RAW BEEF PRODUCT SAMPLING

Objectives

To demonstrate mastery of this module, you will

1. Identify the pathogen of concern for raw beef products.
2. Select from a list those raw beef products subject to sampling.
3. State where to find FSIS raw beef product sampling instructions.
4. Explain the steps of raw beef product sampling.
5. Describe how to determine which raw beef product to sample.
6. State how sample results are received.
7. State when to mail samples to the FSIS laboratory.
8. List the actions associated with positive pathogen results.
9. List the requirements for transportation of raw beef product which has tested positive or presumptive positive for a pathogen.
10. Explain the IPP responsibilities for review of establishment sampling data.

Introduction

Throughout the history of meat and poultry production, various pathogenic bacteria have caused food borne illness. FSIS works with other governmental agencies, industry, and consumer groups to set policy and establish performance standards to reduce or eliminate pathogens from meat and poultry products.

CDC Estimates - The Centers for Disease Control and Prevention (CDC) estimates that there are approximately 175,905 domestically acquired foodborne illnesses associated with all Shiga toxin-producing *E. coli* (STEC) annually (Scallan et al, 2011). *E. coli* O157:H7 is the most well known STEC and, according to the CDC, annually is responsible for approximately 63,153 (36%) of the domestically acquired foodborne STEC illnesses. The remainder of the illnesses associated with STEC (112,752 or 64%) are caused by non-O157 STEC. While more than 50 non-O157 STEC serogroups have been associated with human illness, 70 to 80 percent of confirmed non-O157 STEC illnesses are caused by six STEC serogroups – O26, O45, O103, O111, O121, and O145. These illnesses can be equivalent in severity to those caused by *E. coli* O157:H7. In the U.S, at least one outbreak and several sporadic illnesses from non-O157 STEC serogroups have been associated with ground beef products. In 2012, FSIS began testing beef manufacturing trimming from cattle slaughtered on-site after June 4th for six non-O157 STECs.

Hazard Analysis - *E. coli* O157:H7 is a food safety hazard that establishments need to consider in their hazard analysis if slaughtering, receiving, grinding, or otherwise processing raw beef products. Controls for *E. coli* O157:H7 should be adequate for non-O157 STEC, therefore, establishments do not have to consider non-O157 STECs in their hazard analysis unless sampling history or other information indicates they are a hazard reasonably likely to occur.

Positive Product is Adulterated - Non-intact raw beef products such as ground beef or mechanically tenderized beef, which are contaminated with *E. coli* O157:H7 or one of six non-O157 STECs (O26, O45, O145, O103, O111, and O121) are adulterated. Intact raw beef products contaminated with *E. coli* O157:H7 that are intended to be processed into non-intact products are also adulterated. Establishment records and HACCP documents such as the hazard analysis should identify the intended use of intact raw beef products. Beef manufacturing trimmings are an example of an intact raw beef product that is intended to be used for non-intact product such as ground beef.

Purpose of Sampling - An objective of FSIS's verification sampling program is to test for *E. coli* O157:H7 (and for some products, six non-O157 STECs) and as a result, stimulate industry actions to reduce the presence of that pathogen in raw beef products.

FSIS microbiological sampling programs are part of **FSIS verification activities** to ensure the protection of public health. HACCP systems integrate science-based controls into food production processes. These controls must be combined with some means of verifying that meat and poultry establishments are achieving acceptable levels of food safety performance. Sampling programs are designed to verify that HACCP systems are effective in controlling harmful microorganisms in meat and/or poultry products. Establishments may also include a microbiological sampling program in their HACCP system in order to verify that the system is performing as intended, that is, controlling, reducing or eliminating the identified food safety hazards.

FSIS also protects public health by keeping pace with changes, such as emerging pathogens, new products and processes, and new laboratory analyses methods. FSIS is continuously improving its sampling protocol and techniques, updating sampling and testing programs, and developing more rapid means of reporting results.

FSIS Policy - FSIS directives contain policy details specific to sampling projects and programs (see Attachment 1). Policy changes rapidly; amendments and new issuances are developed to keep you informed. You are responsible for properly selecting products and using appropriate sample collection techniques

to ensure the integrity of samples received by the laboratories. You must review the updated resources *each* time you take a sample. You should review new issuances when they are issued. New policy often requires that IPP meet with establishment management to discuss the information, and those awareness meetings must be documented in a Memorandum of Interview (MOI).

FSIS Directive 10,010.1, Verification Activities for *Escherichia coli* O157:H7 in Raw Beef Products contains key concepts and instructions regarding the testing of raw beef products for *E. coli* O157:H7. These include:

- Collecting and submitting samples of raw ground beef, and other non-intact raw beef products and intact beef products intended for use in raw ground beef products,
- FSIS actions after an *E. coli* O157:H7 positive sample result,
- Verifying *E. coli* O157:H7 positive product disposition when product is shipped to a renderer, landfill operation or another federal establishment,
- Procedures for follow-up sampling after an *E. coli* O157:H7 positive sample result,
- Responsibilities related to establishment generated *E. coli* O157:H7 samples, and
- Verifying instructional and disclaimer statements on labels.

FSIS Notice 47-13, Verification Testing for Non-O157 Shiga toxin-producing *Escherichia coli* (Non-O157 STEC) under MT60, MT52, and MT53 sampling programs, contains instructions on testing for non-O157 STEC under the MT60, MT52 and MT53 programs. Again, it is important that you review new issuances when they are issued because the policy related to sampling and testing will continue to change.

Terminology

Alternative Lot

When an establishment meets specific criteria regarding its own robust sampling program, FSIS may agree to sample from a lot of reduced size, such as single combo bin, as long as the alternative lot represents normal production. Collect samples from the alternative lot following applicable instructions outlined in FSIS Directive 10,010.1.

Recall
A recall is an establishment's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). "Recall" does not include a market withdrawal or a stock recovery.

