and gather more information if available.

   The Food and Waterborne Disease Program (FWDP) is working to get Secret level clearance to join Florida Fusion Center so that environmental epidemiology will be part of the fusion center.

4. How long would it take for Florida Fusion Center, DOH, Epidemiology, Poison Information, etc. to put the pieces of the puzzle together to make the connection with the manifesto and

the food borne outbreak?

The Poison Information Center (Tampa) had narrowed down to the patient symptoms to be related to either ricin or arsenic by Tuesday (1 day post patient symptoms called in). It was stated that they would not release information at this time because there is not laboratory confirmation but would begin discussions with physicians who would call in for treatment advice.

Additionally, the Poison Information Center (Tampa) would possibly consult with BOL about laboratory tests or would direct physicians to contact the BOL.

Within minutes after receiving patient symptoms the Poison Information Center (Tampa) called the FWDP to let them know that there was a public health problem going on.

The FBI stated that they would be in consultation with FBI – WMD headquarters, CDC, and other partners on conference call to determine if it is a credible threat - do they have the behavioral resolve, is it technically feasible and operational practicability (in this case it is since they have already done it). If these criteria were met then they would start rolling assets to where the samples were and would use their hazmat unit to begin collecting samples, and working with RERAs (FDOH Regional Emergency Response Advisors) to transport to the LRN (Laboratory Response Network) for analysis and then ultimately to the FBI laboratory as well.

At this point the Florida Poison Information Center would be preparing information needed to respond to the incident (on both ricin and arsenic) so they could answer questions they might be asked but they wouldn't release any information until confirmation. Also, they would be identifying what laboratory testing should be done.

It was stated by the FWDP that if this wasn't a contamination with an exotic, such as ricin, but a more natural enteric, it would take a complete epidemiological investigation which could take a much longer time and might even be missed that it was an intentional event.

5. Would this incident benefit from setting up an Incident Command System (ICS) for the Department of Health (DOH)? If so, who would initiate the process for DOH?

The FWDP stated that they would begin to set up ICS. The members would include the entire Division of Disease Control, Bureau of Epidemiology, Division of Environmental Health, and the Bureau of Laboratories. The FWDP would rely on the Bureau of Preparedness and Response to organize and maybe take the lead on setting up the ICS.

6. What other chemical agents can the Bureau of Laboratories test for?

The Chemical Threat Program can analyze for ricin and arsenic as well as 10 to 12 other chemical agents including chemical warfare agents. What the Bureau of Laboratories would do would be to consult with the CDC. They would also get samples up to the CDC where they can use the Rapid Toxic Screen to screen for 150 possible chemicals.

Miscellaneous Questions

One of the participants at the County Health Department asked if shipping to the BT lab required special shipping labels that are needed and if so, what would they be.

It was stated that for the CT specimens they would need the UN3373 Category B, Biological Substance and if dry ice used Miscellaneous 9 Label.

For the biological food samples, we will be evaluating the consultation between the BT Coordinators and the CHDs so at this time we will not go into more detail on this call.

APPENDIX C: PARTICIPANT FEEDBACK SUMMARY

PART I: RECOMMENDATIONS AND CORRECTIVE ACTIONS

1. Based on the exercise events and the tasks identified, list the top 3 strengths and/or areas that need improvement that you identified after participating in the exercise.

[Agency X] representative did not seem to be very familiar with the exercise and specimens.
Good timeliness of specimen delivery
Clear instruction on packaging and shipping

STRENGTHS
a. Well thought out exercise with very broad group of participants
b. Great communication throughout the exercise by the core group – great documentation
c. Integrated laboratory focused plan (CDC to DOH to DOH Labs to hospital labs)

IMPROVEMENT OPPORTUNITIES
a. Too many people on conference calls – maybe next time, divide areas of focus (hospital separate from agencies) or limit to one person from each agency or facility
b. No notice to hospital when samples rec'd by local DOH lab

Strength- Communication between the regional epidemiologist, the CHD epidemiologist, and the lab was very good.
Weakness- the CHD epidemiologist had not had previous training or experience with packaging food samples. The correct size coolers were not available at the CHD Epi office for transporting a larger non clinical specimen.

Lab shipping part went very well.
Instructions were complete and the provision of the return shipping materials was very helpful.

Strengths: Sample analysis, P&S notification.
Area for Improvement: Communications across BOL lab regions.

1. Shipping materials were helpful and adequate.
2. The instructions for packing called for fiber strapping tape which our hospital did not have.
3. Would like to have bench technologists involved in the exercise if time permits.

[Partner agencies] need to have training in packaging and shipping just in case this ever does really happen

The CHD's were great in transporting samples to us: two transported and one sent photos of their packaging and shipping step by step via email since they could not fed ex properly due to lack of training

Strengths:
1. all 3 counties that sent packages to Tampa lab did it correctly
2. all 3 counties contacted us before they sent the samples

Needs Improvement:
1. Would have been nice to have more than 3 counties participate
2. [X] county didn't have anyone who was certified to package/ship

Make sure there is someone available to receive emails and/or phone calls.
Email or fax Lab results

Analysis was the strongest area.
Hospital/Health Department awareness of the exercise needs to be improved.
Packaging and shipping needs to be improved.

I thought this was a strong exercise.

Laboratory Analysis
Results Reporting

Sample transport
Communication amongst samplers
Communication amongst CT/BT stakeholders

CDC sent along with samples a chain of custody form.
[Our hospital laboratory] conducted the exercise in an expeditious manner.

a) Did not receive supplies by mail, instead they were physically delivered on the Friday before the start of the Exercise just making it.
b) Exercise Log was not used this year.
c) Additional hospital staff did not participate.

2. Identify the corrective actions that should be taken to address the issues identified above. For each corrective action, indicate if it is a high, medium, or low priority.

Determine who at the CHD may be called upon to collect and transport food specimens. If needed provide the appropriate training on collecting the samples and need to keep the appropriate size shipping containers for transporting the sample to the lab. - MEDIUM

High: We should find out the preferred method of communication and delegate a communications officer in each BOL lab region.

a. We will need to order tape (low).
b. Assign a tech to be involved in next exercise (medium).

The biggest thing that needs to be done is that the [agencies] have at least one person onsite that is trained to package and ship otherwise there could be a big problem in a real event

High---to have certified shippers on staff. We gave them the info to take the class.

a. Include an email "reply requested" to make sure emails are received and not missed or sent to Spam

b. Email or fax Lab results

Awareness – A reminder e-mail can be sent out Monday of the exercise to remind everyone to send out their samples. (This is probably low priority because most of the hospitals remembered.)

P&S – More training needs to be provided. (This is probably a high priority item because if the samples aren't packaged and shipped properly then the data can become skewed.)

I think there are potential issues with relying on the [one agency] for transport if there is a large influx of samples in a short period of time. I think public health officials that take samples should be able to bring us their samples directly instead of waiting for a RERA, law enforcement, or overnighting them. Depending, of course, on scale, scope, and other issues, this might be able to free up key personnel to perform other tasks (medium).

Obviously, there was a communication breakdown between our lab and the [X] CHD which was probably also hampered my mitigating issues not related to the exercise. However, there should probably be a process for ensuring that samples do not get lost or overlooked during a real emergency. There is also a question of when/how do positive results get reported to the requesting agency (high).

Assuming the only information received was through the SIMCELLs, I do not feel we (the BT lab) were adequately provided with the scope of what was going on. This information could be critical to us providing necessary information to our stakeholders and also helping us analyze our data and/or troubleshoot our assays. Some of this was probably lost between the samplers and the lab simply because it was an exercise and everyone "knew" what was going on, however, I think it is critical to let the BT labs know what is going on as soon as possible during an event. In other words, the first contact with the lab shouldn't be when samples are being prepared to be shipped to us. This information would also help us prepare equipment, reagents, personnel, etc. for an above average period of testing (medium).

As per Exercise guidance, a copy of the chain of custody form was sent with the specimens to the regional Bureau of Laboratories.

a) Supplies should be received in a more timely manner.
b) As per the Exercise guidance, the log was not necessary this year.
c) Additional hospital staff will be encouraged to participate in future exercises.

3. Who should be assigned responsibility for each corrective action in your agency?

   It may be a combination of the public health preparedness director, EH director, and environmental epidemiologist.

   CT Coordinator

   Microbiology department manager

   Since packaging and shipping is coming up, that should be part of the BT Trainer's responsibility to reach out to the CHD's

   Each laboratory should have one person that sends out a reminder e-mail. This can be the same person that receives and evaluates sample packaging.

   Each laboratory should already have someone responsible for training.

   Regarding transport, that would have to be a collaborative effort with all stakeholders based on the premise that getting the sample to the lab as fast as practical and with an intact chain of custody is paramount.

   For incoming samples, the BT coordinators are largely responsible for this. The RERAs should also be involved, especially for environmental samples or known BT events.

   For collaboration, I think this is largely a law enforcement function.

4. Is there anything you saw in the exercise that you might not have expected or anticipated in your current plans or SOP's?

   No, it was mostly the size of the shipping container that would be an issue for us. Everything else went as expected.

   No

   What to do if proper shipping materials aren't available

   No

   What to do if a CHD can't package and ship a sample because of lack of training

   n/a

   No

   Packaging and shipping of samples

   Again, I think transportation of the samples is one of the most important parts of an event. If samples are suspected for a BT event, those samples should be sent to the lab as soon as possible. I don't think that FedEx should be used for that unless there's

simply no other option. Even an overnight shipment could delay results for 12+ hours.

5. List the applicable equipment, training, policies, plans, and procedures that should be reviewed, revised, or developed for your agency. Indicate the priority level for each.

   Hospital - Need process to store specimens being held in the freezer for shipment while maintaining a chain of custody.

   Food sample collection, packaging, and shipping and related supplies

   NA

   Communication Flow Chart (for BOL CT and others?)

   None

   None

   n/a

   Each hospital or health department should have packaging and shipping supplies on stock in the event of a real emergency. Therefore, we should not have to send out supplies for an exercise.

   I think in the future we need to simulate what it would be like to receive many samples all at once and spread out over the day to truly assess our surge capacity in an event like this. An event of that nature would require a completely different approach than the one we normally employ when responding to a white powder event (high).

PART II – EXERCISE DESIGN AND CONDUCT: ASSESSMENT

Please rate, on a scale of 1 to 5, your overall assessment of the exercise relative to the statements provided below, with **1** indicating **strong disagreement** with the statement and **5** indicating **strong agreement.**

Participant Assessment (N=15)

Assessment Factor	Strongly Disagree (1) / Strongly Agree (5)
a. The exercise was well structured and organized.	4.6
b. The exercise scenario was plausible and realistic.	4.5
c. The facilitator/controller(s) was knowledgeable about the area of play and kept the exercise on target.	4.9
d. The exercise documentation provided to assist in preparing for and participating in the exercise was useful.	4.8
e. Participation in the exercise was appropriate for someone in my position/agency.	4.8
f. The participants included the right people in terms of level and mix of disciplines.	4.3
g. This exercise allowed my laboratory to practice and improve priority capabilities.	4.4
h. After this exercise, I believe my laboratory is better prepared to deal successfully with the scenario that was exercised.	4.4

PART III – PARTICIPANT FEEDBACK

Please provide any recommendations on how this exercise or future exercises could be improved or enhanced.

Clarification on when chain of custody on urine specimen starts in a real event. At the time of collection or upon receipt of labeled specimen by the laboratory.

Consider targeting conference calls to the needed audience for future exercises as the scope has broadened in terms of agencies, health departments and law enforcement.

I thought that it was very well laid out for what was mostly a simulation. I think that it would be more useful as a full scale on-site exercise, but this way allowed many more people to participate.

I think that the exercise was very helpful to us as a review of how to handle such an event. The materials provided will definitely be held a resource documents.

Make sure all participants understand and commit to their level of involvement.

More participation for the BT side (ie the RERAs, more CHD's)

Provide the Labs with written\electronic or faxed Lab results of Ricin content in patient specimens.

Each hospital or health department should have packaging and shipping supplies on stock in the event of a real emergency. Therefore, we should not have to send out supplies for an exercise.

Powerpoint slides to aid conference calls.

Next time, I would like to see a full-scale exercise in terms of samples and processing. We, as the BT labs, should use this time to simulate (by doing) a large influx of samples. Again, this would help us determine what needs we will need to quickly employ to respond to a large-scale event (versus a small-scale white powder incident).

HOT WASH CALL

Monday, 2/20/12, 10 AM

1. What were some of the issues you ran into?

   No Comments

2. What went as well or better than expected?

   No Comments

3. What did the other players at your agency/facility think of the exercise?

   No Comments

4. Who else at your agency/facility would you like to bring in as a participant in an exercise (Administration, Supervisors, etc.)?

   No Comments

5. What would you do different next time?

   I received verbal results for the specimens our Lab sent out. Will written results also be received via fax or email?

   Only the Tampa Poison Information Center was notified by hospital and CHD Epi. The other Poison Information Centers weren't. Faxing or providing the same information to the others would have been useful. Maybe next time have a dual notification system. Also, the Tampa Poison Information Center didn't receive the patients' laboratory results from the lab.

   [Moderator] – The mix up might have been due to the results reporting coming from the Jacksonville BOL. The call would have been routed to the Jacksonville Poison Information Center.

   The Tampa Poison Information Center didn't get a call from Jacksonville but did receive the SIMCELL inject of the results. The Tampa and Jacksonville Centers had been emailing each other. Also, having multiple hospitals and multiple CHDs for each region call into the Poison Centers would be a more realistic simulation.

   [Moderator] – Perhaps in the next exercise we can increase the number of patients for the patient symptom cards to get more hospitals to call the Poison Centers or perhaps have just a "contact call" from the regional hospitals or CHDs to the FPICs.

6. What activities would you like to see added to the exercise (e.g. ICS, more partner agencies, etc.)?

No Comments

Tuesday, 2/21/12, 2 PM

1. What were some of the issues you ran into?

No Comments

2. What went as well or better than expected?

The P&S Supplies we received at the hospital laboratory were well packaged and adequate.

[Moderator] – This would be the way the Bureau of Laboratories would provide the supplies a real event – "Just in Time". In discussions with other LRN-C laboratories we have found this to work better than having the hospitals store supplies which could expire or get lost.

3. What did the other players at your agency/facility think of the exercise?

It would be good to have a general contact (and a backup) for the hospital laboratory in case the primary contact is not available.

Did the hospital labs and CHDs use the contacts that the [Exercise Planning team] sent out or did they use there other contact lists?

Our CHD was able to use the provided sheet which was the same as the normal contact list we have on hand.

Was there more than one contact provided in case the primary was out.

Yes. On our list there were multiple BT and one CT contact.

4. Who else at your agency/facility would you like to bring in as a participant in an exercise (Administration, Supervisors, etc.)?

No Comments

5. What would you do different next time?

No Comments

6. What activities would you like to see added to the exercise (e.g. ICS, more partner agencies, etc.)?

We would like to see involvement from ED Department. Particularly in being able to recognize symptoms. Especially if it was a chemical agent. And also, how would they process them and treat them.

Wednesday, 2/22/12, 2 PM

1. What were some of the issues you ran into?

No Comments

2. What went as well or better than expected?

No Comments

3. What did the other players at your agency/facility think of the exercise?

In general we need to give more thought as to who we should invite to make sure we don't leave important groups out. The Infection Control Practitioners (ICP) are the main communication for public health department and epidemiology. The County Epi can provide a list of ICPs for contacting to invite to the next exercise. They are like the ambassadors to the hospital. They are the best, best contact at the hospital. They are critical for the public health hospital interaction.

4. Who else at your agency/facility would you like to bring in as a participant in an exercise (Administration, Supervisors, etc.)?

Some people were left off the invitation list in the CHD who would be very important. This includes the Preparedness people, and PIOs. Since this is a response to a public health emergency these people should be leading the response at the CHD level.

[Moderator] - The Bureau of Preparedness and Response (BPR) could be a good source of getting these people involved at the beginning of the exercise.

In the Exercise, we had the CHD Epi involvement with food sample collection, P&S, etc. Actually, the Environmental Health people would have this responsibility. It would have to be an overwhelming event, such as a BT incident, for the CHD Epi to get involved with specimen/sample management. At our CHD we do have an Epidemiology Response Team which is virtual and composed of volunteers from the CHD who have Epi training. We used this team during the 2009 H1N1 epidemic.

5. What would you do different next time?

No Comments

6. What activities would you like to see added to the exercise (e.g. ICS, more partner agencies, etc.)?

No Comments

(General comments for Hot Wash)

The Exercise was a good chance to show what the Epi role would be. We were able to keep our group updated on the progress of the Exercise on our Monday "Surveillance" Meeting.

As a positive remark, the hospital participation was very committed. Our Epi called to consult during the Exercise and we had a good discussion of status, etc.

Our CHD Epi did not receive report on BT samples but did receive the CT report.

[Moderator] – This might have been due to an extenuating circumstance for your region. One of the regional BOL had a "real world event" which temporarily took them out of play.

[Sent in by email]
I wanted to thank you for the opportunity to participate. I am happy to participate in future events as well. It was good to see the steps involved and what role we may or may not play in this situation.

I will say, that there seemed to be some confusion on the first day. I was getting your SIMCEL notices before what would have been the original notifications from the regional epi. When I called the poison center, their response was that they had already been notified. I had to ask her to go over what had been reported and gave her new information from me. The poison center also contacted the [non-participating] CHD which I think confused them greatly since they weren't participating in the exercise. About 3pm on the first day I got a call from two surveillance epi's to see if they should be concerned with their ESSENCE data because they saw the 6 cases related to the exercise. I know [hospital X] wanted to participate, but it may have been helpful to have tweaked that part a little bit. All in all, I thought it was good experience.

