CHAPTER 12
ENVIRONMENTAL SAMPLING AND RECORDS COLLECTION

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1.0. PURPOSE

This document provides a template for Rapid Response Teams (RRTs) to create standard operating procedures (SOPs) for conducting human and animal food investigations, including 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 demonstrate 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.

2.0. SCOPE

This chapter primarily focuses on environmental sampling and records collection as part of the investigations involving bacterial (such as *Salmonella*, *Listeria* or *E. coli O157:H7*) and non-bacterial (such as viruses and 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 guidance: (https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm).

3.0. RESPONSIBILITY

3.1. Steering Committee/Guiding Members Responsibilities

To build a RRT sampling team; a RRT Steering Committee, Guiding Members, or Emergency Response Coordinators (ERCs) may want to consider the following:

- **Team Information**
  - Identify a list of individuals with job titles that may serve on a RRT sampling team (i.e. roster) and include the depth at each team position.
  - 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.

- **Development of SOPs and Policies**
  - Consider how to structure a sampling team to meet investigative goals and where this would fit if the Incident Command System (ICS) is implemented.
  - Discuss preparation, coordination, sampling techniques, and post-sampling activities (for example, see FL: Environmental Sampling Operating Procedures posted in FoodSHIELD).
  - Consider compatibility with other agencies and mutual agreements such as the Partnership for Food Protection (PFP) Food/Feed Testing Laboratory Best Practices Manual.
  - 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.
  - Determine triggers and activation procedures for the team (i.e. analytical results, epidemiology, or investigational evidence will necessitate sampling).

- **Identifying Equipment Needs**
  - 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. An ongoing dialogue should be used to determine if agencies have complimentary equipment or if similar equipment can be used if needed.
  - 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 dates of supplies often.

- Determine logistical needs such as packing/delivering the sampling kits to the sampling team (if necessary).

- **Assignment Details and Coordination**
  - Provide assignment background and briefing to team members (i.e. past violations, causative agent, and facility layout).
  - Deploy the team:
    - Identify the participants, assignment details, and roles and responsibilities.
    - Coordinate with the RRT sampling team to provide instructions as needed for sample collection, transportation, and appropriate laboratory receiving protocols.
  - Coordinate with other agencies (Community Health, FDA, other state agencies, State/Federal Food Emergency Response Network (FERN) laboratories, etc.) to determine what to collect, sample size, laboratory capacity to analyze, etc.. Including:
    - Is the laboratory able to run the number of samples collected?
    - Is the laboratory accredited to run the type of test needed?
    - Are there special requirements for the type of sample?
    - What are the chain-of-custody requirements?
    - When are samples arriving at the lab?
    - What is the timeframe to release the analytical results?

- **Post Sampling Response**
  - Provide notifications to regulatory partners that may have jurisdiction of the product sampled.
    - Internal - within the agency
    - External agencies
    - Affected firm(s)
  - Initiate and coordinate response activities.
    - Coordinate communication with internal and external partners (if necessary) to cover issues such as:
      - Regulatory contact information for those involved
      - Reports of alleged illness associated with the samples
      - Jurisdiction or lead agency
      - Joint investigation, traceback, environmental assessment, or sampling plans
      - Pre-established procedures for Chain of Custody needs for each agency
      - Enforcement, corrective action (i.e. recall, Reportable Food Registry (RFR), etc.), and recovery plans
      - Press talking points or press point of contact
  - 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 two or three 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, which could make it less practical to carry out aseptic sampling.

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).

- **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:
  - Manages communications between the sampling team prior to sample collection (i.e. hold a pre-meeting conference call, review procedures, review forms, serves as the point of contact between the sampling team and the firm, etc.).
  - Manages communications among multiple teams under the same outbreak response, if necessary.
  - Notifies the laboratory personnel of quantity and types of samples and when they may arrive.
  - Ensures sampling supply kit delivery, pickup, or transport to sampling site.
  - Ensures the team has the necessary equipment and forms for the assignment.
  - Prepares sample labels prior to sample collection. Prepares for contingencies regarding sample labeling.
  - Reviews the firm’s file and map of the facility (if available) to identify sampling sites.

- Ensures all significant sites are sampled and that minimum sample quantities are met per sampling assignment or laboratory requirements.
- Ensures timeliness of sample delivery to the laboratory.
- Ensures chain-of-custody is maintained throughout the entire sampling assignment.
- Prepares a summary of daily activities.
- Communicates final laboratory results to the firm, if appropriate.