Product that is adulterated and has left the establishment's control may be subject to a recall. The Recall Management Staff (RMS) is notified immediately if product has left the establishment's control. The DO notifies the RMS (see FSIS Directive 8080.1, "Recall of Meat and Poultry Products"). RMS coordinates all recall activities including issuing a press release and having effectiveness checks performed. The press release has the product name, lot number and the supplier. The recall would involve at least the sampled lot, but the scope of the recall could be expanded depending upon a review by the RMS of all production factors and establishment's control measures in place within the operation to limit potential contamination exposure. All recalls of meat and poultry products are voluntary. Raw beef products produced on the shift represented by the positive sample could be subject to voluntary recall. If the raw beef product, e.g., rework, was used as an ingredient in other raw product formulations, those secondary products could also be subject to recall. If the positive product was used as an ingredient in cooked products or other further processed products, the FSIS Recall Committee evaluates the situation and proceeds on a case-by-case basis.

Sample
A sample for raw products is a collection of product, such as ground beef, beef trimmings, bench trim, and AMR product that represents a larger amount of product (e.g., the sampled lot). A sample unit is an individual package or portion of product. It may take several sample units to make up one sample, depending upon the amount needed for the analysis.

Sampled lot
The sampled lot is the amount of product represented by the sample tested for *E. coli* O157:H7. The establishment defines the sampled lot. "Cleanup-to-cleanup" may be a part of the procedures that the establishment has in place to distinguish one portion of production from another portion of production. "Cleanup-to-cleanup" may be an effective means of preventing *E. coli* O157:H7 cross contamination between raw beef products during production. However, "cleanup-to-cleanup" without other supporting documentation **may not** be adequate to distinguish one portion of production from another (i.e., "cleanup-to-cleanup" is not a stand-alone reason for distinguishing between segments of production because *E. coli* O157:H7 is source material contaminant).

Factors or conditions that may determine the sample lot include an establishment's:

- Use of a scientific, statistically based sampling program for *E. coli* O157:H7 to distinguish between segments of product;

- Sanitation Standard Operating Procedures (Sanitation SOPs) or any other prerequisite programs used to control the spread of *E. coli* O157:H7 cross-contamination between raw beef components during production;

- Use of processing interventions that limit or control *E. coli* O157:H7 contamination;

- Use of beef manufacturing trimmings and raw beef components or rework carried over from one production period to another production period; and

- Production of bench trim, i.e., small pieces of beef trimmings from raw intact steaks and roasts.

If multiple lots of raw ground beef product were produced from source materials from the same production lot of a single supplier, and some of this product was found positive for *E. coli* O157:H7, a scientific basis is necessary to justify why any other raw ground product produced at the grinder from the same source materials should not be considered adulterated. The use of source materials from multiple suppliers and establishment concerns related to potential recalls following a positive sample result are not a reason to not collect a sample.

General Instructions for <u>All</u> *E. coli* O157:H7 Sampling Projects

Establishment Interventions and CCPs

All samples are collected after the establishment has applied all antimicrobial interventions to the production lot, except for any microbiological testing intervention.

If the establishment intends to test the product for *E. coli* O157:H7, non-O157 STEC or virulence markers before completing the pre-shipment review, you **do not** wait for the establishment to receive the test results before collecting and sending a sample to the FSIS laboratory.

If the HACCP plan has a CCP for freezing product, such that the establishment can support that a microbiological reduction occurs, freezing may occur in the process after the establishment's microbiological testing. Under these

circumstances, you are to wait until the product passes the freezing CCP before collecting a sample.

Random Selection
All samples are selected ***randomly*** from the current day's production of the raw beef product requested. You must randomly select a day, shift, and time within the collection window start and end dates indicated in the PHIS establishment task list. In order for the sample to be representative of a lot, every attempt must be made to avoid taking a sample that is ***biased***, or non-random. There should be an equal chance that sampling will occur during all shifts that the establishment operates. You're not required to randomly select the lot, but you do have to randomly select the sample from that lot. One of the best ways to ensure an unbiased sample is to randomly select a **time** to collect the sample. You can use a random number table or generator to determine the day and time. Record the time you collected the sample in PHIS in the additional information questionnaire.

Aseptic Sampling
Samples must be collected using aseptic sampling technique. An aseptic technique implies that you do not add any organisms to the sample when it is collected. You want to assure that the sample is not contaminated with extraneous microorganisms from the environment, hands, clothing, sample containers and sampling devices.

For raw beef products collected in their final package (intact), such as ground beef, you are to clean and sanitize your hands before collecting the sample. For non-intact samples, such as beef manufacturing trimmings and bulk packaged ground beef products, you are to clean and sanitize your hands to the mid-forearm and put on sterile gloves before collecting the sample. The only items that should contact the external surface of the sterile glove on the sampling hand are the sample being collected and the sterile sampling equipment. You **must** put the samples collected from product packaged in institutional or bulk containers in the **sterile** Whirl-Pak® bags. Answer the questions on the additional information questionnaire in PHIS. Raw beef samples collected for *E. coli* O157:H7 sampling must be submitted to the laboratory in either the supplied sterile Whirl-Pak® bag or the establishment's final packaging, or else they will be discarded.

Sample Security and Shipping
You must safeguard the security of the samples when preparing, storing, packaging, and mailing the sample to the FSIS laboratory. Samples are to be sent to the laboratory the same day they are collected, or as soon as the overnight courier service is available.

Use the following guidelines:

- Samples collected before Federal Express pickup Monday through Friday should be held refrigerated until shipped that same day.
- Samples collected after Federal Express pickup Monday through Thursday should be held refrigerated overnight and shipped the next day.
- Samples collected during the weekend (after Federal Express pickup Friday through Sunday night) should be frozen and shipped on Monday. Note: If Monday is a holiday that Federal Express does not pick up samples, they may be held frozen until shipping on Tuesday.
- The only time a frozen sample is collected is when the establishment has a CCP for freezing. If the establishment has a CCP for freezing, the sample you collect is frozen and must be kept frozen.