APPENDIX D: EXERCISE EVENTS SUMMARY TABLE

Table D.1: Exercise Major Events Summary

Date	Time	Simulated Inject or Player Action	Event/Action
2/6/2012	10:00 AM	Player Action	Patient spiked specimens are staged at the hospital laboratories for the Exercise.
2/12/2012	8:00 AM	Simulated Inject	The Big Moose Lodge holds their annual Fund Drive and Fair over the weekend.
2/12/2012	8:00 PM	Simulated Inject	Patients have been presenting to local hospitals with symptoms of of nausea, vomiting, diarrhea, and weakness with bloody diarrhea and abdominal pain.
2/13/2012	8:00 AM	Simulated Inject	**Exercise Play Begins**
2/13/2012	8:00 AM	Player Action	ESSENCE NVD alert triggered within 24 hours
2/13/2012	8:10 AM	Player Action	The Hospital calls the Poison Information Center regarding unusual outbreak with multiple patients.
2/13/2012	8:20 AM	Player Action	The Food and Waterborne Disease Program Epidemiology is notified by the Poison Information Center of an unusual foodborne outbreak with multiple patients.
2/13/2012	8:40 AM	Simulated Inject	Simulated epidemiology investigation.
2/13/2012	9:30 AM	Simulated Inject	The SIMCELL will mimic an EpiCom message for external partners who are not part of FDENS.
2/13/2012	10:00 AM	Player Action	Hospitals package and ship patient specimens to regional BOL.
2/13/2012	12:00 PM	Player Action	BOL begins receiving Patient spiked specimens received from hospital laboratories.
2/14/2012	8:00 AM	Simulated Inject	**Exercise Day 2**
2/14/2012	10:00 AM	Player Action	Patient spiked specimens are sent to the Jacksonville BOL by commercial carrier (FedEx). The Jacksonville BOL is notified to expect the delivery of patient specimens.
2/15/2012	8:00 AM	Simulated Inject	**Exercise Day 3**

Date	Time	Simulated Inject or Player Action	Event/Action
2/15/2012	8:15 AM	Simulated Inject	The newspaper receives a manifesto letter from the Concerned Citizens for the Constitution.
2/15/2012	8:15 AM	Simulated Inject	Law Enforcement contacts the FBI regarding the manifesto letter from the CCC.
2/15/2012	8:15 AM	Player Action	FBI contacts the Florida Fusion Center regarding the manifesto letter.
2/15/2012	9:30 AM	Simulated Inject	Epidemiological investigation traces foodborne outbreak back to Big Moose Lodge.
2/15/2012	10:00 AM	Player Action	Consultation Call with all agencies.
2/15/2012	11:00 AM	Simulated Inject	Health Alert Network (HAN) Message is coordinated with the JIC.
2/15/2012	11:30 PM	Player Action	CHDs package and ship psuedo suspected food samples to the BOL.
2/16/2012	8:00 AM	Simulated Inject	**Exercise Day 4**
2/16/2012	9:00 AM	Player Action	BOL BT reports results for ricin in suspected food samples.
2/17/2012	8:00 AM	Simulated Inject	**Exercise Day 5**
2/17/2012	10:00 AM	Player Action	BOL CT Level 1 laboratory reports results of CT analysis.
2/17/2012	3:00 PM	Simulated Inject	**Exercise Ends**

APPENDIX E: ACRONYMS

Acronym	Meaning
AAR/IP	After Action Report/Improvement Plan
CDC	Centers for Disease Prevention and Control
CDC EOC	CDC Emergency Operation Center
CERT	Chemical Emergency Response Team
CT	Chemical Threat
CTLC	Chemical Threat Laboratory Coordinator
DBX	Discussion Based Exercise
DHS	U.S. Department of Homeland Security
DMAT	Disaster Medical Assistance Team
EMS	Emergency Medical Services
EMT	Emergency Medical Technician
EOC	Emergency Operation Center
EPA	Environmental Protection Agency
ESSENCE	Electronic Surveillance System for the Early Notification of Community Based Epidemics
ExPlan	Exercise Plan
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FDENS	Florida Department of Health Emergency Notification System
FERN	Food Emergency Response Network
FSE	Full Scale Exercise
FE	Full Scale Exercise
HazMat	Hazardous Materials
HSEEP	Homeland Security Exercise and Evaluation Program
ICS	Incident Command System
JIC	Joint Information Center
LRN	Laboratory Response Network
LRN-C	Laboratory Response Network Chemical laboratory
MOU	Memorandum of Understanding
MSEL	Master Scenario Events List
NIMS	National Incident Management System
PIC	Poison Information Center
PIO	Public Information Officer
SitMan	Situation Manual
SME	Subject Matter Expert
SOP	Standard Operating Procedure
SPHL	State Public Health Laboratory
TCL	Target Capabilities List

Attachment D – After Action Report Template

- Attachment D-1: Guidelines for a Formal After Action Review
- Attachment D-2: After Action Review Process Steps, S. Agona Outline
- Attachment D-3: Mad Minute AAR Template
- Attachment D-4: MN RRT Hotwash Template
- Attachment D-5: USAID After-Action Review Technical Guidance

GUIDELINES FOR A FORMAL AFTER ACTION REVIEW

Purpose:
An AAR is a structured review process that allows participants to discover for themselves what happened, why it happened, and how it can improved. An AAR is not a critique; the objective is not to determine the success or failure of a response.

Session Outcome:
To document the lessons learned from the AAR so the improvements can be institutionalized.

Who should be involved in the AAR
All (or a representative group of) participants involved in the incident being discussed. All viewpoints are relevant and beneficial. It is important to consider the different perspectives that event organizers may have from the actual participants.

How to conduct the AAR
- Decide ahead of time:
  - Who will facilitate the session? The facilitator of the session should be neutral and work to ensure all viewpoints are expressed. (For the purposes of this document the term facilitator will refer to the leader of the session.)
  - What supplies will be needed?
    - flipchart, storyboard, handouts.....
- A neutral facilitator focuses the discussion and works to ensure participation. The facilitator does not critique nor judge the success or failure of the incident being discussed.
- Keep the review focused and concise. Discourage debates and excuses.
- Encourage participation from all participants.
- Let the participants identify the situation for themselves (including their mistakes and successes), the facilitator/leader does not critique.
- To encourage participation the facilitator should use leading questions such as:
  - "What were the steps involved?"
  - "In your opinion, what would have been the ideal way of doing that?"
  - "How could communication have been better"
  - "Next time what would you do differently"
  - "What are some ways we could have prevented the incident from occurring "
- Try starting the session by making a storyboard flowchart of the event. In this phase, seek to establish a common understanding of what happened and the order in which the events took place. Do not analyze the event for what should have occurred, merely document WHAT ACTUALLY OCCURRED.
  - After the flowchart is made, analyze the flowchart for improvement opportunities. Ask questions such as,
    - Were the proper individuals notified in a timely fashion?
    - Did all participants in the event have a clear understanding of their roles?
    - Is there a more effective way to communicate?
    - Are there any procedures which are unnecessarily burdensome?
    - How would the ideal flowchart differ?
    - What safeguards can be put into the system?
    - Are there any redundancies?
    - Are there any steps that could have been prevented by doing a prior step correctly?
    - Were the proper resources readily available?

Formal After Action Review Form

AAR for:

Facilitator/Leader

Date: Location:

Start Time: End Time:

Key Lessons Learned From AAR

What should be done differently? What should we continue to do? What policy changes should be made? What does the AAR group recommend?

Action Item List

Assign Action Items for the implementation of the lessons learned.

Person	Task	Deadline

GUIDELINES FOR AN INFORMAL AFTER ACTION REVIEW

Purpose:
An informal AAR is much less structured than a formal AAR. An informal AAR is simply a review of the weeks activities and a discussion of improvement ideas between you and your staff. The purposes include:

- To allow your staff input on how to improve the effectiveness of your operation.
- To help the department take meaningful actions that are ground level specific so the employees can see improvements occurring within their own area.
- To generate improvement actions that will be monitored for completion.

Time Commitment:
The time to conduct an AAR will vary week to week but, on average should take between 10-20 minutes.

Session Outcome:
The ideas gathered during the review should be captured and actions should be generated on improving your area.

Who should be involved in the AAR
Informal AARs should be conducted at every PFD level. Every manager and supervisor should hold an informal AAR with their direct reports.

Frequency of informal AARs
Ideally, each work week would conclude with an AAR. Informal AARs should be held on a regular basis. At the least, an informal AAR with your staff should be held monthly.

How to conduct an informal AAR
An AAR can done at the end of regular staff meetings. The ideas generated should be captured to enable them to be prioritized and acted upon. Some of the key questions to ask are:

- What went well this week? How can we institutionalize the success?
- What went poorly this week? How can we ensure it doesn't happen again?

Some different methods for capturing the ideas are:

- On flipcharts
  A) Use a happy face (for things that went well) and a sad face (for things that went poorly). *Refer to figure 1*
  B) Writing the ideas under appropriate titles *Refer to figure 2*
- Using storyboard cards.

Figure 1

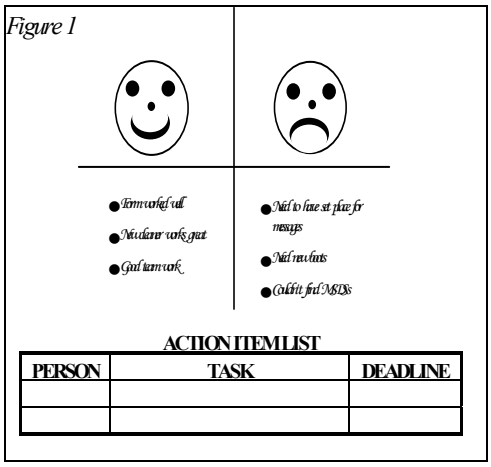
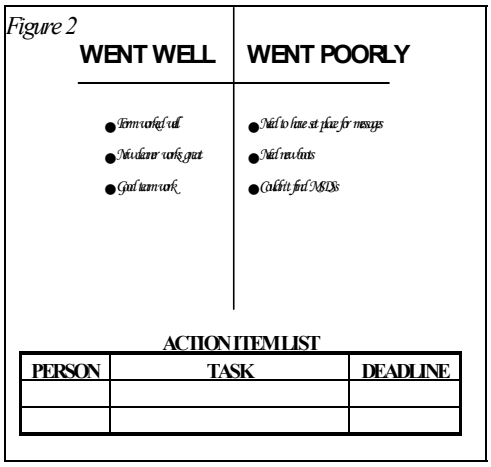


Figure 2



Some tips to make your AAR go more smoothly:

- Keep the review focused and concise. Discourage debates and excuses.
- Encourage participation from all participants.
- Let the participants identify the weeks events for themselves (including mistakes and successes), the facilitator/leader does not critique.
- To encourage participation, the session leader can use leading questions such as:
  - How could we have worked smarter this week?
  - What were some opportunities to increase communication this week?
  - How was our teamwork?
  - Are there any procedures which are unnecessarily burdensome?
  - Were the proper resources readily available?

Capturing action items

The purpose an AAR is to generate ideas for action. These actions must be identified and then monitored until completion. The following format can be effective in keeping track of assigned actions.

Action Item List

Person	Task	Deadline

After Action Review Process Steps

Use the following questions to facilitate the AAR process:

1. What did we set out to do?
   - Establish the facts
   - Determine purpose of the mission and definition of success:

This is a broad outline of the objectives of the Salmonella Agona Texas RRT

The RRT was officially stood up on 6/23/11.
There were two main goals initially:

   a. ***Obtain source records from identified distribution centers.***
   b. ***Contact other RRT states involved in the outbreak for additional information (WA, CA, IL).***

Based upon the findings from the distribution centers the investigation focus changed to:

   c. ***Sample (environmental and product) at 3 locations in Alamo Texas. and Hidalgo Texas (Fresh Tex, Tex Star Distributors, and Agromod. This was accomplished using Two sampling teams comprised of FDA & DSHS.***
   d. ***Review invoices from Mexican firms to look for any commonalities of farm supplier to U.S. distributors.***
   e. ***Request recall of papayas from Agromod.***

On Wednesday 7/27/2011, the Command Staff met and officially deactivated the RRT.

   - Specify conditions under which each task may need to be performed (weather, topography, time restrictions, etc.)
   - Define acceptable standards for success (explain what "right" looks like)

2. What actually happened?
   - Continue to establish the facts.
     - Participants should come to agreement on what actually happened.
     - Pool multiple perspectives to build a shared picture of what happened

3. Why did it happen?
   - Analyze cause and effect
     - Focus on WHAT not WHO
     - Provide progressive refinement for drawing out explanations of what occurred. This will lead into developing possible solutions.

4. What are you going to do better next time?
   - Solutions will arise naturally once problems are identified and understood.
     - Focus on items you can fix, rather than external forces outside your control.
     - Identify areas where groups are performing well and that should be sustained.
       - Areas to Sustain/Maintain Strengths:

<u>After Action Review Process Steps</u>

- Areas to Improve Weaknesses:

5. What are the lessons learned?
   - Identify the process for sharing lessons learned.
   - Determine and describe the most notable successes from the incident.
   - Determine and describe the most difficult challenges faced and how they were overcome.

6. What followup is needed?
   - Be specific about actions, timelines, and responsibilities.
     - What changes, additions, or deletions are recommended to SOP's, plans or training?
     - What issues were not resolved to your satisfaction and need further review?

Discussion Draft: April 13, 2011

After Action Report Template

Incident Title: _____
Incident Date(s):_____
Report Date: _____
Participants: _____

Ground Rules (Review as needed)
The facilitator reviews ground rules at the onset of an AAR

- All participants have equal status
- Plain speaking is essential
- Tact and civility are required
- This is a "No-Fault" evaluation. Focus on "what" and not "who". Avoid finding fault or assigning blame. During the discussion, mistakes are not held against those who admit them. However, this does not grant immunity outside of the AAR for malfeasance or gross negligence.
- Discussion details stay "in house". Relevant information from lessons learned will be incorporated into the after action report.

Executive Summary Key Points - Address what was planned vs. what actually happened

-

Incident Timeline of key dates and events (if available)

-

Areas That Worked Well

-

Suggestions For Further Improvements

-

Other comments

-

Name of Incident/Facility

HOT WASH
Date

Attendance:
Minnesota Department of Agriculture:

FDA MPLS District Office:

Facilitator/Note Taker:

Reason/Purpose for HOT WASH:

- To discuss value of MDA and FDA staff experiences regarding the Rapid Response Team (RRT) involved with a just concluded response activity
- What Worked, what didn't work
- What can be changed/improved upon

Specific areas to be discussed include:

1) Communication/Information sharing
2) Use of ICS structure during an investigation
3) Epidemiological Investigation
4) Traceback
5) Field Investigation (mulitiple firms?)
6) Sample Collection and Submission
7) Laboratory Analysis/Reporting
8)

Outcomes:

- Lessons Learned – Knowledge and experience, positive or negative, derived from actual incidents as well as from observations and historical study of operations, training and exercises
- Best Practices Identified – Exemplary, peer-validated techniques, procedures, good ideas, or solutions that work and are solidly grounded in actual operations, training, and exercise experience.

Name of Incident/Facility

HOT WASH
Date
Improvement Plan

This improvement plan has been developed specifically for the MN RRT as a result of the [name of incident] in [date of incident].

Tasks	Recommendations	Improvement Recommendations	Responsible Party/Agency	Completion Date

USAID
FROM THE AMERICAN PEOPLE

AFTER-ACTION REVIEW
TECHNICAL GUIDANCE

February 2006

PN-ADF-360

Contents

Foreword

As USAID works to achieve its development mission, learning from experience is essential. The After-Action Review (AAR) is a leadership and knowledge sharing tool that helps professionals within USAID and across the partner community to better understand important events, activities, or programs. That knowledge, gleaned from and compiled by those closest to the review, can be used by senior leadership to improve results and then can be shared with others who are planning, developing, implementing, and evaluating similar efforts. Managed and conducted by those closest to the activity, AARs identify how to correct deficiencies, sustain strengths, and focus on improved performance of specific tasks, activities, events, or programs.

It is essential that USAID understands the benefits of the AAR tool. When administered in a climate of openness, honest discussion, clarity, and commitment to identifying and recommending solutions, the AAR can yield many benefits. The participants in the review—managers, leaders, and those planning to pursue similar activities in the future—will understand better what was originally intended, what actually happened, what went well and why, and what can be improved and how. Furthermore, the AAR report makes concrete and actionable recommendations for changes and improvements that will impact future success in carrying out this task or similar activities.

This handbook—the USAID guide on how to plan, prepare, and conduct an AAR—was developed by USAID Knowledge for Development (KfD) using the United States Army's TC (Technical Circular) 25-20 as a guide. The Army developed the concept of AARs as an essential training methodology for soldiers in preparing for both combat duty and ongoing programs such as peacekeeping.

As the USAID Knowledge for Development leader, I take great pride in presenting the USAID AAR Technical Guidance. I can personally attest to the usefulness and strength of the After Action Review based on my 21 years of service in the U.S. Army. I benefited from AARs throughout my

former career and continue to benefit from its use in meeting my responsibilities within USAID.

The KfD team trusts this guidance will be helpful to you as you conduct your own AARs. We encourage your feedback on this guidance and look forward to your suggestions. Please feel free to contact the team at KfD@usaid.gov.

Susan Camarena Wallace
Chair, Knowledge for Development Subcommittee
Business Transformation Executive Committee

CHAPTER 1

The After-Action Review

DEFINITION AND PURPOSE

An after-action review (AAR) is a professional discussion of an event, that focuses on performance standards and enables development professionals and colleagues with similar or shared interests to discover for themselves what happened, why it happened, and how to sustain strengths and improve on weaknesses. The AAR tool affords leaders, staff, and partners an opportunity to gain maximum benefit from every program, activity, or task. It provides:

- Candid insights into specific strengths and weaknesses from various perspectives
- Feedback and insight critical to improved performance
- Details often lacking in evaluation reports alone

The AAR is the basis for learning from our successes and failures. A good manager or leader does not learn in a vacuum: the people involved in an activity—those closest to it—are the ones best poised to identify the learning it offers. No one, regardless of how skilled or experienced they are, will see as much as those who actually carry out the events, program, or activity. The AAR is the keystone of the process of learning from successes and failures.

Feedback compares the actual output of a process with the intended outcome. By focusing on the desired outcome and by describing specific observations, teams can identify strengths and weaknesses and together decide how to improve performance. This shared learning improves team proficiency and promotes bonding, collegiality, and group cohesion. Though not a cure-all for all issues or problems, the AAR provides a starting point for improvements to future activities.

Because AAR participants actively discover what happened and why, they can learn and remember more than they would from a critique or more

formal evaluation. A critique only gives one viewpoint and frequently provides little opportunity for discussion of events by participants. Other observations and comments may not be encouraged. The climate of a critique, focusing on what is wrong, often prevents candid discussion and stifles opportunities for learning and team building.

Refer to Appendix A for a slide that can be used to talk about what the AAR is, is not, and its effectiveness.

TYPES OF AARs

All AARs follow the same general format, involve the exchange of ideas and observations, and focus on improving training proficiency. AAR organizers can decide whether the review will be formal or informal. See Appendix B for a review of key features.

Formal AARs require more resources and involve more detailed planning, coordination, logistical support, supplies, and time for facilitation and report preparation. A facilitator guides the review discussion, and notes are recorded on flip charts with the help of a dedicated scribe. The meeting should follow an agenda, using the four guiding questions to set up the "meat" of the discussion. Following the AAR session itself, a formal report is presented. Recommendations and actionable items are later brought to the attention of Agency management.

Informal AARs are usually conducted on-site immediately following an event, activity, or program. They require a different level of preparation, planning, time to be carried out, facilitation, and reporting. Frequently, an informal AAR is carried out by those responsible for the activity, and if necessary, the discussion leader or facilitator can either be identified beforehand or chosen by the team itself. As with a formal AAR, the standard format and questions guide the discussion.

Team or project leaders may use informal AARs as on-the-spot coaching tools while reviewing overall group or individual performance. For example, the team could quickly

- Evaluate performance against a desired standard or established performance objective

- Identify strengths and weaknesses
- Decide how to improve performance

In addition, informal AARs provide instant feedback: ideas and solutions can be immediately put to use, and the team can learn from them for future or similar application. Providing direct feedback, just in time, is a key strength of the informal AAR.

PLANNING AND CARRYING OUT THE AAR

The date and time of the AAR should be identified as part of the planning schedule for the event. It is imperative that the AAR be considered as an integral part of the entire planning process.

The AAR process has four steps:

- Step 1. Planning the AAR
- Step 2. Preparing for the AAR
- Step 3. Conducting the AAR
- Step 4. Following up (using the AAR results)

Refer to Chapters 2 through 5 for more details about these four steps. The following chart summarizes the actions leaders should follow to ensure effective AARs.

The AAR Process

Planning the AAR

- Identify an event or activity to be reviewed
- Identify the primary point of contact for the review
- Determine when the AAR will occur
- Decide who will attend the AAR
- Select when and where the AAR will take place (plan for no more than 90 minutes)
- Confirm who will support the AAR (technical lead, champion, point of contact, scribe)

Preparing for the AAR

- Select a facilitator
- Confirm the venue and agenda
- Obtain input from interested parties
- Announce the AAR and compile list of attendees
- Make logistical arrangements and set up the venue

Conducting the AAR

- Seek maximum participation
- Maintain focus on a positive and informative AAR
- Ensure honest, candid, and professional dialogue
- Record key points

Following up (using the AAR results)

- Determine actionable recommendations that will improve the process
- Identify tasks requiring senior leadership decisions
- Determine a follow up schedule and point of contact for each follow-up action
- Provide assistance and support as required

Notes:

CHAPTER 2

Planning the After-Action Review

IDENTIFY THE EVENT OR ACTIVITY TO BE REVIEWED

Leadership, or others invested in the sustainability of an event, activity, or process, decides on the topic of the review. The scope and substance of the review can be large-scale or far-reaching, or it can be relatively specific or narrow.

The review may focus on substantive issues: problems being solved, opportunities or challenges that were addressed, a concrete product, or a discrete event or activity. Or the review may focus on process: support, logistics, technology, etc. Regardless of what is decided for the AAR topic's scope, boundaries, and specific content, it is critical to be clear about those parameters so that all review participants, as well as individuals who will read and be affected by the report, understand what is covered.

IDENTIFY PRIMARY POINT OF CONTACT FOR REVIEW

It is important to identify the single Point of Contact (POC) for each review. The POC is someone with a vested interest in completing the review. In addition, the POC should have broad and sufficient access to the necessary people, resources, leadership, ideas, and additional input needed to carry out the review. The POC ensures that notes are captured from the review discussion and that the report is prepared and submitted. Finally, the POC takes responsibility for any required next steps identified in the report or as implied by its production. These could include follow-on actions, securing broader visibility for the report, and addressing any related actionable recommendations.