- **Sampler (or Collector)**
  - Identifies sampling site (considers location, type, and number of samples to be collected).
  - Aseptically collects samples (don sterile gloves, use sterile equipment, and sterile Whirl-Pak® bags or other sterile containers).
  - Ensures collection of necessary control samples to send to the laboratory.

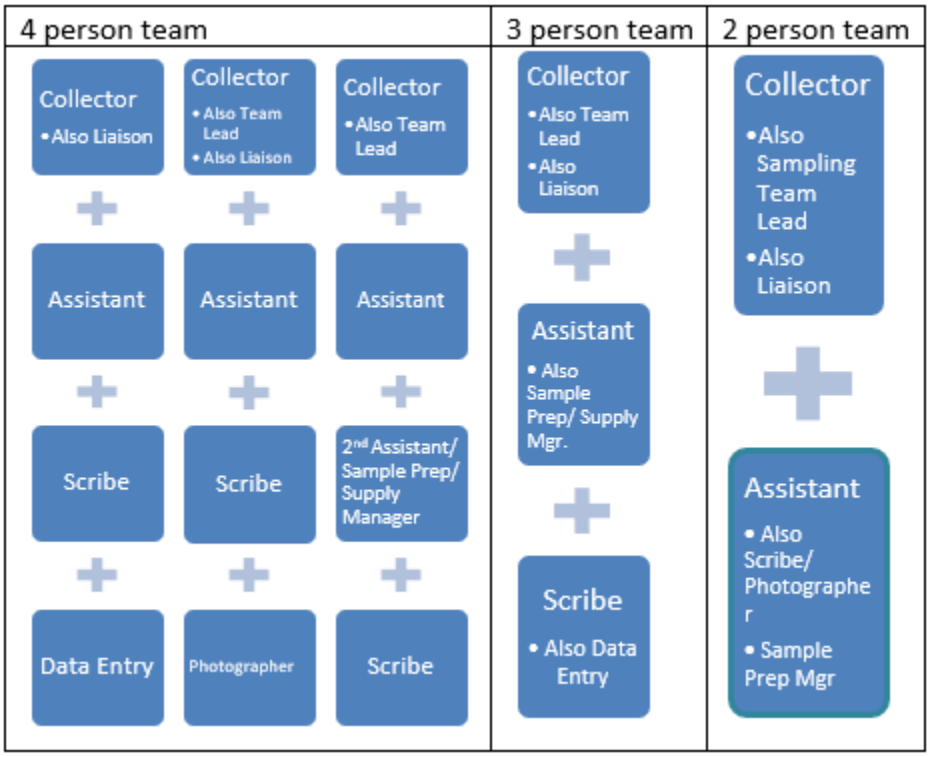
- **Assistant (Handler, Sample Preparation/ Supply Manager)**
  - Dons sterile gloves.
  - Assists the Sampler with donning gloves.
  - Prepares and presents sampling implement to Sampler.
  - Prepares and presents sterile container (e.g., Whirl-Pak® bag) to the Sampler.
  - Labels samples and all sterile containers.
  - Seals samples and places them in cooler.
  - Manages sample preparation area, sample storage, supplies and waste disposal.
  - Verifies that all samples are labeled correctly (match each sample with the report, coordinate with scribe to ensure accurate sample/subsample number).
  - Packs and ships samples; maintains chain of custody.

- **Scribe (Documenter or Recorder)**
  - Verifies and records sample identifier, temperature, time, sampling implement, and sampling location on sample submission form.
  - Takes photographs of each sample locations/collection.
  - Takes Global Positioning System (GPS) readings (using GPS units or cameras with GPS capabilities) of each sample collection when appropriate.
  - Completes sample record and sample submission form (for an example, see FL RRT's Scribe Sheet, posted in FoodSHIELD [1]).

[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.

- **Other Roles**
  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.
    - **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.
    - **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.
    - **Photographer**: A photographer may be assigned to capture the photographic evidence for the sampling assignment. This helps to alleviate the workload of the scribe.
    - **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.
    - **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.).
    - **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:
        - Keeping the Incident Management Team (IMT) informed.
        - Ensuring sample numbers on samples match the Scribe Sheet before and after entering data.
        - 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.