Samples not meeting the above shipping criteria will be discarded upon receipt at the laboratory.

Steps in Sampling

There are 5 steps in product sampling.

1. Determine which product to sample
2. Notify establishment management
3. Collect the sample
4. Pack and mail the sample and form
5. React to the results

Step 1: Determine which Product to Sample

When directed sample request tasks are sent to the establishment task list they will be specific to the type of product to be collected. The project code and the raw beef product or category is specified in the task name, for example “MT43 – Risk-based *E. coli* O157:H7 Sampling of Raw Ground Beef or Veal Products” or “MT60 – *E. coli* O157:H7 Sampling of Beef Manufacturing Trimmings”. More information about the sampling project code can be found in FSIS Directive 10,210.1, including special collection information.

To assist you in determining which product to sample, you need to be familiar with the establishment’s processes and know how the finished product is labeled. Before collecting a sample, review the FSIS Notices and Directives covering that

sample type or program. The sample request may have additional instructions in PHIS in the sample management- sample collection screens.

Sampling Project Codes
The routine sampling project codes for *E. coli* O157:H7 testing at domestic establishments are:

- **MT60** – Routine Testing of Domestic Raw Beef Manufacturing Trimmings
- **MT55** – Routine Testing of Bench Trim, Derived from Cattle Not Slaughtered at the Establishment
- **MT54** – Routine Testing of Domestic Components Other than Trim at Federal Establishments
- **MT43** – Routine Testing of Raw Ground Beef in Federal Establishments

MT 60 - Beef Manufacturing Trimmings that are Sampled from Cattle Slaughtered at the Establishment

MT60 is the sampling program for **beef manufacturing trimmings**. Beef manufacturing trimmings are trimmings produced from cattle (including veal) that are slaughtered onsite, that is, at the establishment where the MT60 sampling is occurring. Beef manufacturing trimmings includes trim of any size; or primal/subprimal cuts, like chucks, rounds, or shanks; or boneless beef of any size, in any packaging. The MT60 sampling project covers any trim that is used at the slaughter establishment for non-intact use, or is intended for raw non-intact use by other establishments.

The purpose of the MT60 beef manufacturing trimmings program is to assess the food safety controls the slaughter establishment has in place to address Shiga toxin-producing *Escherichia coli* (STEC) in the cattle it slaughters. MT60 test results reflect the effectiveness of the establishment's slaughter and dressing operations because the trim is from cattle slaughtered onsite.

In limited cases, beef manufacturing trimmings will be sampled at sister processing establishments that fabricate trim for their supplying sister slaughter establishments (FSIS Directive 10,010.1).

If the establishment commingles the beef trimmings with beef product processed at other establishments, collect the sample before the establishment commingles the product.

Randomly select only one type of trim to collect for each sample. Refer to FSIS Notices for further guidance on how to randomly collect beef manufacturing trimmings.

Do not collect samples of beef manufacturing trimmings from production lots that are going to be further processed into ready-to-eat products or from lots of commingled beef manufacturing trimmings produced at **different** establishments.

To determine the intended use of the products, review establishment records and HACCP documents such as flow charts, and hazard analyses. In cases where the establishment documents are unclear about the intended use, FSIS will sample the trimmings.

Note: FSIS replaced the project code MT50 with project code MT60 in May 2012, to reflect changes to the statistical elements of the sampling design and to facilitate data analysis. FSIS will eventually update previous policy issuances to reflect the new project code. In the interim, follow instructions related to MT50 sampling when conducting MT60 sampling. Refer to FSIS Notices 69-13, 47-13, and 22-12 for a more detailed description and sampling frequency for the testing program.

MT55 - Bench Trim or Beef Manufacturing Trimmings that are Sampled from Cattle NOT Slaughtered on-site at the Establishment

Generally, the same type of beef trimmings are sampled under the MT55 sampling program as under the MT60 sampling program. However, MT55 samples are from beef trimmings the establishment intends for use in raw ground beef or other raw ground beef products collected from cattle **not slaughtered** at the establishment. The purpose of the MT55 project is to verify the further processor's food safety procedures for STEC, for example, purchase specifications, or antimicrobial interventions. In addition, unlike the MT60 sampling program, if the establishment commingles beef trimmings from cattle it slaughtered with bench trim derived from cattle slaughtered at another establishment, those commingled beef trimmings **are** subject to sampling under the MT55 sampling program.

To determine the intended use of the products, review establishment records and HACCP documents. In cases where the establishment records and HACCP documents are unclear about the product's intended use, the bench trim (beef

trimmings) will be considered for use in raw ground beef products and other non-intact raw beef products.

Do not collect samples of bench trim from production lots that are going to be given a full lethality treatment, e.g., further processed into **ready-to-eat (cooked) products** at the establishment or at another official establishment.

MT54 - Raw Ground Beef Components and Beef Patty Components OTHER than Beef Manufacturing Trimmings that are Sampled

Raw ground beef and patty components other than beef manufacturing trimmings subject to FSIS sampling for *E. coli* O157:H7 under the MT54 program are intact or non-intact beef products intended for manufacturing into ground beef products identified in §319.15(a), (b), or (c). Such products include raw beef esophagus (weasand) meat, head meat, cheek meat, beef from AMR systems, and lean finely textured beef (LFTB), partially defatted chopped beef (PDCB) and partially defatted beef fatty tissue (PDBFT).

Note: A beef AMR system is a mechanical process separating skeletal muscle tissue from bones of cattle other than skulls or vertebral column bones of cattle ≥ 30 months of age that meets the requirements in 9 CFR 318.24. Establishments may label the resulting product from beef AMR systems as “beef”.

Note: LFTB, PDCB and PDBFT are low temperature rendered products. The lean is removed from fat or very fat trimmings using heat or in the case of beef fatty tissue a centrifugation, drum drying process.

You only collect samples of raw ground beef **components** or raw beef patty **components** other than beef manufacturing trimmings that are intended for use in raw ground beef and other raw non-intact beef products **that were produced from cattle slaughtered at the establishment**.