DETERMINE WHO WILL ATTEND

The team, project, or activity leader specifies who must attend each AAR. Normally, only key players attend. At times, however, more participants

will yield better or more complete feedback. Leaders must select as many participants as appropriate for the task and the overall conduct of the AAR. In some cases, it might be useful to identify a representative from a particular group, point of view, or interest area to provide additional input into the reviews. A separate discussion can be held beforehand, and one of the key players can "represent" the relevant AAR feedback in the actual AAR session. Or, if appropriate, one or two additional participants can attend the session.

DETERMINE WHEN THE AAR WILL OCCUR

The AAR should occur as soon as possible after an event, and when possible within the first two weeks. Participants will receive better feedback on the overall performance and remember the lessons longer if the AAR is timely and the conduct of the AAR is not rushed. The AAR should last no longer than 90 minutes.

SELECT AN AAR LOCATION

When feasible, the AAR location should be accessible to all participants, well supplied with materials for the AAR, and readily available in case of schedule changes.

CONFIRM WHO WILL SUPPORT THE AAR

The purpose of the AAR is to give management and the team closest to an event, process, or activity the best opportunity to sustain successes and introduce necessary improvements and changes. It is important to enlist key leader support early and keep participants interested, involved, and informed throughout the AAR process. This leadership presence and engagement signals that there is an organizational champion who supports the AAR process and understands its contributions to increased learning, knowledge-sharing, sustainability of success, and change.

Determine the other aspects of support. Identify the event or activity's technical lead, champion, organizational point of contact, and the scribe and/or report writer.

CHAPTER 3

Preparing for the After-Action Review

After the AAR topic has been confirmed, details regarding its conduct should be reviewed. (For a concise list of planning and preparation steps, refer to Appendix C, Checklist for Planning and Holding an After-Action Review). Arranging for facilitation and handling all logistical support should be done by the "owner" of the AAR—the organization or office being reviewed.

FACILITATION

When an outside facilitator is used (normally during the formal AAR), it is important to identify someone who is able to focus and guide the review discussion. While the AAR facilitator should maintain objectivity throughout the review, it may be useful to enlist someone who is somewhat knowledgeable about the subject or topic of the review. That would minimize the learning curve and enable technical discussions to be carried out and recorded clearly. If the team decides to conduct an AAR under its own leadership, the team leader must ensure that all background materials are considered—reports, surveys, planning documents or other input. This will yield an AAR that is complete, thorough, and appropriate.

CONFIRM THE VENUE AND AGENDA

The activity's logistical support staff should make final arrangements for the venue. This includes developing plans or instructions for room set-up, supplies, and any supporting documents and historical materials. The facilitator should finalize the agenda and copy it for distribution to the participants. If needed, flip charts can be prepared, to keep discussion moving swiftly and smoothly and to support notes being captured by the scribe and/or person responsible for the report.

OBTAIN INPUT FROM INTERESTED PARTIES

In many cases, an event, activity, or program attracts interest or engagement from others beyond those comprising the immediate or core team. For example, customers, stakeholders, or others engaged in similar or related activities or programs might be able to offer interesting ideas and recommendations that would be of value to the review process and the AAR report. The facilitator determines whether and how to represent that input for the actual AAR. Before the review session, the facilitator or a designated team member should consult with these outside representatives and then summarize the input for the AAR.

The topic leader should determine whether and how to represent that input in the AAR. It might be useful to identify a representative from a particular group, point of view, or interest area and invite that individual to attend the review session. Selected or relevant observations, ideas, and recommendations could be conveyed to a member of the core group, who would bring them into the AAR discussion when and as appropriate. Additionally, it might be more appropriate to collect this feedback during a separate session, to be carried out later.

SEND ANNOUNCEMENT AND COMPILE ATTENDEE LIST

It is important to know who will be attending the AAR session. Collecting RSVPs ensures that the commitment is being taken seriously by both leadership and those closest to the event, activity, or program. In addition, the leader or organizational point of contact for the review should confirm that a scribe/recorder will attend and that there is clear understanding of what the review notes and the report should include.

MAKE LOGISTICAL ARRANGEMENTS AND SET UP VENUE

See Appendix D for suggested checklist showing the logistical support needed prior to, during, and after an AAR.

CHAPTER 4

Conducting the After-Action Review

INTRODUCTION AND GROUND RULES

The event, activity, or program is completed, AAR preparation is complete, and the key players are at the designated AAR site. It is now time to conduct the AAR.

Each AAR can be opened in a variety of ways. One proven method is to begin the session with an "attention getter"— a joke, an appropriate anecdote, or an example that illustrates the AAR process itself.

Then, the AAR facilitator should review the purpose and sequence of the AAR to ensure that everyone understands what an AAR is and how it works. The introduction should also include some ground rules for conducting and managing the discussion and notes on the role of the facilitator. (See Appendix E for sample ground rules and the role of the facilitator.)

The substantive introduction to the AAR itself should include the following:

- An AAR is a dynamic, candid, professional discussion of the event, activity, or program itself. Everyone can, and should, participate if they have an insight, observation, or question that will help identify and correct deficiencies or maintain strengths.
- An AAR is not a critique or a complaint session. No one, regardless of rank, position, or strength of personality has all of the information or answers. AARs maximize learning by offering a venue for staff and leadership to talk frankly about a topic, produce a report, and better understand how to carry out similar events, activities, or programs in the future.
- An AAR is not a full-scale evaluation or evaluation report. That is, an AAR does not grade success or failure. There are always weaknesses

to improve, strengths to sustain, and opportunities to learn from experience.

- An AAR answers four major questions:
  - What was expected to happen?
  - What actually occurred?
  - What went well, and why?
  - What can be improved, and how?

FACILITATION OF THE AAR

The AAR facilitator should make a concerted effort to draw in and include all participants in the AAR session. A sample agenda for the AAR is included in Appendix F to help structure the discussion. The following techniques can help create an atmosphere that invites and is conducive to maximum participation. The facilitator should:

- Reinforce the fact that it is permissible to disagree
- Focus on learning
- Encourage people to give honest opinions
- Use open-ended questions to guide the discussion
- Paraphrase, re-state, and summarize key discussion points
- Invite input from an activity or program's leadership, to establish context, set discussion parameters (if any), and introduce or reinforce the way ahead

WHAT DID WE INTEND TO DO?

The facilitator can open the discussion by beginning with a big-picture question, such as "Looking broadly at this event/activity/program, how would you describe it, in one sentence?" This will help frame the introduction or background that goes into the report's opening paragraph.

Then the AAR facilitator should ask the participants to talk, in complete detail, about what was intended or envisioned. What was the purpose and objectives? Who was the audience? What was the timing? Who was involved? What outcomes and outputs were intended? What products were to be produced? What were the guidance and standards for those engaged in this event, activity, or program? What were the underlying conditions or issues of context or environment?

The facilitator and/or the recorder/scribe should take notes on all that was discussed. Flip charts are a convenient tool to make these notes visible for all participating in the review and better ensure a common understanding of and agreement to what is said.

WHAT ACTUALLY HAPPENED?

The AAR facilitator now guides the review using a logical sequence of events to describe and discuss what happened. He/she should not ask yes or no questions, but encourage participation and guide discussion by using open-ended and leading questions. An open-ended question has no specific answer and allows the participants to reply based on what they perceived as significant. Open-ended questions are less likely to put participants on the defensive. For example, it is better to ask,

"How did you think the townspeople would respond to your request?"
—rather than—
"Why did you ask the townspeople that question?"

As the discussion expands and more participants add their perspectives, what really happened will become clear. Remember, this is not a critique or lecture; the facilitator does not tell the participants what was good or bad. However, the discussion should ensure that specific issues are revealed, both positive and negative in nature. Skillful facilitation will ensure the AAR does not gloss over mistakes or weaknesses.

DISCUSSION OF KEY ISSUES

What went well and why, and what can be improved and how?

The AAR is a problem-solving process. The purpose of discussion is for participants to discover strengths and weaknesses, propose solutions, and adopt a course of action to correct problems. Leaders can guide the discussion using one of the three techniques described below.

DISCUSSION TECHNIQUES

Chronological Order of Events

This technique is logical, structured, and easy to understand. It follows the flow of the activity from start to finish. By covering actions in the order they took place, participants are better able to recall what happened.

Key Events, Themes, or Issues

A key events discussion focuses on critical events which directly support identified objectives before the event began. Keeping a tight focus on these events prevents the discussion from becoming sidetracked by issues which do not relate to the desired objectives. This technique is particularly effective when time is limited.

Optional Discussion Guide

When relevant or useful, the AAR facilitator can employ a blended discussion technique that draws from elements of a chronological or thematic review. In addition, it may be helpful to collect information by:

- Drilling further into the process or resources behind an event or set of events
- Asking participants to identify unexpected results and discuss their impact on the review topic(s)
- Collecting data through complementary or more detailed review methods (evaluations, studies, statistics, etc.)

FLEXIBILITY

One of the strengths of the AAR format is its flexibility. The facilitator can use a chronological format to structure the discussion, or the discussion can be organized around key events, themes, or issues. Process items (logistics, management, administration, and support) can be discussed separately or woven into the substantive discussion. Each technique will generate discussion and will identify strengths and successes, weaknesses and areas for improvement; and concrete, actionable recommendations. The AAR facilitator must remember to:

- Be specific; avoid generalizations
- Be thorough, covering all relevant aspects of the program or event
- Focus on issues related to the activity's purpose or objective
- Guide participants toward identifying corrective actions and solutions to address areas of weakness
- Summarize often
- Introduce the way ahead

CLOSING COMMENTS (SUMMARY)

To close the AAR session, the facilitator should review and summarize key points identified during the discussion. The session should end on a positive note, linking observations to recommendation for future improvement. The program, activity, or task leader can offer concluding remarks, reinforce plans and an outline for the AAR report, and introduce the way ahead.

PREPARING THE REPORT

Having completed the AAR, the report should be prepared by a participant in the session and structured along the lines of the session itself. For a suggested report outline, see Appendix G.

CHAPTER 5

Following Up: Using the Results of the After-Action Review

BENEFITS

The benefits of an AAR come from applying its results to future situations. AARs provide a dynamic link between carrying out a task and striving for excellent performance. They provide USAID management and leaders a critical tool to use when planning and implementing events, activities, or programs. Through a professional, candid, and complete review discussion, managers and staff can compare their performance against a standard and identify specific ways to improve future activities. By identifying actionable recommendations, the AAR defines necessary steps for improving the process for accomplishing a task or project.

OPPORTUNITIES TO REINFORCE LEARNING AND KNOWLEDGE SHARING

By applying its learning, a team can improve and perform to Agency standards. Remembering that the focus is to improve performance, by the end of an AAR, participants must clearly understand what worked well and why, what did not go well, and where improvements can take place.

The AAR is one aspect of the complete learning cycle and identifies the steps of "learn-before, learn-during, and learn-after." Each phase offers an important learning opportunity. Understanding that learning takes place ***after*** an event or activity is completed, and also ***before*** and ***during*** its conduct, USAID is well aware of the range of potential learning opportunities. "Learning during" allows room for immediately recognizing and correcting performance that is not up to standard. These on-the-spot course corrections are valuable, whether dealing at the small-scale or detailed level or addressing larger or broader issues, challenges, or opportunities.

The ***peer assist***—an opportunity to learn before or during an event—targets a specific technical or programmatic challenge; gains assistance and insight from people outside the team; identifies possible approaches and new lines of inquiry; promotes sharing of learning with each other; and develops strong networks among staff. It is important to hold a peer assist session early enough to make a difference.

As with the AAR, a peer assist is useful when:

- A team is about to respond to a crisis similar to one that another team dealt with earlier
- An individual, new to a role, is about to tackle something difficult and is aware that others have similar experience
- An individual has not done something for a while, so is not sure about how or whether processes, procedures, and other resources have progressed

REVISED PROCEDURES

An AAR may reveal problems with USAID's formal guidance and procedures. If so, leaders and managers must make revisions and ensure that they are communicated across the Agency and into the partner and inter-agency community when needed. This will assure that the changes are clearly understood and that they are able to be applied to support how USAID better accomplishes its development mission.

APPENDIX A

After-Action Review Key Points

The After-Action Review (AAR)

- Is a dynamic, candid, professional discussion
- Focuses on results of an event/task/activity
- Identifies how to sustain what was done well
- Identifies recommendations on how to improve shortfalls
- Requires everyone's participation to help identify and correct deficiencies or maintain strengths

The AAR is Not

- A critique or complaint session (everyone learns from each other)
- A full-scale evaluation (or evaluation report)
- A cure-all for all problems

The AAR is Effective When

- Leaders support it
- It is done immediately—by the team, for the team
- Participants agree to be honest

APPENDIX B

After-Action Review Key Features

Formal Reviews	Informal Reviews
• Are facilitated by an objective outsider • Take more time • Use more complex review techniques and tools • Are scheduled beforehand • Are conducted in meetings or other "formal" settings • Require a more standard and thorough report	• Are conducted by those closest to the activity • Take less time • Use simple review techniques and tools • Are conducted when needed • Are held at the event's site • Can be covered by a less comprehensive report

APPENDIX C

Checklist for Planning and Conducting an After-Action Review (AAR)

☐ Decide on what event or process to cover in the AAR

☐ Perform any research necessary

☐ Identify a facilitator or facilitators

☐ Consult with the facilitator or facilitators on the remaining steps

☐ Decide who should participate and set up the list

☐ Draft the agenda

☐ Identify and confirm the venue(s)

☐ Obtain input from interested parties

☐ Send announcements for the AAR, including RSVPs

☐ Make logistical arrangements for AAR meeting (see separate checklist)

☐ Confirm final attendee list

☐ Set up venue(s) (see separate checklist)

☐ Conduct AAR

☐ Draft AAR notes and action plan

☐ Circulate notes and action plan for comments

☐ Complete action plan

☐ Plan AAR wrap-up session

☐ Hold AAR wrap-up sesssion

APPENDIX D

Logistical Arrangements and Setup Checklist for an After-Action Review

I. Logistics Arrangements in Preparation for the AAR

☐ When your AAR has been confirmed, reserve a conference room.

☐ Send an email invitation with RSVP.

☐ Send an email reminder before the AAR one day before the event.

☐ Check with the facilitator regarding any special needs.

☐ Make adequate copies of handouts.

☐ Make a sign-in sheet.

☐ Locate supplies. Are they provided by the venue? If not, requisition/purchase supplies. (See below.)

II. Setting up the AAR

Plan to arrive at least 20 minutes early.

Bring:

☐ Sign-in sheet

☐ Handouts

Also bring supplies or ascertain that supplies are available in venue.

Necessary:

☐ Flip chart stands

☐ Flip chart paper

☐ Facilitator tape

☐ Flip chart markers (more than one color)

☐ Pens

☐ Pencils

☐ Pads of paper

☐ Laptop for taking notes

☐ Stickies

If necessary:

☐ Overhead projector

☐ TV and VCR

☐ Laptop for projector

☐ LCD projector

☐ Other:_____

☐ Other:_____

Physical set up:

☐ Check to make sure there are enough chairs for everyone.

☐ Check lighting.

☐ Check ventilation.

☐ Check location of restrooms.

☐ Check amenities.

☐ Set up flip charts with paper.

☐ Put flip chart markers and tape near flip charts.

☐ Put out paper, pens, pencils, and handouts as facilitator directs.

☐ If in an unfamiliar building, check fire escape routes.

☐ Set up projector and laptop (if applicable).

☐ Set up laptop for note taking.

Notes:

III. After the AAR:

☐ Remove extra paper, pack up supplies, and pack up equipment.

☐ Take down and bring back flip charts if facilitator wants them. Otherwise, throw them away. Leave the room as you found it.

APPENDIX E

Sample Ground Rules and Role of the After-Action Review Facilitator

GROUND RULES FOR TODAY

- Active participation
- Equal representation (of ideas and perspectives)
- Creativity
- Openness to new ideas
- Critical thinking (about the topic or idea)
- "Yes … and"
- Consensus where possible
- Commitment to carry the results forward

ROLE OF THE FACILITATOR

- Keep group on task and on time
- Encourage participation by all
- Create an environment that supports expression of new ideas, original thinking, and recommended changes or solutions
- Introduce the way ahead

APPENDIX F

Sample After-Action Review Agenda

AGENDA FOR TODAY'S REVIEW

- Welcome, introduction, and context for this review
- Ground rules and role of facilitator
- What was intended?
- What actually happened?
- What went well, and why?
- What can be improved, and how?
- The way ahead: Closing comments and preparation for the report

APPENDIX G

After-Action Review Report Outline

Questions to Address in the AAR:

1) What did we intend (or plan) to do?

2) What actually happened?

3) What went well, and why?

4) What can be improved (and why/what would we change)?

Suggested Report Outline:

[Executive Summary—background, successes, unexpected results, recommendations

or

Executive Summary—background, successes, results, recommendations, management decisions required]

I. Background

II. What did we set out to do?

III. What actually happened?

IV. What went well, and why?

V. Issues and Recommendations

- Issue
- Discussion
- Recommendation

(repeated for each finding, as needed)

VI. Unexpected Results

VII. Conclusions

Appendices (names of team members, budget/actual costs, evaluation comments management or administrative tools, products, other documents and documentation)

Additional References

The USAID After-Action Review Technical Guidance draws heavily from a comprehensive training circular developed and issued by the U.S. Army. For more details and information about their process, see:

Training Circular 25-20, A Leader's Guide to After-action Reviews, Headquarters, Department of the Army, Washington, DC, September 1993, prepared by CALL, Fort Leavenworth, KS (last update: December 1998).

For context and a good overview of knowledge management, see also:

The Complete Idiot's Guide to Knowledge Management. Melissie Clemmons Rumizen, Ph.D., John A. Woods/CWL Publishing Enterprises, 2002.

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Attachment E – After Action Report Template Homeland Security Exercise and Evaluation Program (HSEEP)

- Attachment E-1: HSEEP Template
- Attachment E-2: Iowa HSEEP AAR Exercise Reporting Form

[Protective Marking]

Homeland Security Exercise and Evaluation Program (HSEEP)

After Action Report/Improvement Plan (AAR/IP) **[Full Exercise Name] [Exercise Name Continued]**

[Note for After Action Report/Improvement Plan (AAR/IP) Template:

- Text found in this document that is highlighted and bracketed is included to provide instruction or to indicate a location to input text.
- All text that is not highlighted is to be included in the final version of the AAR/IP.]

[FULL EXERCISE NAME]

[Exercise Dates]

AFTER ACTION REPORT / IMPROVEMENT PLAN

[Publication Date]

[On the cover page, insert additional graphics such as logos, pictures, and background colors as desired. The word "Draft" should be included before the phrase "After Action Report/Improvement Plan" on the cover page and in the header/footer of all versions except the final AAR/IP.]

[Protective Marking]

Homeland Security Exercise and Evaluation Program (HSEEP)

After Action Report/Improvement Plan (AAR/IP)

[Full Exercise Name]
[Exercise Name Continued]

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ADMINISTRATIVE HANDLING INSTRUCTIONS

1. The title of this document is [complete and formal title of document].

2. The information gathered in this AAR/IP is classified as [For Official Use Only (FOUO)] and should be handled as sensitive information not to be disclosed. This document should be safeguarded, handled, transmitted, and stored in accordance with appropriate security directives. Reproduction of this document, in whole or in part, without prior approval from [agency] is prohibited.

3. At a minimum, the attached materials will be disseminated only on a need-to-know basis and when unattended, will be stored in a locked container or area offering sufficient protection against theft, compromise, inadvertent access, and unauthorized disclosure.

4. Points of Contact: [List all points of contact below.]

   [Federal POC:]

   Name
   Title
   Agency
   Street Address
   City, State ZIP
   xxx-xxx-xxxx (office)
   xxx-xxx-xxxx (cell)
   e-mail

   [Exercise Director:]

   Name
   Title
   Agency
   Street Address
   City, State ZIP
   xxx-xxx-xxxx (office)
   xxx-xxx-xxxx (cell)
   e-mail

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CONTENTS

[If an AAR contains graphics, figures, or tables, they should be numbered and listed in the Contents section (e.g. Figure 1, Table 1, etc.).