4.0. DEFINITIONS

- **Lot –** A single grouping of manufactured or processed goods that is identified with a single lot code.
- **Non-funded Rapid Response Team (RRT) –** A RRT that is not receiving funds through the FDA RRT cooperative agreement program.
- **Rapid Response Team (RRT) –** The group of state and federal partners associated with each RRT. This team is responsible for developing and implementing improved rapid response to human and animal food incidents.
- **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 inspectorate division.
- **Sample –** A single container of a collected substance submitted for analysis labeled with a unique identifier.
- **Sampling Kit –** A prepared collection of sampling supplies and equipment that is ready-to-go. This kit should undergo periodic preventive maintenance to ensure all supplies are not expired, with consideration towards interoperability with RRT investigative partners.
- **Subsample ("Sub") –** The FDA's term for one or more containers of product collected under a single sample number. An FDA sample represented by a

single number routinely consists of multiple subsamples or “subs”. Other agencies use a single identifier for each individual container.

- **Swab or sponge –** Generic term for a specialized tool for collecting pathogens that has been wiped over a surface and submitted for analysis.
- **Whirl-Pak® bags –** Sterile plastic bags used to transport samples to the laboratory.

5.0. 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), 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 the 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
- 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/OII investigators (http://www.accessdata.fda.gov/Videos/ORA/Sampling-11-05-09-508.wmv).

6.0. SAFETY

See Section 8.9.

7.0. 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).

- **Routine Equipment –** It is the responsibility of each agency to order and maintain sampling equipment for sampling assignments.
- **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,

[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.

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).

- **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. Most 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).

8.0. 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.

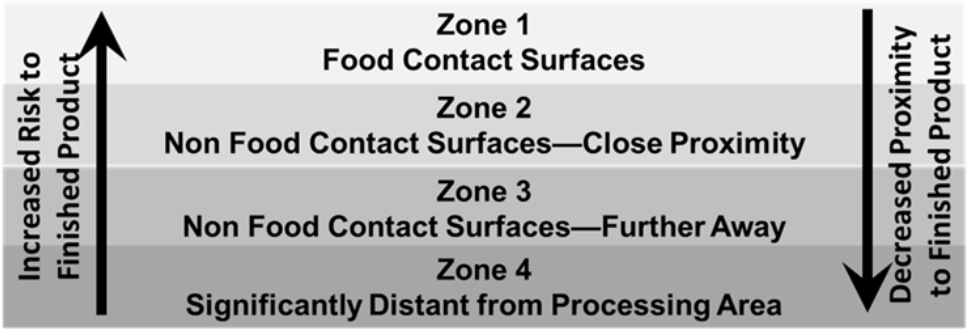
8.1. Sampling Zones (Specific to Processing Operations)

This section was primarily obtained from the October 2014 FDA Food Products Inspectorate Bulletin 30 Food Program Area – Instructions for Environmental Sampling (see FoodSHIELD for a copy of Bulletin 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 to see 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. 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 the 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 an 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

Sampling for *Salmonella*

Salmonella survives well in low moisture environments, especially those that are dry for long periods of time and occasionally get wet. For *Salmonella* detection, all environmental samples should be taken from Zones 2 and 3. Generally Zone 1 areas are unproductive for *Salmonella* 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 *Salmonella*; 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 *Salmonella*, 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, forklift wheels, etc.). Sample collectors should pay attention to the collection of floor sweepings or the dry contents of vacuum cleaner bags or tanks because items that have more exposure to floor surfaces yield frequent positives for Salmonella.
- 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 if 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 (*Listeria* is a common pathogen in drains)
- Pallet jacks, fork lifts, carts, dollies, etc.

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* most 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, fork lifts, carts, dollies, etc.
- Door gaskets to coolers and freezers, and damp insulation around pipes

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.

Currently, 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, assigning a sample identifier and applying a sample sticker to the bag and clearly label as 'Control'. Additional controls must be submitted for each lot, the 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 assignment details as well as your servicing lab(s) prior to collection.

8.4. Sponge/Swab Sampling

Most environmental samples should be collected using either handheld 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.

- **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.
  - 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.
  - Samplers should label the sterile bag containing the Sponge-Stick® with appropriate reference information.
  - 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.