To determine the intended use of the products, review establishment records and HACCP documents. In cases where such documents are unclear about the intended use or consumer, or the establishment lacks control measures to ensure that the product is used as intended, handle the product as if it were for use in a ground beef product or other raw non-intact raw beef product.

When you receive a directed sampling request task for the MT54 sampling project code, you choose among the products produced at the slaughter establishment by following the priority list below. For example, if the establishment produces product from AMR systems (#1 on the list) on the day of

collection, you are to take a sample of it; if not, you are to collect low temperature rendered beef (#2 on the list) if it is available, and move down the list until there is an available product.

1. Product from AMR (Advanced Meat Recovery) Systems
2. Low Temperature Rendered (LTR) Beef (lean finely textured beef--LFTB and ammoniated LFTB)
3. Partially Defatted Beef Fatty Tissue (PDBFT)
4. Partially Defatted Chopped Beef (PDCB)
5. Weasand Meat
6. Head Meat
7. Cheek Meat
8. Heart Meat

When you receive subsequent directed sample request tasks for the project code MT54, start at the top of the list and continue down the list choosing the **NEXT** item on the list that is produced by the establishment on day the sample is collected. Select a different component than previously collected, i.e., rotate between products when possible.

If the establishment commingles components with beef product processed at other establishments, you need to collect the sample before the establishment commingles the product.

Do not collect samples of components from production lots that are going to be further processed into **ready-to-eat products** at that establishment or another official establishment. The low temperature rendered products, (for example LFTB, PDBFT and PDCB) are often added to the formulation of ready-to-eat products. If any of the components listed above such as heart meat, cheek meat or head meat are send to a retail store, these products should be sampled because the official establishment no longer has control over the intended use.

Do not collect 2 piece chucks when sampling components other than beef manufacturing trimmings under the MT54 project code. Two piece chucks are sampled under the MT60 sampling program because the definition for beef manufacturing trimmings includes “trimmings from sub-primal cuts such as 2 piece chucks, boneless chuck, or other primal/sub-primal/boxed beef parts of boneless beef.”

Ammoniated Beef Products that are Sampled

Some establishments inject gaseous ammonia into low temperature rendered (LTR) beef products such as partially defatted chopped beef (PDCB), lean finely

textured beef (LFTB), and product known as boneless lean beef tissue (BLBT)) to raise the pH of the product rapidly. Ammoniated beef products are typically intended as a component of raw ground beef and beef patty products. These products are produced from beef trimmings. The beef trim is warmed to partially melt and loosen the fat portion from the lean portion. The warming allows the connective tissue to be removed and also the edible fat portion can be separated from the lean beef using centrifugation. The edible fat portion can be further processed. The partially rendered beef trimmings are ground into a slurry. The sinew (tendon) and connective tissue are removed from the lean tissue in a subsequent step by forcing the slurry through a "desinewer." The lean beef slurry is then ammoniated with gaseous ammonia to rapidly raise the pH to produce the antimicrobial effect. The ammoniated lean beef portion is rapidly frozen on a drum freezer, broken into chips, and sprinkled with pelleted CO_2. Some processes then grind these chips and compress them into 60 lb blocks using high hydrostatic pressure. The freezing and compressing steps typically provide an additional antimicrobial effect when combined with ammoniation. Production of ammoniated lean finely textured beef from beef trimmings can be done in less than 20 minutes. Scientific studies have demonstrated that raising the pH of the product can reduce *E. coli* O157:H7 to an undetectable level in beef manufacturing trimmings.

When you receive a directed sampling request task for the MT54 sampling project code in establishments that produce ammoniated (pH enhanced) beef products, you are to sample the ammoniated product after it passes the final antimicrobial treatment. If a slaughter establishment produces other beef products in addition to the ammoniated beef products that can be sampled under the MT54 sampling program, sample the ammoniated beef products as LTR beef products in the priority list on the previous page. When you receive a sample request task for the MT54 sampling project code at a processing (non-slaughter) establishment that produces ammoniated beef products, sample that product.

MT43 - Raw Ground Beef Products that are Sampled

Raw ground beef products are subject to FSIS sampling for *E. coli* O157:H7 under the MT43 program. Raw ground beef products are described in the standards of identity for ground and chopped beef (9 CFR 319.15(a)), hamburger (9 CFR 319.15(b)), or beef patties (9 CFR 319.15(c)). They include:

- ground or chopped beef or veal;
- hamburger;
- beef or veal patties;
- beef or veal patty mix; and

- similar ground beef or veal products made with added seasonings or ingredients.

Sampled products may ***contain*** components such as beef derived from AMR systems, LFTB, or PDCB.

When an establishment produces multiple ground beef products and you receive subsequent sample request tasks for project code MT43 in PHIS, unless a specific product is requested, collect a sample from a different product than you submitted with the previous sampling task.

You **are** to collect samples from products that contain a mixture of ground beef and non-beef species (for example, beef and pork patty mix), **unless** the product is labeled in a manner to show that beef is not the predominant meat or poultry component. For example, "Beef Patty Mix, ground pork added" (ingredients: beef, water, pork, corn syrup and seasonings) would be subject to sampling because beef is the predominant species in the product. You are also to collect samples from products that contain seasonings.

Do not sample the ground beef product if the establishment only repacks intact packages and does not expose the product to the environment; for example, if the establishment removes product from bulk containers and breaks the bulk product it into consumer ready packages. Ground beef products intended to be further processed into **ready-to-eat products**, or products made with ground beef but subject to a different standard of identity than in §319.15(a)-(c), such as meatballs, meatloaf, beef sausage (§319.140), and fabricated steaks (§319.15(d) **are not** subject to *E. coli* O157H:7 sampling.

Step 2: Notify Establishment Management

Establishment management must be notified before a sample of its raw beef product is taken. Prior notification enables management to hold the product represented by the sample pending test results. Since the establishment must hold the lot, it needs sufficient time to make the necessary arrangements to do so. You need to give the establishment enough advance notice so the sampled lot may be held but not enough time for the establishment to alter the production process. Always identify the reason why you are taking the sample when you notify the establishment. Inform establishment management that it is responsible for supporting its basis for defining what product is represented by the sample.