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EXECUTIVE SUMMARY

[When writing the Executive Summary, keep in mind that this section may be the only part of the AAR/IP that some people will read. Introduce this section by stating the full name of the exercise and providing a brief overview of the exercise. This brief overview should discuss why the exercise was conducted; the exercise objectives; and what Target Capabilities List (TCL) capabilities, activities, and scenario(s) were used to achieve those objectives. All of these areas will be discussed in more detail in the subsequent chapters of the AAR/IP. In addition, the Executive Summary may be used to summarize any high-level observations that cut across multiple capabilities.]

The [agency or jurisdiction] [scenario type] [exercise type] exercise [exercise name] was developed to test [agency or jurisdiction]'s [Capability 1], [Capability 2], and [Capability 3] capabilities. The exercise planning team was composed of numerous and diverse agencies, including [list of agencies participating in planning team]. The exercise planning team discussed [include a brief overview of the major issues encountered, discussed, and resolved during the exercise planning process. Topics to address in this section could include the length of the planning process, the reasoning behind the planning team's choice of objectives to exercise, etc.]

Based on the exercise planning team's deliberations, the following objectives were developed for [exercise name]:

- Objective 1: [Insert 1 sentence description of the exercise objective]
- Objective 2: [Insert 1 sentence description of the exercise objective]
- Objective 3: [Insert 1 sentence description of the exercise objective]

The purpose of this report is to analyze exercise results, identify strengths to be maintained and built upon, identify potential areas for further improvement, and support development of corrective actions.

[In general, the major strengths and primary areas for improvement should be limited to three each to ensure the Executive Summary is high-level and concise.]

Major Strengths

The major strengths identified during this exercise are as follows:

- [Use complete sentences to describe each major strength.]
- [Additional major strength]
- [Additional major strength]

Primary Areas for Improvement

Throughout the exercise, several opportunities for improvement in [jurisdiction/organization name]'s ability to respond to the incident were identified. The primary areas for improvement,

including recommendations, are as follows:

- [Use complete sentences to state each primary area for improvement and its associated key recommendation(s).]
- [Additional key recommendation]
- [Additional key recommendation]

[End this section by describing the overall exercise as successful or unsuccessful, and briefly state the areas in which subsequent exercises conducted by these jurisdictions and/or organizations should focus.]

SECTION 1: EXERCISE OVERVIEW

[Information in the Exercise Overview should be "structured data"—written as a list rather than in paragraph form—in order to facilitate preparation of other parts of the AAR/IP, maintain consistency within AAR/IPs, and facilitate the analysis of AAR/IPs for program reporting.]

Exercise Details

Exercise Name

[Insert formal name of exercise, which should match the name in the header.]

Type of Exercise

[Insert the type of exercise as described in Homeland Security Exercise Evaluation Program Volume I (e.g. seminar, workshop, drill, game, tabletop, functional exercise, or full-scale exercise.]

Exercise Start Date

[Insert the month, day, and year that the exercise began.]

Exercise End Date

[Insert the month, day, and year that the exercise ended.]

Duration

[Insert the total length of the exercise, in day or hours, as appropriate.]

Location

[Insert all applicable information regarding the specific location of the exercise; including any city, State, Federal region, international country, or military installation.]

Sponsor

[Insert the name of the Federal agency or agencies that sponsored the exercise, as well as any co-sponsors if applicable. Also list any applicable points of contacts.]

Program

[Insert the name of the program (e.g. Fiscal Year 2007 State Homeland Security Grant Program) from which exercise funding originated.]

Mission

[Insert the appropriate mission areas of the exercise (e.g. Prevent, Protect, Response, and/or Recovery).]

Capabilities

[Insert a list of the target capabilities addressed within the exercise.]

Scenario Type

[Name the exercise scenario type (e.g. chemical release).]

Exercise Planning Team Leadership

[The name of each member of the planning team leadership should be listed along with their role in the exercise, organizational affiliation, job title, mailing address, phone number, and e-mail address.]

Participating Organizations

[Insert a list of the individual participating organizations or agencies, including Federal, State, Tribal, non-governmental organizations (NGOs), local and international agencies, and contract support companies as applicable.]

Number of Participants

[Insert a list of the total number of each of the following exercise participants, as applicable:

- Players: [#]
- Controllers: [#]
- Evaluators: [#]
- Facilitators: [#]
- Observers: [#]
- Victim Role Players: [#]

SECTION 2: EXERCISE DESIGN SUMMARY

[The Exercise Design Summary is intended to provide a summary of the exercise design process.]

Exercise Purpose and Design

[This section should contain a brief (one-to-two paragraph) summation of why the exercise was conducted and what the exercise participants hoped to learn. It should also include a brief history of how the exercise was organized, designed, funded, etc.]

Exercise Objectives, Capabilities, and Activities

[The purpose of this section is to list exercise objectives and align them with associated capabilities from the Target Capabilities List (TCL). For each TCL capability, there is an Exercise Evaluation Guide (EEG) which lists specific activities which must be performed to demonstrate a capability. In addition to TCL capabilities, the EEG activities relevant to each objective should also be included in this section. Begin this section with the following text.]

Capabilities-based planning allows for exercise planning teams to develop exercise objectives and observe exercise outcomes through a framework of specific action items that were derived from the Target Capabilities List (TCL). The capabilities listed below form the foundation for the organization of all objectives and observations in this exercise. Additionally, each capability is linked to several corresponding activities and tasks to provide additional detail.

Based upon the identified exercise objectives below, the exercise planning team has decided to demonstrate the following capabilities during this exercise:

- **Objective 1:** [Insert a one sentence description of each objective].
  - [**Capability Title**]: [Activity 1]; [Activity 2]; and [Activity 3].
  - [**Capability Title**]: [Activity 1]; [Activity 2]; and [Activity 3].

Scenario Summary

[For an operations-based exercise, this section should summarize the scenario or situation initially presented to players, subsequent key events introduced into play, and the time in which these events occurred. For a discussion-based exercise, this section should outline the scenario used and/or modules presented to participants.]

SECTION 3: ANALYSIS OF CAPABILITIES

This section of the report reviews the performance of the exercised capabilities, activities, and tasks. In this section, observations are organized by capability and associated activities. The capabilities linked to the exercise objectives of [full exercise name] are listed below, followed by corresponding activities. Each activity is followed by related observations, which include references, analysis, and recommendations.

[The format for Chapter 3, as described above, represents the preferred order for analysis of exercise observations. However, observations that are cross-cutting and do not apply to one, specific activity within the capability should be listed first, directly under the capability summary. Below the cross-cutting observations, you may then present the complete list of activities which apply to the observation.]

Capability 1: [Capability Name]

Capability Summary: [Include a detailed overview of the capability, drawn from the TCL capability description, and a description of how the capability was performed during an operations-based exercise or addressed during a discussion-based exercise. The exact length of this summary will depend on the scope of the exercise.]

Activity 1.1: [Using the EEGs, identify the activity to which the observation(s) below pertain.]

Observation 1.1: [Begin this section with a heading indicating whether the observation is a "Strength" or an "Area for Improvement." A strength is an observed action, behavior, procedure, and/or practice that is worthy of recognition and special notice. Areas for improvement are those areas in which the evaluator observed that a necessary task was not performed or that a task was performed with notable problems. Following this heading, insert a short, complete sentence that describes the general observation.]

References: [List relevant plans, policies, procedures, laws, and/or regulations, or sections of these plans, policies, procedures, laws, and/or regulations. If no references apply to the observation, it is acceptable to simply list "N/A" or "Not Applicable."]

1. [Name of the task and the applicable plans, policies, procedures, laws, and/or regulations and 1-2 sentences describing their relation to the task]
2. [Name of the task and the applicable plans, policies, procedures, laws, and/or regulations and 1-2 sentences describing their relation to the task]
3. [Name of the task and the applicable plans, policies, procedures, laws, and/or regulations and 1-2 sentences describing their relation to the task]

Analysis: [The analysis section should be the most detailed section of Chapter 3. Include a description of the behavior or actions at the core of the observation, as well as a

brief description of what happened and the consequence(s) (positive or negative) of the action or behavior. If an action was performed successfully, include any relevant innovative approaches utilized by the exercise participants. If an action was not performed adequately, the root-causes contributing to the shortcoming must be identified.]

Recommendations: [Insert recommendations to address identified areas for improvement, based on the judgment and experience of the evaluation team. If the observation was identified as a strength, without corresponding recommendations, insert "None.]

1. [Complete description of recommendation]
2. [Complete description of recommendation]
3. [Complete description of recommendation]

[Continue to add additional observations, references, analyses, and recommendations for each capability as necessary. Maintain numbering convention to allow for easy reference.]

SECTION 4: CONCLUSION

[This section is a conclusion for the entire document. It provides an overall summary to the report. It should include the demonstrated capabilities, lessons learned, major recommendations, and a summary of what steps should be taken to ensure that the concluding results will help to further refine plans, policies, procedures, and training for this type of incident.

Subheadings are not necessary and the level of detail in this section does not need to be as comprehensive as that in the Executive Summary.]

APPENDIX A: IMPROVEMENT PLAN

This IP has been developed specifically for [identify the State, county, jurisdiction, etc., as applicable] as a result of [full exercise name] conducted on [date of exercise]. These recommendations draw on both the After Action Report and the After Action Conference. [The IP should include the key recommendations and corrective actions identified in *Chapter 3: Analysis of Capabilities*, the After Action Conference, and the EEGs. The IP has been formatted to align with the *Corrective Action Program System*.]

Table A.1: Improvement Plan Matrix

Capability	Observation Title	Recommendation	Corrective Action Description	Capability Element	Primary Responsible Agency	Agency POC	Start Date	Completion Date
[Capability 1: Capability Name]	1. Observation 1	1.1 Insert Recommendation 1	1.1.1 Insert Corrective Action 1	Planning	State X EMA	EMA Director	Dec 1, 2006	Sep 1, 2007
			1.1.2 Insert Corrective Action 2	Planning	State X EMS System	EMS System Director	Dec 1, 2006	Feb 1, 2007
		1.2 Insert Recommendation 2	1.2.1 Insert Corrective Action 1	Training	State X EMA	EMA Director	Dec 1, 2006	Jan 1, 2007
			1.2.2 Insert Corrective Action 2	Systems/ Equipment	State X EMA	EMA Director	Dec 1, 2006	Mar 15, 2007
	2. Observation 2	2.1 Insert Recommendation 1	2.1.1 Insert Corrective Action 1	Planning	State X EMS System	EMS System Director	Dec 1, 2006	Jan 15, 2007
			2.1.2 Insert Corrective Action 2	Systems/ Equipment	State X EMA	EMA Director	Dec 1, 2006	Jan 1, 2007

[Optional]

APPENDIX B: LESSONS LEARNED

While the After Action Report/Improvement Plan includes recommendations which support development of specific post-exercise corrective actions, exercises may also reveal lessons learned which can be shared with the broader homeland security audience. The Department of Homeland Security (DHS) maintains the *Lessons Learned Information Sharing* (LLIS.gov) system as a means of sharing post-exercise lessons learned with the emergency response community. This appendix provides jurisdictions and organizations with an opportunity to nominate lessons learned from exercises for sharing on *LLIS.gov*.

For reference, the following are the categories and definitions used in LLIS.gov:

- **Lesson Learned:** Knowledge and experience, positive or negative, derived from actual incidents, such as the 9/11 attacks and Hurricane Katrina, as well as those derived from observations and historical study of operations, training, and exercises.
- **Best Practices:** Exemplary, peer-validated techniques, procedures, good ideas, or solutions that work and are solidly grounded in actual operations, training, and exercise experience.
- **Good Stories:** Exemplary, but non-peer-validated, initiatives (implemented by various jurisdictions) that have shown success in their specific environments and that may provide useful information to other communities and organizations.
- **Practice Note:** A brief description of innovative practices, procedures, methods, programs, or tactics that an organization uses to adapt to changing conditions or to overcome an obstacle or challenge.

Exercise Lessons Learned

[Insert an account of any observations nominated for inclusion in the DHS LLIS.gov system. If there are not any nominations, a simple statement to that effect should be included here.]

[Optional]

APPENDIX C: PARTICIPANT FEEDBACK SUMMARY

[Appendix C of the AAR/IP should provide a summary of the feedback received through this form.]

[Optional]

APPENDIX D: EXERCISE EVENTS SUMMARY TABLE

[In formulating its analysis, the evaluation team may assemble a timeline of key exercise events. While it is not necessary to include this timeline in the main body of the AAR/IP, the evaluation team may find value in including it as an appendix. If so, this section should summarize what actually happened during the exercise in a timeline table format. Focus of this section is on what inputs were actually presented to the players and what actions the players took during the exercise. Successful development of this section is aided by the design, development, and planning actions of the exercise design team. Prior to the exercise, the exercise design team should have developed a timeline of anticipated key events.]

[An example of the format for the Exercise Events Summary Table is presented below.]

Table D.1: *Exercise Events Summary*

Date	Time	Scenario Event, Simulated Player Inject, Player Action	Event/Action
02/20/06	0900	Scenario Event	Explosion and injuries reported at subway station 13
02/20/06	0902	Player Action	Subway services stopped in accordance with protocols; notifications started
02/20/06	0915	Player Action	Evacuation ordered for planning zone 2A
02/20/06	0940	Simulated Player Inject	Traffic at a standstill on major egress route 1 reported to players (Response generated issue because personnel to staff traffic control points were not deployed)

[Optional]

APPENDIX E: PERFORMANCE RATING

[When a jurisdiction/organization elects to use performance ratings, or when initiatives require a rating within the AAR/IP, the following approach can be used. A qualitative performance rating is assigned to each activity demonstrated within its capability area. The performance rating is based on a systemic review by the lead evaluator of exercise performance based on evaluator analysis of how well the participants demonstrated the capability outcome. The results should be summarized within this appendix and should be based on the supporting narrative contained within the body of the AAR/IP.]

The performance rating categories refer to how well each activity was performed during the exercise and are detailed in the table below.

Table E.1: *Performance Ratings*

Rating	Description
Performed without Challenges	The performance measures and tasks associated with the activity were completed in a manner that achieved the objective(s) and did not negatively impact the performance of other activities. Performance of this activity did not contribute to additional health and/or safety risks for the public or for emergency workers, and it was conducted in accordance with applicable plans, policies, procedures, regulations, and laws.
Performed with Some Challenges, but Adequately	The performance measures and tasks associated with the activity were completed in a manner that achieved the objective(s) and did not negatively impact the performance of other activities. Performance of this activity did not contribute to additional health and/or safety risks for the public or for emergency workers, and it was conducted in accordance with applicable plans, policies, procedures, regulations, and laws. However, opportunities to enhance effectiveness and/or efficiency were identified.
Performed with Major Challenges	The performance measures and tasks associated with the activity were completed in a manner that achieved the objective(s), but some or all of the following were observed: demonstrated performance had a negative impact on the performance of other activities; contributed to additional health and/or safety risks for the public or for emergency workers; and/or, was not conducted in accordance with applicable plans, policies, procedures, regulations, and laws.
Unable to be Performed	The performance measures and tasks associated with the activity were not performed in a manner that achieved the objective(s).

APPENDIX F: ACRONYMS

[Any acronym used in the AAR should be listed alphabetically and spelled out.]

Table F.1: *Acronyms*

Acronym	Meaning

State of Iowa HSEEP Compliant Exercise Reporting Form

NOTE: HSEEP Guidance recommends that all after-action reports/improvement plans from exercise conducted with DHS funding be uploaded to the HSEEP portal. According to the DHS point of contact for Iowa, the only personnel with access to the portal are the "DHS Exercise Managers and the LLIS Team. Any information that LLIS compiles is scrubbed for location and other specifics that could help identify jurisdictions involved prior to being posted on LLIS.com. The only time the DHS Exercise Managers will share the information provided in AARs/IPs with external personnel is if Congress or the White House requests it."

Based on the federal recommendation, we will upload all AARs/IPs submitted for credit unless you request otherwise. If you would prefer that this AAR/IP not be uploaded to the HSEEP portal please select NO in the following box This form will default to "Yes" –releasing the information– unless otherwise specified. **Yes**

Executive Summary

Enter below a brief overview of the exercise - Major strengths demonstrated during the exercise and *areas that require improvement.*

Chapter 1: Exercise Overview

Exercise Name: _____ **County:** _____

Exercise Date: _____ **Duration:** _____ (days or hours)

Type of Exercise: - - - -

Funding Source: _____

Program: _____

Exercise Focus:	**Preparedness** ☐	**Mitigation** ☐	**Response** ☐	**Recovery** ☐
	Prevention ☐	**Protection** ☐	**Detection** ☐	
Primary Hazard	**Natural** --------	**Technological** ------	**Terrorism** --------	**Other** _____
Secondary Hazard	**Natural** --------	**Technological** ------	**Terrorism** --------	**Other** _____
Actual Event	**Natural** --------	**Technological** ------	**Terrorism** --------	**Other** _____

Location(s): _____ (City, State or address/specific location(s) in City, State)

Participating Organizations / Agencies: (list each specific agency for NIMS Compliance)

_____

Total Number of Participants: _____
Players: _____
Victim Actors: _____
Controllers / Evaluators: _____
Observers: _____

Chapter 2: Exercise Goals and Objectives

Note: *The "Exercise Goals and Objectives" section should be used to briefly list the goals and objectives for the exercise. List each Goal followed by the Objective for the respective Goal.*

Goal:
Objective:
Objective:
Objective:
Objective:

Goal:
Objective:
Objective:
Objective:
Objective:

Goal:
Objective:
Objective:
Objective:
Objective:

Goal:
Objective:
Objective:
Objective:
Objective:

Chapter 3: Exercise Events Synopsis

Note: *The "Exercise Events Synopsis" section should be used to provide an overview of the scenario.* ***Paste the exercise scenario below and send the exercise timeline and/or Master Scenario Events (MSEL) List as a separate attachment.***

Chapter 4: Analysis of Mission Outcomes

Note: Overall how did this exercise succeed in meeting or accomplishing the goal(s) identified?

Chapter 5: Analysis of Critical Task Performance

Note: *The "Analysis of Critical Task Performance" section reviews performance of the individual tasks, as defined in the evaluation guides. Each task that was identified by the exercise planning team as a critical task to be performed to respond to the simulated attacked defined by the scenario should be discussed in this section. Below is the format that each Task should be presented in.*

Task: *List the overall task and number.*
Reference: *List the reference Exercise Evaluation Guide (EEG) task and number.*
Summary of Issue: *Briefly describe the issue.*
Consequence: *Briefly state the consequence of the action.*
Analysis: *Briefly explain the issue and the consequences.*
Recommendations: *List the recommendation that would help to rectify the issue.*
Actions: *List the action steps required to ensure that the recommendation is followed.*

Task
Reference
Summary of Issue
Consequence
Analysis
Recommendations
Actions

Task
Reference
Summary of Issue
Consequence
Analysis
Recommendations
Actions

Task
Reference
Summary of Issue
Consequence
Analysis
Recommendations
Actions

Task
Reference
Summary of Issue
Consequence
Analysis
Recommendations
Actions

Chapter 6: Conclusions

Note: *The "Conclusions" section of the report should be used as a summary of all the sections of the AAR. It should include the following:*

- *Participants demonstrated capabilities*
- *Lessons learned for improvement and major recommendations*
- *A summary of what steps should be taken to ensure that the concluding results will help to further refine plans, procedures, training for this type of incident.*

Chapter 7: Improvement Planning

An Improvement Plan is a method by which issues and concerns brought out by the exercise are turned into measurable steps that result in improved response capabilities. The local jurisdictions take the lead in developing these steps. When complete, it specifically details what actions should be taken to address each issue or concern, who or what agency(s) is responsible for taking the action, and the timeline for completion. Any identified areas above needing improvement, shall be documented on the improvement plan.