- 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.
- The Sampler should massage the Sponge-Stick® from the outside of the bag to facilitate absorption of the D/E neutralizing broth.
- 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.
- 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.
- 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).
- 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.
- 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.
- 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.
- 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-Stick® at a point below the thumb stop; allowing the sponge to drop into the excess D/E neutralizing broth in the Whirl-Pak® bag.
- 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.
- Discard any used sterile gloves in the sample team trash bag.
- 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:
    - Between every sub when sampling Zone 1 Food Contact Surfaces, during an outbreak follow up, or if sampling is "for cause"
    - When sterility may be compromised (i.e. touching clothing, area you are sampling, equipment, floor, non-sterile surfaces, or if glove is damaged)
    - When sampling a lower numbered Zone after a higher numbered one (i.e. collecting a Zone 1 sample after collecting a Zone 2 sample)
    - Sanitize gloved hands between every sub when sampling in Zones 2-4.
- Collected samples must be placed in a dedicated cooler with ice packs to keep samples cold but not frozen.
- 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.
- 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 hour restriction. It is imperative that the RRT coordinates with the laboratory before deviating from standard protocols.

- **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 like 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.

- **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 in 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.

- Sampler's hands should be washed and sanitized thoroughly before beginning to collect sample(s).
- Aseptically, a sterile glove is placed on the hand used for swabbing.
- 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.
- 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.
- 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.
- After completion of swabbing, the swab is returned to its tube.
- 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.
- Collected samples should be placed immediately in a dedicated cooler with ice packs to keep samples cold but not frozen.
- 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.

- **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:

  - Moisten a dry sponge with sterile water, sterile saline, or sterile phosphate buffer (any of these are acceptable).
  - Swab the surface.
  - 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.

- **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 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 because 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 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. *Salmonella* tends to be more difficult to detect in a contaminated plant vs. *Listeria* and a greater number of samples are needed for *Salmonella* environmental sampling to have confidence in negative findings.

- ***Salmonella* Sampling**

  Collect at least 100 subsamples and ideally 300 subsamples if possible, depending on facility size and process complexity.

- ***Listeria* Sampling**

  Collect at least 50 swabs and ideally 100 or more subs if there are enough 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, and sample type, collector information, analytical laboratory, analysis requested, and analytical findings
- 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 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.

- **Documentation of Collected Samples**

  To further document environmental sampling activities, the data elements contained within an “Environmental Sample Collection Record" spreadsheet should include:
  - Date/Time and Outbreak name in the record's header.
  - Manufacturer’s lot numbers of control samples.
  - Detailed documentation of environmental samples.
  - Information on whether the sample was taken from a Food Contact Surface (FCS) in addition to the zone number the sample was collected from, if applicable.

- Photo file name captured by the digital camera for each sample.
- Signature of person delivering samples to the laboratory, or an authorized person at the shipping location on the bottom of each record.
- 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.
- Documentation linking sample number to the location of each sample taken on the facility map (investigation site).
- 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.

- **Photo Documentation**

Digital photographs should be taken of each sampling location: one from afar to capture the view of the room and one close to show the exact location where the sample was taken. All photographs should be stored at the end of each day in 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

- **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 sampling team (e.g. packaging of sampling materials) must all be removed by the team and disposed of appropriately off-site.

- **Garments**

    - Clean pants and shirt shall be worn to the investigation site and on each day of the investigation.
    - 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 sampling team should be ready with their own supply of clean clothes or lab coats.
    - 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).

- **Onsite Packing**

    Samples must be closed, sealed, labeled, and double bagged (in sterile bags) to establish chain of custody, and then they may be grouped in packs of 10-15 subs into large, labeled zip-top bags. 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 ensure that the samples are not in contact with water or coolant.

- **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 fieldwork. During a response, RRTs should review all facility safety requirements and inquire about any site-specific hazards during their 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 their surroundings 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 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 or 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. Throughout 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 the 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 the Food Safety Modernization Act (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).

9.0. 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

- Review the steps identified in the RRT FERP Chapter which are appropriate for agencies interested in developing any RRT Capacity.
- 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.

[3] U.S. Food and Drug Administration (FDA) Investigations Operations Manual (IOM) http://www.fda.gov/ICECI/Inspections/IOM/default.htm

- 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).
- Use information from exercises and actual responses to assess the cost/benefit of developing a higher environmental sampling and records collection capacity level.