The purpose of FSIS sampling is to verify the establishment is producing unadulterated product, not to interfere with the establishment's operations. **You need to be knowledgeable concerning the establishment's production practices.** Give establishment management 1 day's notice before you collect a

sample if that's enough time for the establishment to hold the sampled lot or less than 1 day's notice if it does not cause a hardship to the establishment. However, after becoming familiar with the establishment's process, you may realize that 1 day's notice before collecting a sample is not adequate time for the establishment to hold all of the product represented by the sample. You may provide 2 day's notice, if necessary.

If the establishment requests more than 2 days' notice prior to collection of the sample, consider the establishment product and process flow. The District Office or the Policy Development Staff (PDS) should be contacted for guidance before allowing more than 2 days' notice You should discuss the notification and time frames with establishment management ***prior*** to any sample requests being received in order to have a notification protocol in place when a sample must be collected.

Each time you collect samples tested for adulterants such as STECs, verify that establishments are holding or controlling product per the instructions in FSIS Notice 07-13. When you collect the sample, record in PHIS whether the product is held on-site, off-site under company control, or not held. If an establishment does not hold or maintain control of product, immediately contact the District Office.

Step 3: Collect the Sample

Collecting Beef Manufacturing Trimmings, 2-Piece Chucks, and Primals and Sub-primals

Follow the general sampling instructions outlined in this handout, e.g., randomly collect a sample (day, shift and time for routine sampling) using aseptic technique from one production lot after all of the establishment's interventions except for a microbiological testing intervention within the 30-day sampling window. The exception is now the MT60 samples will have a 60 day window. The N60 method is used for sampling various raw beef cuts **intended for use in raw ground beef products**.

The N60 method is used for sampling:

- Beef manufacturing trimmings,
- 2-piece chucks,

- Primal/sub-primal cuts (e.g., rounds, briskets, etc.) when the establishment (or another establishment) intends to grind the entire cut into ground beef, and
- Raw beef products when the **intended use is unclear** (includes primals or sub-primals in which the establishment is unable to identify whether the final end product will be intact (steaks and roasts) or non-intact product (ground beef products).

Before sampling, be sure you have the proper supplies. A plastic caddy, sharp boning knife, hook, sterile gloves and sterile sampling bag are needed for the N60 sampling procedure. It is critical that the knife used for sampling be kept sharp and properly steeled for collecting samples. Also available from the FSIS laboratories, are disposable sampling surfaces (for locations where samples are not collected and cut in the combo bin or where an easily sanitized surface in the production area is not available), cut resistant mesh gloves, sampling templates and sanitizable clips which can be used to clip the wire at the top of the sampling bag to either the top of the combo bin or the edge of the sampling caddy during collection. The Whirl-Pak® sampling bags have a gusseted bottom (flat bottom) which allows the bags to stand without a rack or stand to hold them up. This allows you some assurance that the bag will be anchored in place while samples are cut and that the sampling bag will remain standing while sample pieces are placed in the bag.

You are to sanitize the caddy, knife, and hook before collecting the samples by using the establishment's sanitizing solution according to label instructions. If the establishment uses hot water only, then use hot water to sanitize sampling equipment.

You may order small bottles of sanitizing solution from the FSIS Laboratory, if needed to sanitize the caddy, knife, hook or clip. Use sterile gloves and handle all sanitized surfaces so that they do not become contaminated. To use the mesh glove in an aseptic manner when collecting samples, you place the sterile glove over the mesh glove.

Collect samples by using the N60 method of sample collection (as described below).

- If a specific production lot is composed of greater than 5 containers of beef manufacturing trimmings, 2-piece chucks, primal or sub-primal cuts or bench trim, randomly select 5 containers for sampling; and
- If the specific production is composed of 5 or less containers, use the table below for sampling.

Number of Sample Pieces to Collect Per Container

# of containers in each specific production	*# of sample pieces to select from each container*
5	12 pieces
4	15 pieces
3	20 pieces
2	30 pieces
1	60 pieces

Note: If the establishment has its own *E. coli* O157:H7 testing program and meets the alternative lot definition criteria on page 12, the sample pieces may come from one container, e.g., combo bin or box.

Aseptically collect the appropriate number of pieces of beef trim, 2-piece chucks, primal or sub-primal cuts, or bench trim based on the number of containers that represent one specific production period. Use the sanitized hook to reposition and anchor a piece of meat at the top of the container. For larger pieces of meat, a curved boning knife and short boning hook may work better than the standard meat inspection hook and straight boning knife.

Cut off a slice of the surface that is approximately 3 inches long by 1 inch wide and 1/8 inch thick from each of the 60 pieces of meat. The priority is to collect samples from pieces of product taken from the original external surface of the beef carcass (this is the outside surface of the carcass when it is first dehided). **You must make every effort to ensure that at least 60 thinly (approximately 1/8 inch thick) excised external surface tissue samples are included in the sample.** Using the sampling template to lightly score the surface in 2 parallel cuts approximately 1 inch apart and 3-4 inches long may facilitate obtaining the appropriately sized sample piece. For raw ground beef components, IPP are to use the Whirl-Pak® bag, but the fill line will not apply. When sample collection is completed, each bag will hold the equivalent of 325g of product. For beef manufacturing trimmings, each bag will hold 30 pieces. The laboratory will analyze the contents of one or two bags and hold a third bag as a reserve in case of a need to conduct additional analysis on positive samples. IPP are to use only the laboratory supplied Whirl-Pak® bags for submitting these samples. Do not use any other bag, for example a zip-top bag.

The 60 pieces that are 3 inches long by 1 inch wide and 1/8 inch thick should weigh approximately ¾ lb (325g ± 10%). Place a total of 30 pieces in each of the first 2 bags for a total of 60 pieces.