UTL Task # (If applicable)	Issue	Improvement Actions	Responsible Person / Agency	Completion Date

Chapter 8: Annexes Exercised (if applicable)

List annexes exercised - *This information will be used to evaluate county Emergency Management Performance Grant (EMPG) compliancy. As per EMPG requirements, 100% of county emergency response plan annexes must be exercised every 5 years.*

Total number of annexes in the County Emergency Response Plan: _____

Number of annexes tested in this exercise: _____

Please list any other county, municipality, or private sector plans that this exercise tested:
-- Such as Chemical Facility Emergency Plan, School Emergency Plan, etc. --

Chapter 9: Exercise Report - Completion Information

Prepared By: _____ Title: _____ Date: _____

Address: _____ City: _____ County: _____

Email: _____

Please email this Report to: exercise@iowa.gov

---------- HLSEM Official Use Only ----------

State Approving Official **Date:** **Approved:**

Exercise Requirements Met for NIMS Requirements: ----

Comments:

Type of Credit Approved: ----

Attachment F – Lessons Learned/Recommendations Report Template

- Attachment F-1: Lessons Learned/Recommendations Report Template

RRT Name:

Recommendations from:

Date:

Participants:

Incident Response Challenges, Recommendations, and Action Items

1. ***Recommendation category***

- Challenge:
- Recommendations:
- Action Items:

2. ***Recommendation category***

- Challenge:
- Recommendation:
- Action Item:

3. ***Recommendation category***

- Challenge:
- Recommendations:
- Action Items:

4. ***Recommendation category***

- Challenge:
- Recommendations:
- Action Items:

Other Noted Information

Guide for completing the Recommendations Report:

1. **Recommendations from:**
   - This title refers to the outbreak for which the recommendations refer to.
   - Include the pathogen/food vehicle/year of the outbreak
   - Example: *Recommendations from the 2012 Salmonella Newport outbreak associated with Fresh Whole Cantaloupes*

2. **Date:**
   - Date that the call or meeting was held that discussed the recommendations

3. **Participants:**
   - List of participants in the recommendations discussion
   - Include Name and Organization/Office of participants

4. **Recommendation Category:**
   - List the category or subject area the recommendation refers to
   - Examples: *Communications, Information sharing, Epidemiology, Sampling, Traceback, etc.*

5. **Challenge:**
   - List the specific challenge that was faced during the response
   - Include background information on why this was a challenge during the outbreak
   - Example: *Ensuring that FDA, state and local partners were on the same page as far as timing and content of press releases. When states were ready to issue press, FDA was just beginning to respond to the outbreak.*

6. **Recommendations:**
   - List the recommendation(s) the discussion group has agreed on to address that specific challenge
   - Example: *In the future, it would be beneficial for FDA/Coordinated Outbreak Response and Evaluation (CORE) Communications to work with the FDA Districts to talk directly with State public affairs officers during an incident response. If the FDA District has a Public Affairs Specialist (PAS) or State Liaison, FDA/CORE Communications can work with that individual, and if not or if the District PAS isn't involved in outbreak responses, FDA/CORE Communications can act as the District's PAS by working with the State communications officers. This approach will be used on a case by case basis since each FDA District has a different relationship with their State partners.*

7. **Action item(s):**
   - List any action items to address the recommendation
   - Include any short-term or long-term follow-up to be done to address the proposed recommendation
   - Example: *FDA/CORE Communications will work through the FDA Districts and request to work directly with State communication officers during outbreak responses, as needed*

8. **Other Noted Information:**
   - List any additional information discussed during the call such as positive outcomes or other follow-up information
   - Example: *The FDA Environmental Assessment (EA) Team greatly appreciates all of the support they received from the RRT. The logistical assistance for the EA Planning Meeting and the assets made available to assist with the EA were valuable.*

Metrics

Chapter 15. Metrics

TABLE OF CONTENTS

1. PURPOSE

This chapter provides a set of metrics that identifies key goals and benchmarks for an RRT. Application of these metrics over time will provide a data set that will inform improvement of individual RRTs, as well as improvement of the RRT concept and program.

2. SCOPE

This chapter provides metrics for specific RRT capabilities, as outlined in Volumes 1 and 2 of the RRT Best Practices Manual, as well as overarching response metrics and baseline response data.

3. RESPONSIBILITY

3.1. RRT Leadership (or investigatory team leadership, in states without an RRT)

RRT leadership is responsible for ensuring a response capability assessment is conducted on a yearly basis, and that appropriate improvements are made based on the results of the assessment to ensure continual improvement of the RRT.

3.2. RRT Members (or investigatory team, in states without an RRT)

RRT members are each responsible for playing an active role in maintaining both their subject matter expertise and ability to work effectively in multi-disciplinary and multi-agency response teams.

4. DEFINITIONS

4.1. **Intervention –** The physical and/or administrative actions implemented by the RRT that attempt to cease or mitigate the *public health threat* associated with a specific human or animal food emergency. These actions may include but are not limited to product recalls, embargoes, seizures, import alerts, and license revocation.

4.2. **Mobilization** – The activation of RRT members shortly after notification in order to initiate preliminary response activities such as correspondence with partner agencies/entities, and recommending RRT activation to Agency Executives.

4.3. **Notification** – The date and time when at least one core member agency of the RRT receives information regarding a human or animal food emergency within its jurisdiction. This notification can originate from an entity that originally discovered the incident, has responded to the incident in a different jurisdiction or capacity, or has begun collecting/interpreting epidemiological data pertaining to the incident (if applicable).

4.4. **Responder Endangerment** – Factors, both physical and mental, that may negatively impact the health and welfare of a RRT responder as a direct result of responding to an incident. Endangerment may occur in all environments associated with a response including office settings and vehicles. Physical factors include illnesses and injuries while mental factors may include personal threats, disturbing imagery or experiences, etc. Physical injury or illness can be further classified based on severity (categories based on CDC guidance for field triage):

- **4.4.1.** "Green" – "Walking-wounded," who exhibit injuries that do not require immediate treatment and/or transportation to a medical facility.
- **4.4.2.** "Yellow" – Moderate to serious injury or illness, but is not immediately life threatening (e.g., fracture, mild burns).
- **4.4.3.** "Red" – Serious but salvageable life-threatening illness or injury (e.g., severe bleeding, amputation, heart attack, severe burns).
- **4.4.4.** "Black" – Individual is deceased at the scene with no apparent vital signs.

4.5. **Response** – Activities that are officially conducted by the RRT in response to a human or animal food emergency (may be part of a RRT Response or RRT Activation). These activities are specific to the incident and typically would not be conducted in the absence of a human or animal food emergency (e.g., focused product sampling, traceback/trace forward, product-specific pathogen analysis, etc.).

4.6. **RRT Activation** – Agency Executives or designees approve activation of RRT (e.g., stand up of an IMT). Actual definition and triggers for activation are determined by each RRT individually and must be properly documented in SOPs or other RRT agreements/plans. Triggers which may be considered prior to a potential RRT activation could include the number of ill persons or deaths, possibility of incident escalation, severity of the health hazard, etc.

4.7. **RRT Response** – RRT response activities, other than RRT Activations, to incidents with increased potential public health risk. These do not include routinely scheduled regulatory activities and may involve a broad range of incidents, including but not limited to: human illness clusters and outbreaks, human or animal food contamination incidents with no human illnesses, requests for emergency assistance from another agency, large planned events, severe weather events, and other human or animal food emergencies. RRT Responses are those requiring enhanced coordination,

communication, subject matter expertise, and technical skills that RRT members have developed.

5. BACKGROUND

This set of metrics seeks to identify key goals and benchmarks for an RRT, and was developed by a working group representing several different RRTs. The group discussed a variety of factors and variations for these metrics. This group sought to identify metrics as specific, measurable benchmarks to be achieved. While some may look at these as best practices, these metrics are a way to measure how groups implement key components of the best practices.

Note the subsection of section of Process Description titled "Baseline Response Data." These are separate from the metrics; identifying a range of variables that can be tracked over time for informational purposes (not for scoring).

It is expected that these metrics will continue to be modified and developed over time to optimize appropriateness, effectiveness, etc.

6. SAFETY

N/A

7. EQUIPMENT/MATERIALS

N/A

8. PROCESS DESCRIPTION

8.1. Metrics for RRT Manual Chapters

8.1.1. Working with other Agencies (WWOA)

1. Completes at least one HSEEP qualified exercise or real time event with relevant partner agencies to test/implement response procedures within the last 18 months. Documents lessons learned from the exercise or the event and develop a plan to improve or enhance any procedures that are developed. Score: _____ (Full=5, Partial=3, Not started=0)

8.1.2. Industry Relations

1. Has written SOPs to contact industry partners early on in investigations where appropriate to increase awareness or share technical assistance. (Rephrase as a metric?) Score: _____ (Full=5, Partial=3, Not started=0)
2. Process established to identify lessons learned from foodborne outbreak investigations and share them with industry or incorporate them into training for industry. Score: _____ (Full=5, Partial=3, Not started=0)

8.1.3. Food Emergency Response Plan (FERP)

1. Has a FERP and reviews it every 24 months. Score: _____ (Full=5, Partial=3, Not started=0)
2. Identifies all principal agencies (see NASDA Template) providing representation from state, federal, tribal, and local agencies, and their responsibilities in the state FERP. Score: _____ (Full=5, Partial=3, Not started=0)

8.1.4. Communication SOPs

1. Maintains a **contact list** for applicable local, state, and federal agencies. Updates list at least every 12 months. Score: _____ (Full=5, Partial=3, Not started=0)
2. Reviews and tests a **written procedure for notifying** members of the RRT and other applicable agencies of emerging events every 12 months. Score: _____ (Full=5, Partial=3, Not started=0)

8.1.5. Incident Command System

1. Uses Incident Command System (ICS)/Unified Command System (UCS) with state and local or state and federal entities in 100% of foodborne illness responses in which the RRT is activated*. Score: _____ (Full=5, Partial=3, Not started=0)
2. Uses Incident Action Plans (IAPs) during 100% of RRT activations, regardless of event magnitude. Score: _____ (Full=5, Partial=3, Not started=0)

*RRT activation may not occur for every event where an agency responds. The small scale of many incidents does not warrant the formation of Unified Command or the use of the Incident Command Structure. The intent of this metric is to capture data relative to those events where the RRT was activated for the response.

8.1.6. Training

It is understood that there will always be some timing and other circumstantial factors (e.g., when these metrics are assessed, staff changes, when certain courses are available) that would impact the percentages identified below. Several of the metrics below include a timeframe under which it is expected that these goals be approached. (During that timeframe, teams may want to exclude “member-in-training” staff from these calculations.)

It is also understood that these components may build upon each other so there may be some necessary differences in progress for different goals.

1. 100% (from the start) of field teams and the program's RRT food subject matter experts (SMEs) have completed the basic inspection training program described in the Manufactured Food Regulatory Program Standards (MFRPS). (SMEs brought in from other areas for unique responses are excluded for this. However, this is required for those frequently involved in RRT responses.) Score: _____ (Full=5, Partial=3, Not started=0)
2. 100% (within 3 months of assignment to RRT) of staff in a leading position (Command Staff, General Staff, and Field Team Leads) responding to emergency have completed ICS 100, 200, 700, and 800. Score: _____ (Full=5, Partial=3, Not started=0)
3. 100% (within 12 months of assignment to RRT) of Command Staff, General Staff, and Field Team Leads responding to emergency have completed ICS 300 and ICS 400. Score: _____ (Full=5, Partial=3, Not started=0)
4. 75% of field team staff and 100% of field team leaders have completed advanced courses in epidemiology and foodborne illness investigations including Epi-Ready or the equivalent. (Note: Field team percentage not intended to include staff assigned in surge capacity where they are coming to support the response and carry out specific assigned tasks that are within the scope of their training and routine work (ie. sampling, etc.) Score: _____ (Full=5, Partial=3, Not started=0)
5. Each field team when deployed has at least 1 team member with advanced training in the activities needed to conduct investigation. For example, seafood HACCP, juice HACCP, sampling, etc. Score: _____ (Full=5, Partial=3, Not started=0)
6. RRT conducts a training review every 12 months. An improvement plan is developed for any gaps in meeting the requirements above. (This is intended for non-MFRPS states. MFRPS States would include RRT-specific Training (program training) as a part of the MFRPS review.) Score: _____ (Full=5, Partial=3, Not started=0)

8.1.7. Tracebacks

1. Conducts an annual review of written traceback procedures. Score: _____ (Full=5, Partial=3, Not started=0)
2. Includes use of traceback procedure in at least one response or exercise every 12 months. Score: _____ (Full=5, Partial=3, Not started=0)

8.1.8. Environmental Assessments

1. 100% of RRT field response team leads and SMEs have been trained in conducting environmental root-cause assessments and/or using the

environmental investigation tools. Score: _____ (Full=5, Partial=3, Not started=0)

8.1.9. Recalls

1. RRTs share 100% of the retail distribution lists they developed for recalled food products with the agencies responsible for overseeing retail food safety, when this information is not subject to restriction by MOU, FDA Commissioning rules, or other legal requirements. Score: _____ (Full=5, Partial=3, Not started=0)
2. Maintains written procedures for conducting recall activities. Conducts a review of these procedures every 12 months and develops an improvement plan for any gaps identified during the review. Score: _____ (Full=5, Partial=3, Not started=0)
3. Recall coordinators (federal/state/local) participate in meetings at least every 6 months with partner agencies' recall coordinators to share information and review procedures for coordinating recall activities. Score: _____ (Full=5, Partial=3, Not started=0)

8.1.10. After Action

1. Completes an after action meeting with state, local and federal partners (as appropriate) that participated in a multi-agency response within 45 days of completion of the response investigation. Score: _____ (Full=5, Partial=3, Not started=0)
2. 100% of after action issues related to team performance or skill development are incorporated into improvement plans. If improvement plans are not utilized due to legal or other issues, all action issues are incorporated into future trainings. Score: _____ (Full=5, Partial=3, Not started=0)

8.1.11. Tools and Equipment

1. RRT has conducted and documented an inspection and/or function testing of key response equipment and supplies within the last 12 months. Perishable supplies nearing the end of their usable shelf life and broken equipment identified during the inspection was replaced or scheduled for replacement. Score: _____ (Full=5, Partial=3, Not started=0)

8.2. Overarching (Response) Metrics

This metric serves to identify overall capacity for an RRT. This was developed by the Working Group and is expected to develop further in the future based on use of the metrics.

8.2.1. Concepts for Evaluating "Overall Effectiveness"

1. Scoring criteria are identified for each of the 24 metric items[1] (e.g., 5 = full achievement of the metric, 3 = partial achievement, 0 = not started). For purposes of scoring each metric, scores of 1, 2 and 4 are not used.
2. Use the following equations to calculate the overall effectiveness score (a measure of program effectiveness) and the average score for each RRT:
   a. Overall Effectiveness Score = Sum of all metric items
   b. Average Score = Overall Effectiveness Score ÷total number of metric items (current number=24)
3. To be considered a functional RRT, one needs to have an average of 4.0 or higher, with no metric items that are "not started."

8.2.2. Yearly Goals in the Development of an RRT

1. End of 1st year: Average score of 2.0 across all metric items.
2. End of 2nd year: Average score of 3.0; ≤4 metric items that are "not started"
3. End of 3rd year: Average score of 3.5; ≤ 2 metric items that are "not started"
4. End of 4th year (and beyond): Average score of 4.0; 0 metric items that are "not started"

8.3. Baseline response data

This is a list of data elements with potential utility for baseline data gathering, identifying trends, etc. Please note that these are data elements for which benchmarks have not been identified and that are often for complex outcomes. These are not used for any kind of scoring. The utility of this data in its current form is for exploring the feasibility of routinely collecting this data and informing future metrics. Over time, the RRT Program will evaluate the feasibility of routinely collecting these data elements and determine their utility for developing future metrics.

8.3.1. Average time from RRT mobilization to field team deployment. (Approximate hours, over 12 months)

8.3.2. Average time from identification of implicated food until boots on the ground (deployed on-site to the facility) at the responsible facility/operation. (Approximate hours, over 12 months)

8.3.3. Average time from identification of implicated food to completion of traceback (identification of the source or determination that a source could not be identified). (Approximate hours, over 12 months)

8.3.4. Average time from the identification of adulterated food item until a consumer advisory is issued. (Approximate hours, over 12 months)

8.3.5. Average time from RRT mobilization to intervention. (Approximate hours, over 12 months)

[1] Metric item = an individual metric question resulting in a score of 5, 3 or 0

8.3.6. Average time from sample receipt by lab to serotyping results reported. (Approximate hours, over 12 months)

8.3.7. Average time from sample receipt by lab to PFGE results reported and entered into Pulse-Net. (Approximate hours, over 12 months)

8.3.8. Percentage of traceback investigations that successfully result in identification of an implicated food. (Over 12 months)

8.3.9. For all incidents where a root cause analysis was initiated[2], identify the percentage of incidents where a root cause or significant contributing factors were identified in a 12-month period. (Over 12 months)

8.3.10. Short of root cause identification, percentage of incidents (out of all incidents where a root cause analysis was initiated) in which at least one contributing factor to the contamination was identified? (Over 12 months)

8.3.11. Number of responder endangerments per year. (Over 12 months)

9. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

N/A

10. RELATED DOCUMENTS

10.1. Chapters of the RRT Best Practices Manual

11. REFERENCES AND OTHER RESOURCES

11.1. FDA Manufactured Food Regulatory Program Standards: Standard 8 resources assessment.

12. ATTACHMENTS

12.1. Attachment A – Field Equipment and Supplies Example Checklist (from MA RRT)

12.2. Attachment B – Metrics Worksheet

13. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	7/16/12	RRT Metrics WG (CA**, MA, NC, TX, WA)
1.1	R	1/23/13	ORA/OP
1.2	R	5/26/17	ORA/OP

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)

**Workgroup Lead

Change History

1.1 – Revisions for clarification purposes as per RRT submitted recommendations.

[2] A root cause analysis should be initiated in all investigations, where possible and practical. Identification of root cause/contributing factors is an indicator of the quality of the investigation. A root cause analysis is any systematic process for identifying a root cause, such as an environmental assessment.

1.2 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.

Attachment A – Field Equipment and Supplies Example Checklist

Massachusetts Department of Public Health
Bureau of Environmental Health
305 South Street
Jamaica Plain, MA 02130-3597
(617) 983-6700 (617) 983-6770 – Fax

Food Protection Program
Policies, Procedures and Guidelines

Issue: Field Equipment and Supplies **No:** OP-18

FIELD EQUIPMENT	Assigned	Available	Pending
Inspector Badge			
Inspector Business Cards	X		
State I.D.	X		
Cell Phone/Charger	X		
Laptop Computer/Case	X		
Equipment Storage Bin	X		
Digital Camera/Batteries	X		
Infra Red Thermometer		X	
150º-160ºF Temp. Sensitive Tapes	X		
Disposable Gloves (Non-Latex)	X		
Flashlight/Batteries	X		
Sanitizer Test Kits (chlorine, iodine, quaternary ammonia)	X		
pH test papers	X		
Measuring Tape	X		
Thermocouple		X	
Black Light/Battery/Bulb		X	
Food Stem Thermometer	X		
Briefcase	X		
FPP Seals	X		
Alcohol Swabs	X		

DOCUMENTS			
Regulations		X	
Policies	X		
Emergency Response Plan		X	
Emergency Contact Form	X		
Inspection Forms	X		
Enforcement Forms	X		
Food Security Documents	X		
State-wide Maps	X		
PROTECTIVE EQUIPMENT			
TYVEK Coveralls	X		
Disposable Foot Covers	X	X	
Protective Eyewear	X		
Hearing Protection	X		
Protective Breathing Equipment	X		
Reflective Safety Vest	X		
SAMPLE COLLECTION KIT			
Duffle Bag	X		
FPP Specimen/Sample Receipt Forms	X		
BT Collection Forms		X	
Biohazard Labels		X	
Exterior Transport Bag		X	
Interior Specimen Bag	X		
Collection Tubes		X	
Document Pouch			
First Aid Kit			
Indelible Markers	X		
Scissors/Utility Tool	X		
Cotton Applicators	X		
Tongue Depressors	X		
Sterile Wipes/Swabs	X		
Forceps	X		
Utility Knife	X		
Cooler	X		
Ice/Gel Packs		X	
Magnifying Glass		X	
Biohazard Bag		X	

Attachment B – Metrics Worksheet

Metrics for RRT Manual Chapters & Overall Effectiveness Score

Chapter/Metric Item		Score: Full=5, Partial=3, Not started=0
8.1.1 WWOA	1	
8.1.2 Industry Relations	1	
	2	
8.1.3 FERP	1	
	2	
8.1.4 Communication SOPs	1	
	2	
8.1.5 ICS	1	
	2	
8.1.6 Training	1	
	2	
	3	
	4	
	5	
	6	
8.1.7 Tracebacks	1	
	2	
8.1.8 Environmental Assessments	1	
8.1.9 Recalls	1	
	2	
	3	
8.1.10 After Action	1	
	2	
8.1.11 Tools & Equipment	1	

Overall Effectiveness Score (SUM)
Average (=SUM/24)

III. Relevant Concepts & Tools

A. RRT Capacity Building Process & Framework for Developing Rapid Response Capability

Framework for Development of Rapid Response Capabilities for Food Incident Response[1]

CORE COMPONENTS	PHASES OF A FOOD INCIDENT RESPONSE									
	Preparedness	Reassess/Improve Sustainability	Surveillance/ Detection	Reassess/Improve Sustainability	Investigation	Reassess/Improve Sustainability	Mitigation/ Control	Reassess/Improve Sustainability	Post-Response/ Prevention	Reassess/Improve Sustainability
A. Collaboration										
B. Communication										
C. Policies & Procedures										
D. Resources										

The RRT Concept focuses on the development and maintenance of rapid response capabilities by the RRT. Rapid response capabilities fall within the framework for human and animal food incident response, which consists of five phases: preparedness, surveillance/detection, investigation, control/mitigation, and post-response/prevention. The framework also delineates four core elements (collaboration, communication, policies and procedures, and resources) that are essential to having an effective capability for each of these phases; and lastly, this framework identifies how continuous improvement and sustainability must be involved throughout the entire system.