10.0. RELATED DOCUMENTS

See FoodSHIELD Website[4]

- RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Sampling, Subfolder: FL ES Documents.
  - FL: ICS Check List for Environmental Sampling.
    - File name: FL_ICS Roles_Responsibilities_FDACS_V4_May 2015.pdf
  - FL: RRT Scribe Sheet.
    - File name: FL_Scribe_Log_Sheet_FIMSversionMay2015.pdf
  - FL: Environmental Sampling Information Handout.
    - File name: FL_ES_Handout_Operators_June2014.pdf
  - FL: Environmental Sampling Operating Procedures.
    - File name: FLIRRT_ESprotocolMay2015.pdf
  - FL: Environmental Sampling – Competency Requirements for Staff.
    - File name: FL_Environmental Sampling ComptencyLevel_V2.0May2015.pdf
- RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Sampling, Subfolder: MI Sampling Resources.
  - MI: Sample Kit Equipment Usage Guide
    - File Name: MDARD Sample Kit Equipment Usage Guide.doc
  - MI: MDARD Environmental Sampling Fact Sheet for Industry
    - File Name: MDARD Environmental Sampling Fact Sheet for Industry.doc
- RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Sampling.
  - FDA Field Alert 41 - Collecting Surveillance Samples on Farms
    - File name: FA41-On Farm Sample Collection_Nov2014.docx
  - FDA Division of Field Investigations Bulletin 30 (2014) – Food Program Area – Instructions for Environmental Sampling.
    - File name: DFI Field Bulletin_Oct2014.pdf.
- RRT Program Workgroup, Folder: Best Practices Manual.

[4] FoodSHIELD website information: https://www.foodshield.org/. Note that access to the related documents is limited to personnel participating in the RRT Program.

- Communications Chapter of this RRT Best Practices Manual
- ICS Chapter of this RRT Best Practices Manual
- Training Chapter of this RRT Best Practice Manual

11.0. REFERENCES AND OTHER RESOURCES

- CalFERT Manual v. 5-5 (2017)[5]
- FDA Investigations Operations Manual: Chapter 4[6]

12.0. ATTACHMENTS

- Attachment A – Sample Equipment List
- Attachment B – Michigan Dept. of Agriculture and Rural Development Environmental Sampling Fact Sheet for Industry
- Attachment C – Suggested Resources to Inform RRT Chain of Custody Procedures
- Attachment D – Examples of Generic and Commodity Specific Questionnaires

13.0.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)
3.0	R	6/1/2023	ORA/OP-AFDO Compiled Revisions
4.0	R	12/1/2024	ODP-AFDO Compiled Revisions

*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.

[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

3.0 – AFDO compilation for 2023 Edition of RRT Manual
4.0 – AFDO compilation for 2025 Edition of RRT manual. Updated FDA program names resulting from the 10/2024 FDA reorganization.

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 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 the 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/ODP/DDPCI Coordination and Integration 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 Inspections and Investigations (OII) HFP/OLOAS Food Labs/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).
    - 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 OII 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": https://www.fda.gov/media/71878/download
    - 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.
    - 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 Inspections and Investigations (OII) Outbreak Response Field Guides:
  - http://www.fda.gov/ICECI/Inspections/ucm211781.htm
- FDA Farm Investigation Questionnaire (Nov. 2014):
  - https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/guide-produce-farm-investigations-1105
    Also available in FoodSHIELD, RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Investigations and Traceback, Subfolder: Revised FDA FIQ (2014)
- Colorado Integrated Food Safety Center of Excellence (see 'Toolbox'):
  - https://coloradosph.cuanschutz.edu/research-and-practice/centers-programs/foodsafety
- 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
  - Available in FoodSHIELD, RRT Program Workgroup, Folder: Examples and Sharing, Subfolder: Investigations and Traceback, Subfolder: FDA Environmental Assessment Process Overview

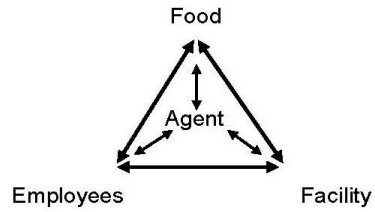
Attachment D-1 – Food Establishment Environmental Assessment Quick Reference Tool for Foodborne Illness Investigation (Not Routine Inspections)

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

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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

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.	