In addition, you are to collect available smaller pieces of beef manufacturing trimmings or bench trim from the same specific production lot and place this product in the third Whirl-Pak® sample bag. You do not need to cut or trim the

pieces to any particular dimension or count the pieces. You can just grab smaller pieces. However, you need to collect pieces with as much external surface area as possible. Cut larger trim pieces so they fit in the bag. Leave at least 2 inches of space at the top of the bag to prevent leakage. The total weight of the 3 bags of samples should be approximately 2 pounds. Do not under- or over fill the bag.

Collecting Bench Trim

Bench trim (sampled under the MT55 project code) may include beef trimmings from boning carcasses, boning primal parts, and the secondary trimming of primals and subprimals resulting in small or large pieces, or any other beef cuts designated for use in ground beef product derived from cattle **NOT** slaughtered on site at the establishment.

Follow the general sampling instructions outlined in this handout, e.g., randomly collect a sample (day, shift, and time for routine sampling) using aseptic technique from one production lot after all of the establishment's interventions, except for a microbiological testing intervention within the 30-day window.

If the establishment produces **large pieces of bench trim** derived from carcasses or primals and sub-primals, you are to sample product using the N60 sampling procedure described above when taking samples under project code MT55. If the establishment produces bench trim derived from primals and sub-primals such as steaks, roasts or other cuts designated for non-intact use that are too small to be sampled using the N60 sampling procedure, just collect three grab samples aseptically up to the fill line for each of the 3 Whirl-Pak® bags.

Note: If an establishment produces both large pieces of bench trim derived from primals and sub-primals and small pieces of bench trim derived from trimming steaks, roasts and other cuts, you are to sample only the product that can be sampled using the N60 sampling procedure. If the establishment commingles both types of trim, you are to collect samples from the product that lends itself to N60 sampling procedure described above.

Collecting Raw Ground Beef and Beef Patty Components OTHER than Beef Manufacturing Trimmings

Follow the general sampling instructions outlined in this handout, that is, randomly collect a sample using aseptic technique from one production lot after all of the establishment's interventions except for a microbiological testing intervention within the 30-day sampling window.

For component types that you can collect using a grab sample, such as AMR product or low temperature rendered products, you would collect 3 grab samples and fill up the fill lines of each of the 3 Whirl-Pak® bags. If you are sampling larger components, such as hearts, you can collect one or more pieces to fill each of the 3 bags. Leave at least 2 inches of space at the top of each Whirl-Pak® bag to avoid overfill and leakage incidents.

Always place samples taken aseptically from bulk packaged raw ground beef components in sterile Whirl-Pak® bags provided by the laboratory, not ordinary zip-top bags.

Training for the N60 Sampling Procedure

The N60 sampling collection procedure outlined in your handout is the same as the method shown in the training posted on the FSIS intranet at the following website.

https://inside.fsis.usda.gov/fsis/emp/static/employee/training/eLearning/eLearning.jsp

If you perform the N60 sampling procedure, you must complete the training. You are to complete the training as soon as practical before collecting samples. The training video has been captioned and streamed so that it will run on the FSIS intranet; *InsideFSIS* (see attachment 2 in FSIS Directive 10,010.1 for instructions on accessing the training). After reviewing the training, participants must pass a 10 question exam with a score of 70% or better to receive credit for the course.

NOTE: The Agency will allocate up to one hour of official time (code 01 time) for you to complete the requisite training.

The Center for Learning in the Office of Outreach, Employee Education and Training will track the individuals who take the training and provide a list to the Office of Field Operations. If you have problems accessing the course, or need to request a CD with the training, contact the Center for Learning through this Outlook e-mail address: FSISAgLearn@fsis.usda.gov.

Collecting Raw Ground Beef Products

Follow the general sampling instructions outlined in this handout, that is randomly collect a sample using aseptic technique from one production lot after all of the establishment's interventions, except for a microbiological testing intervention within the requested sample task start and end dates.

You are to collect a 2 lb sample of ground beef product from the current day's production in final packaged form (whenever possible). You are to put the product in its final packaging in the larger, non-sterile bag provided with the sampling supplies. Collect the appropriate number of packaged products so that the sample equals two pounds. For example, 2 1-pound packages may be included in the larger, non-sterile bag. If product in final packaging is not available, aseptically collect a 2 lb sample using 3 Whirl-Pak® bags to the fill-line. By filling all 3 bags to the fill-line, this will equal 2 pounds. When an establishment produces multiple raw ground beef products, the IIC should oversee sampling procedures to ensure that a different product within the requested product type is sampled each time a sample request form is received.

You may receive a request to collect a raw ground beef product sample for *E. coli* O157:H7 testing under the MT43 sampling program at the following monthly rates:

- Up to 4 times within a calendar month for establishments that produce greater than 250,000 lbs of ground beef product per day from the estimated production volumes calculated in PHIS up to 3 times within a calendar month for establishments that produce between 50,000 to 250,000 lbs of ground beef product per day from the estimated production volumes calculated in PHIS

- Up to 2 times within a calendar month for establishments that produce between 1,000 to 50,000 lbs of ground beef product per day from the estimated production volumes calculated in PHIS

- Generally, no more than once within a calendar month for establishments that produce less than 1,000 lbs of ground beef product per day from the estimated production volumes calculated in PHIS. FSIS will ensure that these establishments are sampled at least once per quarter.

When more than 1 sample is scheduled to be collected during a month, you are to randomly select a day, shift, and time to collect each sample. You can collect a maximum of two samples per day as long as each sample corresponds to a microbiologically independent and individually identifiable lot of product. However, when the establishment cannot continue to operate under the 2 sample per day frequency (e.g., because the establishment cannot fill orders and hold all sampled product) or because your workload cannot accommodate this sampling frequency, you should only collect a single sample. **You must collect at least one sample whenever a sample request task is received and product is available during the collection window start and end dates.**

Note: If an establishment ***requests*** that IPP collect more than 2 samples per day, IPP are to instruct the establishment:

- to make a request to the Risk and Innovations Management Staff (RIMS), Office of Policy and Program Development via http://askfsis.custhelp.com for review.
- to type "sampling" in the subject line in askFSIS.
- that the question in askFSIS should include a description of the control program that the establishment has in place that ensures microbiological independence between lots.