Each chapter within the RRT Manual represents a unique rapid response capability that falls within one of the five phases of response, and incorporates each of the four core elements as described above, as well as a series of achievement levels for measuring and assessing continuous improvement of that rapid response capability.

[1] Developed by crosswalking multiple food response-relevant frameworks including the Emergency Management, CIFOR Toolkit structure, International Association for Food Protection Procedures to Investigate Foodborne Illness, National Center for Biomedical Research and Training (NCBRT) Framework for a Coordinated Response, National Food Program Standards (Manufactured Food and Voluntary Retail), FDA/CDC/FSIS Outbreak Response Workgroup, etc.

Overview: RRT Capacity Building Process & Mentorship Framework

RRT CONCEPT	The Rapid Response Team (RRT) concept facilitates long-term improvements to the national food safety system by strengthening interagency collaboration, both to improve effectiveness of multi-jurisdictional/multi-disciplinary responses and to build programs on nationally shared best practices and tools.
OBJECTIVE	▪ This document provides a three phase framework for use by any State/District/Program Division wishing to establish a RRT with functional rapid response capabilities aligned with the RRT Best Practices Manual and the NIMS preparedness cycle (see diagram, left). ▪ Application of this document, including establishment of a mentorship relationship with an established RRT, will facilitate the development of RRT capabilities that are aligned with a proven, successful model, and result in increased protection of the public health.

FOUNDATIONAL ELEMENTS	***STEPS***	***DESCRIPTION***

	1) Assess the need for an RRT	• Delineate the need to develop rapid response capabilities and teams
		• Conduct a meeting[2] to assess "Foundational Elements" that support development of rapid response capabilities and teams. These include:
		  • Enrollment in Regulatory Program Standards
		  • The day to day working relationship between the state program and the FDA District/Program Division (considerations)
		  • Adherence to FMD-50 by the State Program and FDA District/Program Division
		  • State Program recall process
		  • State Program process for responding to Reportable Food Registry (RFR) notifications

	2) Address assessment results	• Develop a plan to address gaps

PHASE 1 Laying the Groundwork	***STEPS***	***DESCRIPTION***
	1) Obtain Commitment	• Determine if change to existing response coordination practices is needed, and if so, make the case for change • Designate individual(s) to lead coordination and be responsible for the RRT initiative
	2) Review Expectations	• Review supporting materials and clarify expectations for RRT participants (namely, the lead state agency, other key state agencies and the FDA District/Program Division Offices)
	3) Establish Key Relationships	• Establish the District/Program Division/State Partnership: Initiate/maintain a regular schedule of meetings with set

[2] *Several meetings are suggested as part of RRT development (Foundational Elements assessment, introduction meeting, and kick-off meeting – see Phase 1, steps 4 and 7). While each meeting represents a distinct purpose/task, please note that it may be possible and beneficial to combine these meetings, depending on team members' dispersion, the amount of work to be done, etc.*

		agendas to foster an integrated District/Program Division/State team • Establish the Mentor/Mentee Relationship: If available, a mentor will be assigned to assist new RRTs with the development process
	4) Establish a Vision (Introduction Meeting)	• Hold a meeting with key staff from RRT partners (District/Program Division/State) and the RRT Mentor • Define the vision/strategy for the RRT and set clear objectives • Address sustainability
	5) Identify the Team	• Identify the response team structure and skills that will be needed • Select team members using a multi-disciplinary approach • Identify and maintain mechanisms for intra and interagency communication
	6) Conduct a Baseline Assessment	• Incorporate into the kick-off meeting, if possible (see step 7) • Determine the training level of current staff • Review and document current process and flow • Identify lessons learned/conclusions from assessment.
	7) Develop an RRT Improvement Plan (Kick-Off Meeting)	• Establish short, medium and long-term objectives • Identify resources (both dedicated and those that can be strategically leveraged) • Re-clarify roles/responsibilities and ensure agreement among agencies (as needed) and identify point person(s)/decision-maker(s) • Review foundational elements assessment, baseline capability assessment, and RRT vision • Consider Phase 2 activities as a model for the plan
PHASE 2	***STEPS***	***DESCRIPTION***
Launching & Building	1) Maintain relationships	• District/Program Division/State partnership • Mentor/mentee relationship
	2) Construct a Written Framework	• Establish a clear operational plan • Create a standardized response structure • Establish a Training Plan, including ICS knowledge and practical skills • Begin to develop/revise written SOPs
	3) Address Sustainability	• Draft a sustainability plan to address resources (especially new resources) being utilized for RRT development
	4) Equip the Team and Provide Training	• Purchase needed equipment and supplies • Begin training RRT members
	5) Exercise the Team	• Conduct the first (learning) exercise early on in the development process • Respond to incidents using RRT processes and procedures
	6) Evaluate	• Conduct a Yearly RRT Capability Assessment and update the

	performance	RRT Improvement Plan • Conduct after action reviews (AARs) for any RRT exercises, responses or activations to learn from experiences
	7) Celebrate Team Success	• Reinforce the team mindset and build the relationship, especially among team members from different agencies
PHASE 3	***STEPS***	***DESCRIPTION***

Maintaining & Improving	1) Plan	• Maintain a written framework:
		  • Standardized response structure
		  • Operational Plan
		  • Training Plan
		  • Specific SOPs
		  • Address sustainability (as needed)

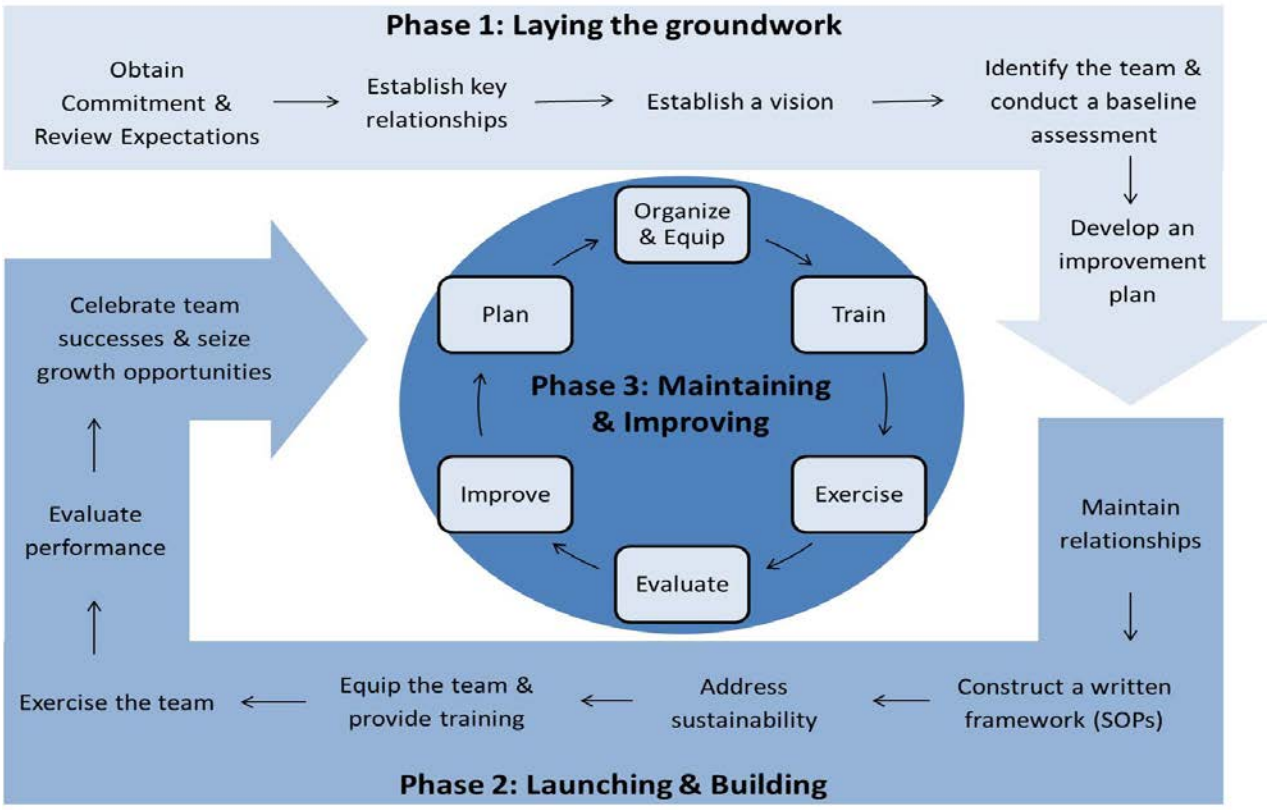
	2) Organize & Equip	• Maintain, coordinate and routinely engage the team • Maintain the team's equipment

	3) Train	• Execute the Training Plan
		  • Maintain RRT skills
		  • Provide additional appropriate training
		  • Provide incentives to address identified gaps and keep staff engaged.

	4) Exercise	• Conduct multijurisdictional, multidisciplinary exercises and respond to incidents (RRT responses and activations)

	5) Evaluate & Improve	Routinely Evaluate, Assess & Realign as needed by doing the following:
		• Conduct AARs for RRT activations and exercises to learn from experiences
		• Complete yearly RRT Capability Assessment as part of continuous process improvement efforts
		• Support each other & celebrate success within the community
		  • RRT Mentorship & a Regional approach
		  • Share with and learn from others: Participate in RRT Program activities where RRTs can introduce new team members and share information about new partnerships, initiatives, training opportunities, success stories, etc.
		• Strategically align resources and initiatives to increase efficiency
		  • Intra-agency alignment, such as integration of core response team and regulatory program field staff.
		  • External alignment: If/when possible, work with analogous programs (e.g., RRTs in other states) to leverage resources and share ideas
		• Re-assess what RRT level is desired and affordable
		  • Top agency support for making changes
		  • Refocus in light of changing agency priorities
		• Maintain a long-term perspective
		  • Evaluate what was learned during Phases 1 & 2
		  • Look to the future: 1, 5, 10 years out. What is the next

	step? What tools are needed to go to the next level? • Revisit your RRT vision over time and adjust supporting infrastructure as needed
PROBLEM SOLVING STRATEGIES	***FOCUS ON THE TEAM*** • Relationship building is "Job One" • Address personality issues early on • Be intentional about breaking down disciplinary/agency silos ***EXPEND ENERGY & RESOURCES WISELY TO MAXIMIZE RETURN ON INVESTMENT*** • Address competing priorities & status quo mentality (tactics- identifying incentives, resources, action plans) • Streamline SOP/document writing process where possible • Balance – avoid both "cookie cutter" approaches and "reinventing the wheel" • Leverage the synergy of multi-disciplinary teams – example: "feed is food"
THE RRT ENVIRONMENT	***WORDS OF WISDOM FOR CULTIVATING AN ENVIRONMENT CONDUCIVE TO INTEGRATION*** • An environment of trust and collaboration among staff is essential in making inter-agency efforts such as the RRT successful • Senior leaders in each organization need to set the tone and support the time and travel necessary for staff to meet regularly and get to know one anothe • Being open and honest when there are concerns about the other organization's inspectional or investigational approach or work quality is paramount • For state and federal staff and managers, being willing to accept that not all in your organization may be working effectively and demonstrating a willingness to strive for continuous improvement is critical for a successful relationship



B. Response Concepts/Frameworks

There are numerous concepts and frameworks that are central to the RRT project as it works to improve response in a national, integrated food safety system. These central concepts include the following:

1. **Incident Command System (ICS)**
   ICS is a "standardized, on-scene, all-hazards incident management approach." Its concepts are expected to be used by organizations at all levels of government in responding to emergencies. (http://training.fema.gov/EMIWeb/IS/ICSResource/index.htm)

2. **The "Three-Legged Stool" of Food Incident Investigations**
   The "Three-Legged Stool" of Food Incident Investigations includes laboratory, epidemiology, and environmental health investigations, all of which are necessary and integrated in an effective and complete investigation of food emergencies.

3. **The CIFOR Guidelines for Foodborne Disease Outbreak Response**
   The Guidelines describes the overall approach, roles of key organizations, recommend-ations for improving communication and coordination, and performance indicators for responses to outbreaks of foodborne diseases. Initiatives like the RRT work to align with these Guidelines. (http://www.cifor.us/CIFORGuidelinesProjectMore.cfm)

4. **The Manufactured Food Regulatory Program Standards (MFRPS)**
   The MFRPS "establish a uniform foundation for the design and management of State programs responsible for the regulation of food plants... The program standards are comprised of ten standards that establish requirements for the critical elements of a regulatory program designed to protect the public from foodborne illness and injury." Note that Standard #5 addresses "Food-Related Illness Outbreaks and Response." (https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf)

5. **The National Response Framework (NRF)**
   The NRF "establishes a comprehensive, national, all-hazards approach to domestic incident response"; this identifies the broader national approach to all incidents, under which federal, state, and local responses to human and animal food incidents would fall. (https://www.fema.gov/national-response-framework)

6. **The National Infrastructure Protection Plan (NIPP): Food and Agriculture Sector-Specific Plan (SSP)**
   The NIPP provides a structure for efforts to protect the nation's critical infrastructure and key resources (CIKR). Sector-Specific Plans (SSPs) complement the NIPP by detailing the application of the NIPP risk management framework for each sector. Food and Agriculture is 1 of 17 sectors. (https://www.dhs.gov/publication/nipp-ssp-food-ag-2015)

C. Crosswalks of Frameworks/Concepts

1. Comparison Table- RRT Best Practices Manual to CIFOR Guidelines

This table aims to identify related sections between the RRT Best Practices Manual and the CIFOR Guidelines and Toolkit, and should not be interpreted as interchangeable. Please note that while these documents may contain content that touches on similar topics or is complementary, each of these documents serve a specific program or constituency. While it is encouraged for human and animal food regulatory and public health programs to leverage multiple response tools as appropriate for their program, human and animal food regulatory and public health programs receiving federal funding for response capacity development should always defer to the requirements set forth in that funding agreement.

DESCRIPTION OF CHAPTER		CIFOR GUIDELINES AND TOOLKIT
Chapter 1	Working with Other Agencies	Chapter 3.1 – Agency Roles
Chapter 2	Federal-State Cooperative Programs	No corresponding CIFOR content at this time
Chapter 3	Industry Relations	Chapter 3.6 – Communication Chatper 6.5.4 – Communication with the Industry
Chapter 4	Exercises	No corresponding CIFOR content at this time
Chapter 5	CIFOR	
Chapter 6	Food Emergency Response Plans (FERPs)	Chapter 3 – Planning and Preparation
Chapter 7	Communication Standard Operating Procedures (SOPs)	Chapter 3.6 – Communication
Chapter 8	Incident Command System Concepts in RRTs	Chapter 3.10 – Incident Command System
Chapter 9	Rapid Response Team (RRT) Training	Chapter 3.2 – Outbreak Investigation and Control Team
Chapter 10	Tracebacks	Chapter 6.2 – Control of the Source
Chapter 11	Joint Inspections & Investigations	Chapter 5.2.5 – Coordinate Investigation Activities Chapter 7 – Special Considerations for Multijurisdictional Outbreaks
Chapter 12	Environmental Sampling & Records Collection	Chapter 3.2 – Outbreak Investigation and Control Team
Chapter 13	Recalls	Chapter 6 – Control Measures
Chapter 14	After Action Reviews	Chapter 5.2.8 – Conduct a Debriefing at End of Investigation Chapter 6.7 – After-Action Meetings and Reports Chapter 7.5 – Multijurisdictional Outbreak Investigations After-Action Reports and Reporting to eFORS

DESCRIPTION OF CHAPTER		CIFOR GUIDELINES AND TOOLKIT
Chapter 15	Metrics	Chapter 8 – Performance Indicators for Foodborne Disease Programs
Relevant Concepts & Tools	Subsection A: RRT Capacity Building Process & Framework for Developing Rapid Response Capability	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection B: Response Concepts/Framework	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection C: Crosswalks of Frameworks/Concepts	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection D: Useful Tools in Improving Foodborne Outbreak Response	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection E: Conference Call Etiquette	Chapter 3.6 – Communication
Relevant Concepts & Tools	Subsection F: Overview: Incident Action Plans, Situation Reports, and After Action Reports	Chapter 7.5 – Multijurisdictional Outbreak Investigations After-Action Reports and Reporting to eFORS
Reference	Subsection A: Acronyms	No corresponding CIFOR content at this time
Reference	Subsection B: Glossary of Key Terms (Definitions)	Appendix 1 – Glossary
Reference	Subsection C: List of Reference Documents	Appendix 3 – List of Key Websites and Resources Cited
Reference	Subsection D: About the RRT Program	No corresponding CIFOR content at this time

2. MFRPS Standard 5 Food-related Illness, Outbreak and Hazards Response Crosswalk with RRT Best Practices Manual, CIFOR Guidelines and Partnership for Food Protection (PFP) Resources

These tables aim to identify related sections between the RRT Best Practices Manual, CIFOR Guidelines, PFP Resources, and MFRPS Standard 5, and should not be interpreted as interchangeable. Please note that while these documents may contain content that touches on similar topics or is complementary, each of these documents serve a specific program or constituency. While it is encouraged for human and animal food regulatory and public health programs to leverage multiple response tools as appropriate for their program, human and animal food regulatory and public health programs receiving federal funding for response capacity development should always defer to the requirements set forth in that funding agreement.