RIMS will review the request and consider the establishment's FSIS testing history, System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS) history, and FSIS's resources. RIMS will provide a response to the establishment as to whether the establishment qualifies to have up to 4 samples taken per day by the IPP. If you have questions about RIMS's response you may contact RIMS through askFSIS or at 1-800-233-3935 by pressing 1 and then 4.

An establishment with a sound basis for defining lots and sub-lots of raw ground beef product and has production schedules that define the specific raw ground beef components used at specific times, may request that you collect the sample at the start of operations rather than at the randomly chosen time during the day. When the establishment requests the use of this **alternative sampling method**, you are to determine if the establishment:

- has treated the source materials for the ground beef product that you intend to sample differently from other source materials used for grinding, e.g., has applied antimicrobial interventions it does not normally use on the source materials of the ground beef product you intend to sample.

- has ground the source materials distinctly different (e.g., different suppliers, different types of source materials) from those source materials it typically grinds on the day you intend to collect the sample.

If the establishment **has not** made any changes to how the source materials are treated and how it ground them and the establishment has documentation showing that a specific lot of product is scheduled to be ground at the random time you selected, you are to allow the establishment to grind that lot of product at the beginning of operations on the day that you randomly selected for sampling. At the weekly meeting, you are to discuss the alternative parameters that allow a sample to be taken at the beginning of production.

You must understand the establishment's lotting and sub-lotting practices and the establishment's standard practices for scheduling, or "staging," product the establishment grinds on production days because you **must** verify that the establishment has a sound method of lotting and sub-lotting source materials. Use the questions in Chapter 2, III. C.—Verifying Establishment Lotting and Sub-lotting— in FSIS Directive 10,010.1, to assist you in determining the establishment lotting and sub-lotting practices. The responses to these questions will determine if an establishment meets the **alternative parameters** that allow a sample to be taken at the beginning of production.

Collecting Samples in Establishments that Slaughter, Produce Manufacturing Trimmings and/or Other Raw Ground Beef Components and Grind Beef

Some establishments may produce raw beef products that are subject to different routine verification sampling programs, for example, MT43, MT60, MT54 and MT55. Therefore, you may receive **multiple** routine sample request tasks (MT60 or MT55 and MT43 or MT54) during the same 30-day sampling window. You are to complete **all** sample requests by selecting samples from independent production lots, **unless** you are only able to collect one sample (because the establishment produces 1,000 pounds or less of product on a daily basis, or only on an intermittent basis). In this situation, you prioritize by sampling the beef manufacturing trimmings under the MT60 and MT55 sampling programs using the N60 collection method.

Some slaughter establishments may grind all the beef trimmings and other raw ground beef or beef patty components they produce and not ship any beef trim or other components. In this situation, IPP are to sample the trim under the MT60 sampling program or the other components under the MT54 sampling program when they receive sampling requests with these codes.

Additional Analysis for **Salmonella** *Under the Sampling Programs for Shiga Toxin-Producing Escherichia Coli (STEC)*

Certain raw beef samples that are analyzed for STEC will now be analyzed for Salmonella, including MT43 (raw ground beef product), MT60 (beef manufacturing trimmings), MT55 (bench trim), MT54 (other raw ground beef components), and follow-up sampling. IPP are to inform the establishment that all samples analyzed for STEC will now also be analyzed for Salmonella. However, the establishment only has to hold and control lots until the results for STEC are received.

Collecting Supplier Information at the Time of Sample Collection

In accordance with FSIS Notice 06-13, IPP are to record source material and supplier information **when they collect a sample** of ground beef product (MT43) or bench trim (MT55) or any follow-up sampling for these sampling programs (MT44, MT52, or MT53) to be submitted to the FSIS laboratory for *E. coli* O157:H7 testing. IPP are not to wait for a confirmed positive test result before they gather the supplier information as stated in FSIS Directive 10,010.1. These new instructions will better serve FSIS's goal to respond to FSIS presumptive positive results by identifying all affected product and all potential suppliers as quickly as possible to protect public health.

When ***the establishment produced the source materials in-house*** that were used in the production of the sampled lot, you are to obtain and record the following information.

- Establishment name and number,
- Lot numbers or slaughter dates,
- Production dates including slaughter production days if available,
- Name of the beef components used in the production of the sampled product (e.g., beef trimmings, subprimal cuts, beef hearts, veal trimming, weasand, head or cheek meat) or any information that identifies the material, such as product labeling if used, and
- Approximate amount of the beef component produced in each lot (in lbs).

When the establishment uses ***source materials from another domestic establishment (outside source)*** to prepare the sampled lot, you are to obtain and record the following information.

- Establishment name and number that produced the source materials,
- Establishment phone number,
- Establishment point of contact (name, title, e-mail address, and fax number),
- Supplier lot numbers,
- Production dates,
- Name of the beef components used in the production of the sampled product, or any information from the label of the product that identifies the source material used, and
- Approximate amount of the beef component produced in each lot (in lbs).

Note: You can keep the actual label from empty packages.

If the ***source materials are imported from a foreign establishment***, you will need to gather additional information (country of origin, foreign establishment

number, shipping mark, I-house, and bar-coding or other information to aid in identifying the product as outlined in FSIS Notice 06-13).

You document source material and supplier information in a ***memorandum of interview (MOI)*** and maintain the MOI in the official file. Provide a copy of the MOI to establishment management. You also make a note of any information that the establishment is unable to provide in the MOI. If the sample is reported as presumptive positive, notify management of the presumptive positive as soon as possible.

Also, when collecting for STEC record the sample source as:

- Veal;
- Beef; or
- Mixed (beef and veal, or beef or veal and other species).