Table 1: RRT, CIFOR and PFP Resources Supporting Section 5.3.1 Coordination with Other Authorities

2016 MFRPS Std. 5 Program Elements	RRT Manual, CIFOR & PFP Resources

1. Have an MOU for foodborne illness outbreak investigations, if required.	RRT Manual Chapter 1, WWOA
	• Section 8.2.4 (Chapter Page 1-9) – Memorandum of Understanding (MOU)
	• Attachment A (Chapter Page 1-23) – Epidemiological MOU between Agencies
	  • *Example from North Carolina*
	• Attachment B (Chapter Page 1-27) – Laboratory MOU between Agencies
	  • *Example from North Carolina*
	CIFOR Guidelines, 2nd Edition
	• Chapter 3.8 Legal Preparedness
	• Chapter 9.0.2 Ensuring Legal Preparedness for Foodborne Disease Outbreaks

2. Have a written procedure that identifies and describes the roles, responsibilities and duties of each program responsible for supporting foodborne illness outbreak response in requirements 5.3.1-5.3.4.	RRT Manual Chapter 1, WWOA • Section 8.3 (Chapter Pages 1-13 through 1-17) – Defining Roles and Responsibilities in an Investigation/Response • Attachment C (Chapter Page 1-30) – Flowchart – Communications between Agencies (Epi, Lab, Environmental) CIFOR Guidelines, 2nd Edition • Chapter 3.1 Agency Roles • Chapter 3.2 Outbreak Investigation and Control Team

2016 MFRPS Std. 5 Program Elements	RRT Manual, CIFOR & PFP Resources

3. Have a written procedure that describes collaboration with FDA and other agencies in multi-jurisdictional FOOD-RELATED INCIDENTS.	RRT Manual Chapter 1, WWOA
	• Section 8.2.3 (Chapter Page 1-8) – Legal Framework
	  • *Talks about need for appropriate information sharing agreements with FDA*
	• Section 8.3 (Chapter Pages 1-13 through 1-17) – Defining Roles and Responsibilities in an Investigation/Response
	RRT Manual Chapter 7, Communication SOPs
	• Section 8.3 (Chapter pages 7-8 through 7-10) – Assess to Achievement Level 3
	  • *Talks about specific topics that need to be included in a Communication SOP that is coordinated between the State and the FDA District/Program Division (a similar process should be done for other RRT member agencies/partners as well).*
	• Attachments (Chapter pages 7-14 through 7-28)
	  • *Attachment A – Information Sharing Best Practices*
	  • *Attachment B – Meeting Etiquette and Best Practices*
	  • *Attachment C – Sharing Confidential Information Best Practices*
	  • *Attachment D – Notification Worksheet*
	  • *Attachment E – Response Modes and Associated Communication Best Practices*
	  • *Attachment F – Team Member Staffing and communication roles*
	  • *Attachment G – Activities Conducted/Coordinated During a Response*
	  • *Attachment H – Contact List Example*
	  • *Attachment I – Early Notification Form*
	  • *Attachment J – Foodshield Best Practices for States/Locals/FDA during Incidents (PFP surveillance, Response, and Post Response Workgroup)*
	  • *Attachment K – Alert Systems/System Testing*
	CIFOR Guidelines, 2nd Edition
	• Chapter 3.1 Agency Roles
	• Chapter 3.2 Outbreak Investigation and Control Team

2016 MFRPS Std. 5 Program Elements	RRT Manual, CIFOR & PFP Resources

4. Have a written procedure that designates a response coordinator(s) to guide program investigation efforts in collaboration with all agencies involved.	RRT Manual Chapter 7, Communication SOPs
	• Section 8 (Chapter pages 7-5 through 7-10) Assess to Achievement Levels 1-5
	  • *See sections on Notifications and Updates, Identification of Partners*
	• Attachments (Chapter pages 7-14 through 7-28)
	  • *Attachment A – Information Sharing Best Practices*
	  • *Attachment D – Notification Worksheet*
	  • *Attachment E – Response Modes and Associated Communication Best Practices*
	  • *Attachment F – Team Member Staffing and communication roles*
	CIFOR Guidelines, 2nd Edition
	• Chapter 3.2.2.1 Team Leader (Outbreak Investigation and Control Team)

5. Have a written procedure that notifies all relevant agencies of FOOD-RELATED INCIDENTS.	RRT Manual Chapter 7, Communication SOPs
	• Section 8 (Chapter pages 7-5 through 7-10) Assess to Achievement Levels 1-5
	  • *See sections on Notifications and Updates*
	• Attachments (Chapter pages 7-14 through 7-28)
	  • *Attachment D – Notification Worksheet*
	  • *Attachment E – Response Modes and Associated Communication Best Practices*
	  • *Attachment H – Contact List Example*
	CIFOR Guidelines, 2nd Edition
	• Chapter 3.6.2.2 Communication among the agencies and units of the outbreak investigation and control team (e.g., among epi, lab, EH)
	• Chapter 3.6.2.3 Communication with other local, state and federal authorities.
	• Chapter 7.4.1-7.4.3 Outbreak detection and investigation at the local, state and federal levels
	  • Subsections on ensure notification

2016 MFRPS Std. 5 Program Elements	RRT Manual, CIFOR & PFP Resources
6. Have written procedure that provides instructions for notification of appropriate law enforcement agencies when intentional food contamination is suspected or threatened.	RRT Manual Chapter 1, WWOA • Section 8.3.7, 8.3.8 (Chapter Pages 1-16 through 1-17) – Defining Roles and Responsibilities in an Investigation/Response RRT Manual Chapter 7, Communication SOPs • Section 8 (Chapter pages 7-5 through 7-10) Assess to Achievement Levels 1-5 • *See sections on Notifications/Updates and Contact Lists* • Attachment D – Notification Worksheet (Chapter page 7-18) • *Has a list of appropriate Local, State and Federal partners to contact for a variety of food contamination scenarios* CIFOR Guidelines, 2nd Edition • Chapter 6.3.2 Actions to take when intentional contamination is suspected
7. Have a written procedure that describes the maintenance of a list(s) relevant agencies and emergency contacts that is updated at least yearly.	RRT Manual Chapter 7, Communication SOPs • Section 8 (Chapter pages 7-5 through 7-10) Assess to Achievement Levels 1-5 • *See sections on Contact Lists* • Attachment H (Chapter page 7-23) – Contact List Example CIFOR Guidelines, 2nd Edition • Chapter 3.6.2.1 Contact lists

Table 2: RRT, CIFOR and PFP Resources Supporting Section 5.3.2 Surveillance

2016 MFRPS Std. 5 Program Elements	RRT Manual, CIFOR & PFP Resources
1. Use epidemiological information from local, state, or federal agencies to detect incidents or outbreaks of foodborne illness or injury.	RRT Manual Chapter 1, WWOA • Section 8.3.2 (Chapter page 1-14) – Defining Roles and Responsibilities in an Investigation/Response, Epidemiology to Environmental RRT Manual Chapter 7, Communication SOPs • Section 8.2 (Chapter pages 7-7) Assess to Achievement Level 2 • *See section on Identification of Partners* • Attachment D – Notification Worksheet (Chapter page 7-18) • *Has a list of appropriate Local, State and Federal partners to contact for a variety of food contamination scenarios* • Attachment C – Early Notification Form (Chapter page 7-26) • Attachment F – Team Member Communication Roles (Chapter page 7-20) CIFOR Guidelines, 2nd Edition • Chapter 4.2 Pathogen-Specific Surveillance

2016 MFRPS Std. 5 Program Elements	RRT Manual, CIFOR & PFP Resources
2. Maintain notifications of FOOD-RELATED INCIDENTS that are reported to the program, in a log or database.	CIFOR Guidelines, 2nd Edition • Chapter 4.3 Notification/Complaint Systems

Table 3: RRT, CIFOR and PFP Resources Supporting Section 5.3.3 Investigation/Environmental Assessment

2016 MFRPS Std. 5 Program Elements	RRT Manual, CIFOR & PFP Resources

1. Use established procedures with recommended timeframes to investigate reports of FOOD-RELATED INCIDENTS.	RRT Manual Chapter 11, Joint Investigations
	• Entire chapter, Chapter pages 11-1 through 11-10
	  • *Note: This chapter is specific to joint on-site investigations and does not specify recommended timeframes*
	RRT Manual Chapter 7, Communication SOPs
	• Section 8 (Chapter pages 7-5 through 7-10) Assess to Achievement Levels 1-5
	  • *See sections on Timelines and Notifications (or Updates) Content*
	CIFOR Guidelines, 2nd Edition
	• Chapter 5.2 Complaint, Cluster and Outbreak Investigation Procedures
	• Chapter 8.2 Performance Indicators
	PFP FoodSHIELD Best Practices for use of FoodSHIELD During Food and Feed Incidents

2. Collect ENVIRONMENTAL ASSESSMENT data using established procedures similar to those found in IAFP and CIFOR.	RRT Manual Chapter 12, Environmental Sampling • Attachment D-1 (Chapter page 12-38) – Food Establishment Environmental Assessment Quick Reference Tool for Foodborne Illness Investigation (Not Routine Inspections) • Attachment D-2 (Chapter page 12-40) – Environmental Assessment Generic Worksheet • Attachment D-3 (Chapter page 12-41) – FDA Environmental Assessment Process Overview CIFOR Guidelines, 2nd Edition • Chapter 5.2.4.1.6 Conduct an environmental health assessment International Association for Food Protection (IAFP) Procedures to Investigate Foodborne Illness (6th Edition) • Seek Sources and Modes of Contamination and Ways by Which the Contaminants Survived and/or Proliferated (Pages 23-40) • Keys A-F (Free): Situations that likely contributed to outbreaks of foodborne diseases (by commodity group). Identifies organisms of concern and contamination/ contributing factors to consider at various points on the farm to fork continuum for each commodity group.

2016 MFRPS Std. 5 Program Elements	RRT Manual, CIFOR & PFP Resources
3. Coordinate the TRACEBACK and TRACEFORWARD of food implicated in an illness, injury, outbreak or found to contain a HAZARD.	RRT Manual Chapter 10, Tracebacks • Entire chapter, Chapter pages 10-1 through 10-40. • *Contains process description and a variety of diagrams, templates and worksheets for use in conducting tracebacks.* CIFOR Guidelines, 2nd Edition • Chapter 5.2.4.1.7 Conduct traceback/traceforwards of food items under investigation

4. Have access to laboratory support for investigation of reports of FOOD-RELATED INCIDENTS.	RRT Manual Chapter 1, WWOA
	• Attachment B (Chapter page 1-27) - Laboratory MOU between Agencies
	  • *Example from North Carolina*
	RRT Manual Chapter 7, Communication SOPs
	• Section 8.2 (Chapter pages 7-7) Assess to Achievement Level 2
	  • *See section on Identification of Partners*
	• Attachment F – Team Member Communication Roles (Chapter page 7-20)
	• Attachment G – Activities Conducted/Coordinated During a Response (Chapter page 7-21)
	CIFOR Guidelines, 2nd Edition
	• Chapter 3.2.2.4 Laboratory investigator

5. Correlate and analyze ENVIRONMENTAL ASSESSMENT data to identify contributing factors and antecedents.	CIFOR Guidelines, 2nd Edition • Chapter 5.2.4.1.6 Conduct an environmental health assessment

Table 4: RRT, CIFOR and PFP Resources Supporting Section 5.3.4 Control Measures

2016 MFRPS Std. 5 Program Elements	RRT Manual, CIFOR & PFP Resources
1. Mitigate and contain food-related illness, injury and HAZARDS through strategies that include industry education, enforcement and public awareness activities.	RRT Manual Chapter 1, WWOA • Section 8.2.9 (Chapter pages 1-11 through 1-13) – Task Forces RRT Manual Chapter 3, Industry Relations • Entire chapter, Chapter pages 3-1 through 3-12 RRT Manual Chapter 11, Joint Investigations • Section 8.5 (Chapter page 11-5) – Seizures, Embargoes, Condemnation, Destruction of Products & Other Regulatory Actions RRT Manual Chapter 13, Food Recalls • Entire chapter, Chapter pages 13-1 through 13-40 PFP Best Practices for Improving FDA and State Communication During Recalls CIFOR Guidelines, 2nd Edition • Chapter 6.2 Control of the Source • Chapter 6.9 Other follow-up activities

2016 MFRPS Std. 5 Program Elements	RRT Manual, CIFOR & PFP Resources
2. Maintain a written media procedure with criteria for releasing prevention information to the public.	RRT Manual Chapter 7, Communication SOPs • Section 8 (Chapter pages 7-5 through 7-10) Assess to Achievement Levels 1-5 • *See sections on Public Message* • Attachment G – Activities Conducted/Coordinated During a Response (Chapter page 7-21) RRT Manual Chapter 11, Joint Investigations • Section 8.9 (Chapter page 11-6) – Public Information CIFOR Guidelines, 2nd Edition • Chapter 3.6.2.7 Communication with the media

Table 5: RRT, CIFOR and PFP Resources Supporting Section 5.3.5 Post Response

2016 MFRPS Std. 5 Program Elements	RRT Manual, CIFOR & PFP Resources
1. Maintain written program investigation and ENVIRONMENTAL ASSESSMENT findings and reports.	RRT Manual Chapter 7, Communication SOPs • Section 8 (Chapter pages 7-5 through 7-10) Assess to Achievement Levels 1-5 • *See sections on Post Response* • Attachment E– Response Modes and Associated Communication Best Practices (Chapter page 7-19) CIFOR Guidelines, 2nd Edition • Chapter 6.8 Outbreak Report Other Resources: • EA reports from FDA CORE are available on CORE's Website • EA report template from RRT EA Elements document (not in the RRT Manual); email Lauren.Yeung@fda.hhs.gov and Travis.Goodman@fda.hhs.gov).
2. Distribute final program investigation report, including an ENVIRONMENTAL ASSESSMENT, if completed, of illness or injury implicating food to relevant agencies responsible for reporting contributing factors and antecedents to CDC.	RRT Manual Chapter 7, Communication SOPs • Section 8 (Chapter pages 7-5 through 7-10) Assess to Achievement Levels 1-5 • *See sections on Post Response* CIFOR Guidelines, 2nd Edition • Chapter 6.8 Outbreak Report
3. Distribute recommendations, when available, from investigation and ENVIRONMENTAL ASSESSMENT findings and reports to relevant agencies and stakeholders responsible for prevention, education and outreach.	RRT Manual Chapter 1, WWOA • Section 8.2.9 (Chapter pages 1-11 through 1-13) – Task Forces CIFOR Guidelines, 2nd Edition • Chapter 6.8 Outbreak Report • Chapter 6.9 Other Follow-Up Activities International Association for Food Protection (IAFP) Procedures to Investigate Foodborne Illness (6th Edition) • Use Outbreak Data for Prevention (Page 76)

D. Useful Tools in Improving Foodborne Outbreak Response

1. Guidelines/Procedures

i. International Association for Food Protection: Procedures to Investigate Foodborne Illness
ii. CIFOR Guidelines
iii. Multistate Foodborne Outbreak Investigations: Guidelines for Improving Coordination and Communication (National Food Safety System Project, Outbreak Coordination and Investigation Workgroup, February 2001)

2. Evaluation Tools

i. CIFOR Toolkit
ii. FAS-CAT
iii. CARVER+SHOCK
iv. FARM Toolkit
v. LEAN Manufacturing/Process

3. Commodity-Specific Tools[3]:

i. Sprouts
ii. Tomatoes
iii. Cheese
iv. Berries

4. Information Technology Systems

i. North Carolina Task-Tracker
ii. Health Alert Network (HAN)
iii. National Environmental Assessment Reporting System (NEARS)
iv. PulseNet Web Board
v. National Outbreak Reporting System (NORS)
vi. The Epidemic Information Exchange (Epi-X)

[3] See Attachment D of the Environmental Sampling and Records Collection Chapter for examples of commodity-specific tools.

E. Conference Call Etiquette

Below are some details on factors to consider for conference calls. In general, it is best to ensure ground rules are clearly established (in writing when possible) among all those who may be participating in joint conference calls.

A. General Approach

1) Ensure all participants are aware of meeting plans and receive all relevant call-in information ahead of time.
2) Whenever possible, provide an agenda in advance.
3) Notify all relevant parties of their possible involvement as soon as possible to allow time for preparation.
4) Identify who will provide a brief summary of key points (e.g., investigational directions) or details (e.g., sample results) for the meeting and ensure all come away with the same understanding.
5) Ensure all participants are aware of what to expect and what is expected of them on the call (e.g., listening only, provide reports).

B. Meeting Order

1) Have a pre-identified moderator.
2) Follow established agenda. New topics raised may be added to the end of the agenda.
3) Generally, 3-5 minutes per speaker. (Also, limit time spent on roll call.)

C. Discussion Etiquette

1) Announce who you are before speaking (e.g., name, organization).
2) Don't interrupt speakers.
3) Mute phones to cut down on background noise. (*6 if you do not have a mute button.)
4) Determine if information is pertinent to the group before speaking.

D. Multi-Agency Calls

1) Conference calls are extremely helpful during investigations to ensure that accurate, up to date information is shared among all agencies that need to know.
2) Initiation:
    a. Calls may be initiated by a local, state or federal health agency, usually hosted by CDC, FDA or one of the states.
    b. Several conference calls may occur on any given day (traceback group, epidemiological (or "epi") group, etc) to discuss:
        - Epidemiologic investigations
        - Epidemiologic and laboratory procedures
        - Multi-state case control studies
        - Environmental/product investigation and updates
        - Any new testing results (laboratory)
        - Information on methods, findings and conclusions
        - Coordination of media issues
        - Legal issues and potential enforcement or regulatory issues

F. Overview: Incident Action Plans, Situation Reports, and After Action Reports

A. Incident Action Plans (IAPs)

1) General

a. **Purpose:** The Incident Action Plan (IAP) establishes the response-wide priorities and objectives, guiding response activities for the operational period.
b. **Responsibility:** It is the responsibility of the Planning Section and Incident/Unified/Area Command to complete this at the beginning of each operational period. (See "Operational Planning P" – Attachment A.)
c. **Distribution:** Information should be shared with all groups involved in the response (e.g., by email, alert networks) on a pre-established schedule (e.g., operational period).

2) What the IAP Should Include

a. ICS Forms 202-206. (See RRT ICS Chapter for additional details.)

B. Situation Reports

1) General

a. **Purpose:** The Situation Report provides an up-to-date report of the current conditions and circumstances of a particular incident so that all involved in an incident know the current status of the incident and what is expected from each section and role. (Additional awareness is conducted through other exchanges of information such as conference calls and emails.)
b. **Responsibility:** It is the responsibility of the Planning Section, usually the Situation Leader, to communicate this information to all involved in the response. The Public Information Officer is also critical to ensuring situational awareness.
c. **Distribution:** Information should be shared with all groups involved in the response (e.g., by email, alert networks) on a pre-established schedule (e.g., operational period).

2) What the Situation Report should include:

a. Incident information:

- Confirmed or verified information regarding the specific details relating to the incident
- Possible prediction scenarios of an incident
- May include report of weather potentially affecting the operation

b. Response Activity:

- Any updates to the IAP
- Location(s) of assignment (for multiple facilities or fields)

- Availability or assignment of resources (e.g., number of participating team members)
- Progress accomplished (e.g., specific activities)
- Significant findings
- Details the collection and analysis of information (e.g., number and type of samples collected, selection of laboratories)
- Reports from technical specialists
- Assignments still pending
- Other (e.g., safety concerns)

C. After Action Review/Report (AAR)

1) General

Note: The acronym "AAR" is often used to represent either the After Action Review or the After Action Report, which have two different roles. The After Action Review (sometimes called a hotwash) is a process of discussing strengths and weaknesses of a response. By contrast, an After Action Report is the documentation of lessons learned, etc. identified through processes like the After Action Review.

The Incident Commander (or Unified Command) should establish a timeline with deadlines and clear assignment of responsibilities for the After Action Review components described below. The After Action Review should be scheduled as soon as possible after the close of the incident/investigation. (A suggested timeframe is within 2 weeks after the last investigative step is taken and no new illnesses are reported.) This ensures events are within recent memory for accurate identification of lessons learned.

2) What the AAR should Include

a. Report of the incident:

- Drafted by the Incident Commander or designee.
- Starts with the first notification and ends with the final outcome or current status of the incident. (This should be clear, concise, and not longer than half a page.)
- Identifies the major issue, commodity, and suspected or confirmed agent.
- Identifies the findings and outcome of the incident.

b. Review of the response process:

- Drafted by the Incident Commander or designee.
- Includes the activities that took place throughout the response and rationale for those actions.
- Identifies solutions and future actions that would rectify any adverse actions and promote effective actions. These can be based upon the top 3 items that were done well and the top 3 items that need further improvement, as determined by the investigation or response team.

- Includes specific actions for follow up, assignment of tasks and responsibilities, and timelines.

c. A timeline of the events

This identifies the events that developed through the course of the response. This helps others to understand the sequence of events.

d. Flowchart of communication among the various agencies

This may help clarify and highlight the communication exchange areas that require further improvement.

e. Full summary: The "After Action Report"

- Includes the incident summary, process review, timeline, and flowchart.
- Should be limited to a few pages whenever possible.
- Should be distributed to all who contributed information or had a need to know during the incident (e.g., inspectors, local partners, epidemiologists, laboratory, leadership). Closing the loop is a vital part of sustaining a collective federal, state, and local rapid response.

IV. Reference

A. Acronyms

AAR – After Action Review or Report
AFRPS – Animal Feed Regulatory Program Standards
CD – Communicable Disease
CDC – Centers for Disease Control and Prevention
CIFOR – Council to Improve Foodborne Outbreak Response
CORE (Network) – Coordinated Outbreak Response and Evaluation Network (FDA)
DHS – Department of Homeland Security
EH – Environmental Health
EHS-Net – Environmental Health Specialists Network
EOP – Emergency Operations Plan
EPA – Environmental Protection Agency
FDA - Food and Drug Administration
FEMA – Federal Emergency Management Agency
FERP – Food Emergency Response Plan
FoodCORE - Foodborne Disease Centers for Outbreak Response Enhancement (CDC)
FSDTF – Food Safety and Defense Task Force, also called FPTF (Food Protection Task Force)
FSIS – Food Safety Inspection Service (USDA)
FRMAC – Federal Radiological Monitoring and Assessment Center
HAN – Health Alert Network
HHS – U.S. Department of Health and Human Services
IAP – Incident Action Plan
ICS – Incident Command System
LHD – Local Health Department
MFRPS – Manufactured Food Regulatory Program Standards
MOA – Memorandum of Agreement
MOU – Memorandum of Understanding
NIMS – National Incident Management Plan
NRF – National Response Framework
NEARS – National Environmental Assessment Reporting System
OP – Office of Partnerships
PFGE – Pulsed-Field Gel Electrophoresis
QMS – Quality Management System
RRT – Rapid Response Team
SOP – Standard Operating Procedure
USDA – US Department of Agriculture
WGS – Whole Genome Sequencing
WWOA – Working with Other Agencies (RRT Manual Chapter)

B. Glossary of Key Terms

Below is a list of definitions for key terms frequently used throughout the RRT Best Practices Manual.

When specific terms are used in a unique way within a chapter, these terms and respective definitions are described in the Definitions section within those particular chapters. Over time, additional definitions will continue to be identified and can be added to this section.

Agency – Refers to any government organization (federal, state, local, etc.) that represents a regulatory, public health, or other role in a human or animal food emergency response. This does not refer to the FDA or any other specific organization.

After Action Review – A learning tool intended for the evaluation of an incident (event, investigation, etc.) in order to improve performance by sustaining strengths and correcting weaknesses. The written After Action Report also provides investigation and response partners a final summary of the incident, including issues raised during the After Action Review process.

Environmental Health – Refers to all inspectional, sanitarian, and response staff involved in a food incident. Primarily, these are the individuals in the field conducting visits, inspections, and compliance activities at food service, retail and manufacturing operations. This includes those who conduct similar actions in feed programs. Responsibility for these activities may fall under the jurisdiction of one agency or administration may be jointly handled by two or more programs (e.g., both the State Department of Health and State Department of Agriculture). This may also include inspection and field staff with federal partners such as FDA, USDA, and EPA.

Environmental Assessment/Investigation (Also called "Environmental Health Assessment") – On-site food product investigations, conducted in conjunction with investigations (e.g., traceback) as needed to assess and rule out the potential that the contaminant of concern was introduced at a point in the distribution or production system. This is achieved by identifying contributing factors and environmental antecedents.

Epidemiology – The study of the occurrence of disease or other health-related conditions or events in defined populations. The control of disease in populations also is often considered to be a task for epidemiology. Epidemiologists conduct surveillance and carry out investigations using hypothesis testing and analytic research to identify the causes of diseases, including the physical, biological, social, cultural, and behavioral factors the influence health. *(Based on the definition identified in the Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines for Foodborne Disease Outbreak Response. Appendix 1: Glossary - http://www.cifor.us/documents/CIFORGuidelinesAppendices.pdf)*

Food – "The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." *(Section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321))*

Food Emergency Response Plan (FERP) – In this manual, a "Food Emergency Response Plan" refers to a capabilities-based state emergency operations plan as referenced in the National Preparedness Goal that is applicable for food emergencies. A food-related emergency involves the adulteration and/or contamination, threatened or actual, of food that impacts or may impact human health. A food emergency could occur at any point from farm to fork, including pre-harvest production, processing, distribution, and retail sales. *(National Association of State Departments of Agriculture (NASDA) Food Emergency Response Plan Template http://www.nasda.org/Policy/6460/9885/6138/11681.aspx).*

Food Program – In this manual, a "Food Program" refers to a Food-safety regulatory agency: Government agencies at the local, state, or federal level that are granted regulatory oversight of some aspect of the food industry. The goal of food-regulatory agencies is to ensure the public food supply is safe from disease caused by infection from human handling or by contamination from chemical or other hazardous substances. *(Council to Improve Foodborne Outbreak Response (CIFOR). Guidelines for Foodborne Disease Outbreak Response. Appendix 1: Glossary - http://www.cifor.us/documents/CIFORGuidelinesAppendices.pdf)*

FoodSHIELD – FoodSHIELD is a web-based system for communication, coordination, education, and training among the nation's food and agriculture sectors. This secure system allows public health and food regulatory officials at the local, state, and federal levels across the nation to work together. It also helps communicate food safety information. *(For more information, see www.foodshield.org)*

Human or Animal Food Incident – An unintentional or deliberate contamination, threatened or actual, of food that may impact human health at any point in the production system (e.g., pre-harvest production, processing, distribution).

Note that a **human or animal food emergency** is an incident in which the response needs exceed the capacity of the initial responding entity or jurisdiction response. *(See NASDA Template Version 4.0. Preface - http://www.nasda.org/File.aspx?id=4065)*

Incident Command System (ICS) – A flexible, scalable response organization providing a common framework within which people can work together effectively to respond to an emergency. *(For more information, see: http://training.fema.gov/EMIWeb/IS/ICSResource/index.htm)*

Investigator –

- Epidemiology: Any person involved in determining the agent, mode of transmission and factors leading to an illness or outbreak.
- Regulatory: A person specially trained to collect evidence of violations of regulatory requirements. This evidence is collected for use in possible enforcement actions by the regulatory agency.

(Multistate Foodborne Outbreak Investigations Guidelines for Improving Coordination and Communications. Glossary - http://www.cifor.us/clearinghouse/tooldetail.cfm?id=212)

Laboratory – Analysts and management of the facility or facilities that provide scientific data in the form of sample results to investigational (epidemiology and environmental) personnel during an incident. Testing may be accomplished at one central, consolidated location or divided among several organizations based on specific commodity and analytical requirements. Chemical, microbiological, and other associated testing provided by federal partners such as FDA, USDA, and EPA may also be included in this category.

Rapid Response Team (RRT) – The group of state and federal partners associated with each Rapid Response Team. This team is responsible for developing and implementing improved rapid response to human or animal food incidents. There are typically two tiers of RRT member agencies/partners: core and auxiliary. **Core RRT member agencies/partners** include the FDA District/Program Division, state food regulatory program, state feed regulatory program, state epidemiologist, and state laboratory; and may also include others, as defined by each RRT. **Auxiliary RRT member agencies/partners** include other regulatory programs within the state (retail/restaurant inspections, raw molluscan shellfish, grade A dairy, etc.), local health departments; these will vary and are defined by each RRT.

RRT as a "Response Team" – In this manual, RRT often refers to the group of individuals who conduct specific investigation activities and coordinate the RRT's response to an incident. These personnel will be selected from the subset of RRT member agencies or partners that will assume responsibility for the RRT response or activation (e.g., State Departments of Agriculture and Health, FDA District/Program Division Offices, USDA/FSIS). This response team may be in the form of an Incident Management Team (IMT) stood up under Incident Command System (ICS)/Unified Command, constituting a RRT activation, or could operate under a non-ICS structure that would constitute a RRT Response.

RRT Activation – Agency Executives or designees approve activation of RRT (e.g., stand up of an IMT). Actual definition and triggers for activation are determined by each RRT individually and must be properly documented in SOPs or other RRT agreements/plans. Triggers which may be considered prior to a potential RRT

activation could include the number of ill persons or deaths, possibility of incident escalation, severity of the health hazard, etc.

RRT Response – RRT response activities, other than RRT Activations, to incidents with increased potential public health risk. These do not include routinely scheduled regulatory activities and may involve a broad range of incidents, including but not limited to: human illness clusters and outbreaks, human or animal food contamination incidents with no human illnesses, requests for emergency assistance from another agency, large planned events, severe weather events, and other human or animal food emergencies. RRT Responses are those requiring enhanced coordination, communication, and subject matter expertise, and technical skills that RRT members have developed.

RRT Steering Committee – A selected number of key representatives from core RRT member agencies that provide oversight and strategic direction to the RRT (development and function). Must include at least a representative from the State Food Regulatory Agency and corresponding FDA District/Program Division Office.

Traceback –

a) The method used to determine the source and scope of the product/processes associated with an outbreak and document the distribution and production chain of the product that has been implicated in a foodborne illness or outbreak. *(Multistate Foodborne Outbreak Investigations Guidelines for Improving Coordination and Communications. Glossary - http://www.cifor.us/clearinghouse/tooldetail.cfm?id=212)*

b) The process by which the origin or source of a cluster of contaminated food is identified. *(Council to Improve Foodborne Outbreak Response (CIFOR). Guidelines for Foodborne Disease Outbreak Response, 2009. Appendix 1: Glossary - http://www.cifor.us/documents/CIFORGuidelinesAppendices.pdf)*

Traceforward – The determination of where an implicated food product was shipped, sold, or distributed from the location under investigation, starting with the source and tracing the product forward to the consumer through each point of service. This process is often used during a product recall and can be useful in outbreak investigations.

C. List of Reference Documents

	References (including "Related Documents")	Chapter(s)
1	Council to Improve Foodborne Outbreak Response (CIFOR). *Guidelines for Foodborne Disease Outbreak Response.* Atlanta: Council of State and Territorial Epidemiologists, 2014. http://www.cifor.us/CIFORGuidelinesProjectMore.cfm	WWOA, FERP, Training
2	Committee on the Control of Foodborne Illness. *Procedures to Investigate Foodborne Illness, 6th Edition*. Des Moines: International Association for Food Protection, 2011. http://www.foodprotection.org/publications/other-publications/	Traceback
3	Fla. Stat. §500.033. (2016). http://leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0500-0599/0500/Sections/0500.033.html	WWOA
4	National Association of State Departments of Agriculture. *Emergency Response Plan – Food Emergency Template, Version 4.0*, 2011. http://www.nasda.org/File.aspx?id=4065	FERP
5	Re-establishing the Food Safety and Defense Task Force, North Carolina Executive Order of the Governor No. 38 (Dec. 23, 2009). http://www.foodsafetytaskforce.nc.gov/documents/Executive_Order_2009-2013_1.pdf	WWOA
6	Outbreak Coordination and Investigation Workgroup, National Food Safety System Project. *Multistate Foodborne Outbreak Investigations Guidelines for Improving Coordination and Communication,* 2001. http://www.cifor.us/clearinghouse/tooldetail.cfm?id=212	WWOA, FERP
7	Smith, K., Miller, B., Vierk, K., et al. "Product Tracing in Epidemiologic Investigations of Outbreaks due to Commercially Distributed Food Items - Application, Utility, and Considerations." October, 2015. http://www.cifor.us/clearinghouse/uploads/Product%20Tracing%20in%20Epidemiologic%20Investigations.pdf?CFID=42475325&CFTOKEN=78980292&jsessionid=6BF72ED79E866E9079E8077EE94664B6.cfusion	Traceback
8	Treadwell, Randy J.; 2014 International Food Protection Training Institute (IFPTI) Fellowship in Food Protection: Factors Influencing Multi-Jurisdictional Collaboration within State Food Emergency Rapid Response Teams (RRTs). https://3fxgnc3uy9ywv72fc3hj7rdd-wpengine.netdna-ssl.com/wp-content/uploads/2016/11/JTreadwell-Article.pdf	WWOA
9	US Department of Health and Human Services. *ESF #8 Pre-Scripted Mission Assignments (PSMAs).* Washington, DC: Last updated August, 2012. http://www.phe.gov/Preparedness/planning/playbooks/rdd/Pages/subtask.aspx	ICS
10	US Department of Homeland Security. *Food and Agriculture Sector Specific Plan: An Annex to the National Infrastructure Protection Plan*. Washington, DC: 2010. https://www.dhs.gov/publication/nipp-ssp-food-ag-2015	Training, Joint Insp./ Investig.

11	US Department of Homeland Security. *Homeland Security Presidential Directives (HSPDs)*. Washington, DC: Government Printing Office, 2007. http://www.gpo.gov/fdsys/pkg/CPRT-110HPRT39618/pdf/CPRT-110HPRT39618.pdf	ICS
12	US Department of Homeland Security. *Presidential Policy Directive (PPD)-8: National Preparedness*. Washington, DC: 2011. https://www.dhs.gov/presidential-policy-directive-8-national-preparedness	ICS
13	US Department of Homeland Security. *National Emergency Communications Plan*. Washington, DC: 2014. https://www.dhs.gov/publication/2014-national-emergency-communications-plan	Comm SOPs
14	US Department of Homeland Security. *National Preparedness Guidelines*. Washington, DC: 2011. https://www.fema.gov/media-library/assets/documents/16886	FERP, Training
15	US Department of Homeland Security. *National Response Framework*. Washington, DC: 2016. https://www.fema.gov/national-response-framework	FERP, Training
16	US Department of Homeland Security. Federal Emergency Management Agency. "Incident Command System." Accessed 22 May 2017. https://www.fema.gov/incident-command-system-resources	ICS
17	US Department of Homeland Security. Federal Emergency Management Agency. "National Incident Management System (NIMS) Courses." Accessed 22 May 2017. https://training.fema.gov/nims/	Comm SOPs, ICS
18	US Food and Drug Administration. *Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations.* June, 2006. https://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm075005.htm	Traceback
19	US Food and Drug Administration. *FDA Emergency Operations Plan, Version 2.0.* Silver Spring, MD: 2014. https://www.fda.gov/downloads/emergencypreparedness/emergencypreparedness/ucm230973.pdf	ICS
20	US Food and Drug Administration. *FDA-State Communication Field Management Directive (FMD-50).* Silver Spring, MD: 2011. https://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm056669.htm	Comm SOPs
21	US Food and Drug Administration. *Investigations Operations Manual (IOM).* Silver Spring, MD: 2017. http://www.fda.gov/ICECI/Inspections/IOM/default.htm	Comm SOPs, Traceback
22	US Food and Drug Administration. *Manufactured Foods Regulatory Program Standards (MFRPS).* Rockville, MD: 2016. https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf	FERP, Training
23	US Food and Drug Administration. *Regulatory Procedures Manual (RPM).* Silver Spring, MD: 2014. https://www.fda.gov/ICECI/compliancemanuals/regulatoryproceduresmanual/default.htm	Comm SOPs

24	US Food and Drug Administration, Division of Human Resource Development. "Training Curriculum for State, Local & Tribal Regulators: Level 1." Rockville, MD: 2006. https://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm119027.htm	Training

D. About the RRT Program

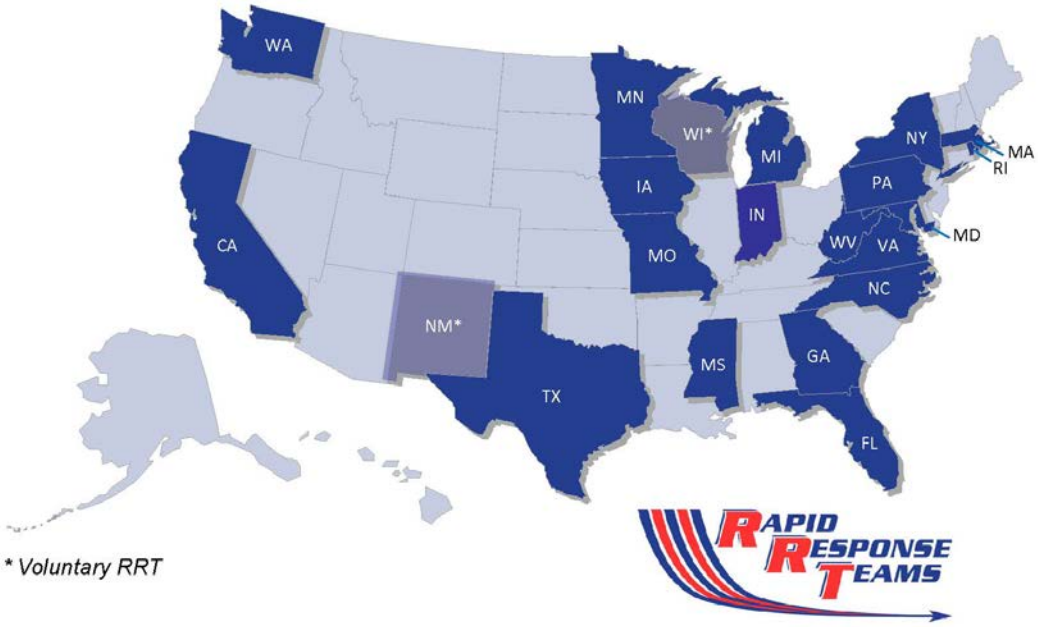
The FDA Rapid Response Team (RRT) Program is multi-year cooperative agreement in which FDA partners with States to form and maintain RRTs. These cooperative agreements require RRTs to engage partners across disciplines and jurisdictions to build core capabilities and explore innovative approaches to response.

The following states were selected in 2008 and 2009 as "Pilot RRTs": CA, FL, MA, MI, MN, and NC began in 2008 and TX, VA, and WA began in 2009. Each pilot was provided funding and works with FDA through the years to improve state food program infrastructure through the FDA Manufactured Food Regulatory Program Standards (MFRPS) and to develop, implement, and exercise an all-hazards food and foodborne illness RRT concept, incorporating ICS, to respond to incidents in the farm-to-fork continuum. Since 2009, the RRT Program has welcomed ten new awardees and two voluntary (non-funded) RRTs. These RRTs implement and build upon the best practices and lessons learned identified by the pilot RRTs.

The Requests for Application (RFA) to which the selected RRTs applied for initial and continuation funding can be found online at the following web addresses:

- 2009 Version: http://grants.nih.gov/grants/guide/pa-files/PA-09-183.html
- 2011 Version: http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-11-013.html
- 2012 Version: http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-12-014.html
- 2013 Version: https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-13-006.html
- 2015 Version: https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-15-020.html

A map of RRTs for the 2016-2017 grant year is below.



To learn more about the RRT Program, please visit our webiste: https://www.fda.gov/ForFederalStateandLocalOfficials/ProgramsInitiatives/ucm475021.htm. For additional information, contact the FDA Office of Partnerships at OP.Feedback@fda.hhs.gov.

The 2017 Rapid Response Teams (RRT) Best Practices Manual
- List of Contributors -

Rapid Response Team (RRT) States & FDA Field Offices

California: CA State, San Francisco District, Los Angeles District; **Florida:** FL State, Florida District; **Georgia:** GA State, Atlanta District; **Indiana:** IN State, Detroit District; **Iowa:** IA State, Kansas City District; **Maryland:** MD State, Baltimore District; **Massachusetts:** MA State, New England District; **Michigan:** MI State, Detroit District; **Minnesota:** MN State, Minneapolis District; **Mississippi:** MS State, New Orleans District; **Missouri:** MO State, Kansas City District; **New York:** NY State, New York District; **North Carolina:** NC State, Atlanta District; **Pennsylvania:** PA State, Philadelphia District; **Rhode Island**: RI State, New England District; **Texas:** TX State, Dallas District, Southwest Import District; **Virginia:** VA State, Baltimore District; **Washington:** WA State, Seattle District; **West Virginia:** WV State, Baltimore District; **Wisconsin:** WI State, Minneapolis District

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The 2013 Rapid Response Teams (RRT) Best Practices Manual
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9 Pilot Rapid Response Team (RRT) States & FDA Field Offices

California: CA State, San Francisco District, Los Angeles District, Pacific Region
Florida: FL State, Florida District, Southeast Region
Massachusetts: MA State, New England District, Northeast Region
Michigan: MI State, Detroit District, Central Region
Minnesota: MN State, Minneapolis District, Central Region
North Carolina: NC State, Atlanta District, Southeast Region
Texas: TX State, Dallas District, Southwest Import District, Southwest Region
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