This information will be recorded in PHIS when completing the sampling task.

PHIS Hands-on Activities

Collection of Supplier Information

The situation: Robert Barclay, an IPP at Groveton, has collected a MT43 sample - "Routine Sampling for *E. coli* O157:H7 in Raw Ground Beef Patties" and must document the supplier information in an MOI.

Overview
In this hands-on learning, Barclay:

- Acquires the supplier data for the product that was sampled from the establishment
- Records his findings in an MOI
- Schedules a meeting with establishment management to confirm his findings
- Confirms his findings at the meeting and finalizes the MOI

Information needed for Hands-on

- Barclay has determined that Groveton does not have their own sampling program.
- Today's Lot 9225B was produced entirely from beef trimmings purchased from Open Beef, Establishment Number M38581

Barclay observed that beef trimmings for the raw ground beef patties were from 2 combo bins of a 5 combo bin shipment:

- Received from Open Beef
- Labeled "Beef Trimmings, 90/10, 2-9-2012"
- Net weight 2122 lb
- A production lot number was stamped on the combo bins, "020912B".

1. Log in to PHIS as Robert Barclay

2. From the left Navigation Menu, click on Inspection Verification, then Select Establishment, and select Groveton Meats

3. Click on Memorandum of Interview in the Navigation Menu

4. On the MOI List, click the Add MOI link

5. On the Memorandum of Interview (MOI) page - the Status tab:

a) Use today's default Meeting Date as the date you plan to meet with establishment management

b) Select the planned meeting time

6. On the Memorandum of Interview (MOI) page, go to the Issues tab.

a) Enter the example Sample Form Number 100006478

b) Leave the reason for the MOI blank

c) Enter the following supplier information in the Comments field

Supplier Information

- Establishment: Open Beef, M38581
- Supplier phone number: 707-845-2145
- Supplier point of contact: Frank Lutz
- Supplier production lot: 020912B
- Production date: 2/9/2012 (assumed)
- Beef components used: beef trimmings
- Amount of the beef component produced/lot: 2,122 lbs.
- 2 combo bins of a 5 combo bin shipment
- Bill of lading # 15677

7. On the Issues tab

a) Click the Save button, then click Cancel

The MOI List page is presented

b) Click the Print icon for the MOI

The MOI will open in another window for review or printing

8. On the window showing the MOI:

a) Close the window showing the MOI

b) Sign out of PHIS

Meeting Info

Barclay meets with Groveton's management to share the MOI. He will return to PHIS to add the information provided by management during the meeting, in

order to have an official record. He shows a copy of the MOI to the establishment management in order to confirm accuracy, and then he finalizes the MOI.

Log in to PHIS as Barclay

9. From the left Navigation Menu, click on Inspection Verification, then Select Establishment, and select Groveton Meats

10. Click on Memorandum of Interview on the Navigation Menu

11. Find the MOI you created to capture the supplier information

12. Click the edit icon

13. On the Memorandum of Interview (MOI) page, go to the Issues tab:

14. Enter pertinent information provided by plant management during your meeting in the Comments field:

    Plant management (Jeff Irvine) provided the following information:
    - Confirmed supplier information, including that Open Beef was the sole supplier of the lot that was sampled for *E. coli* O157:H7
    - Groveton is holding the production lot on-site
    - Lot 9225B is the only lot of raw ground beef product that Groveton produced on (today)
    - There was no rework used in this lot nor any rework saved from it and a complete cleanup was done before and after the sample was taken

Finalize MOI

15. Check the Finalize box

16. Click the Save button

17. On the MOI List page

    a) Select the Print icon in order to create a record

    b) Click the "Save" button to save it as a PDF to your laptop's Desktop

       Include the Sample ID number in the file name for future reference

    c) Close the window showing the MOI

    d) Sign out of PHIS

Step 4: Packing and Mailing the Sample

On the day of sample collection, you will enter sample collection data and additional product info in PHIS, click "submit to lab" to submit the Sample Analysis Request Form electronically to the laboratory, and then you will print and sign the form and include it with the sample, in the sample shipment container. If the lab receives a sample with missing or incomplete paperwork, or if the sample is the wrong type of raw beef product, the lab ***will*** discard the sample. Also, if the lab receives an insufficient amount of product to perform the specified analyses, the sample is discarded (see Attachment 2 for discard reasons). Be sure the identification on the sample and the paperwork match, otherwise the lab will discard sample.

All samples received by the lab ***without*** a collection date are discarded.

The Sample Collection Data and Additional Information screens in PHIS for microbiological pathogen samples will have specific questions depending on the product requested. All requested data must be accurately recorded; otherwise the lab will discard the sample. For example, PHIS may ask for the date collected, the date sent to the lab, the product temperature, whether product was held by the establishment management, and whether the sample was collected in the final packaged form. There will be a question regarding with product is veal or beef. Other data requested may include the raw beef component sampled, the production volume, the shift, or other information needed for the type of sample submitted. When the form has been submitted electronically, print it out and sign it, and include the printed copy in the sample container.

One or more individually identified samples may be submitted in a shipping container. Follow the instructions in FSIS Directive 7355.1, "Use of Sample Seals for Program Samples and Other Applications." You may need to include additional cooling packages in the shipping container to keep the sample or samples cool during transportation. To submit multiple samples, you may request larger boxes from the laboratory identified by sending an e-mail message to their e-mail addresses on page 9 of this handout. If you include more than one sample in the shipping container, include one of the identifiers (bar code) for the other sample on the Container Seal, 7355-2A. This lets the lab know that there are multiple samples in the box. The labs will discard them if it is not clear which sample goes with which sample form.

Double-check and compare the address on the expanded billable stamp to make sure it is going to the lab indicated in PHIS and on the sample form. The lab will discard the sample if you mail it to the wrong lab.

The shipping containers you receive should have the top and bottom sealed by the lab with tamper-evident tape. You will ***not*** receive any tamper-evident tape to use. If the tape is cut or missing, ***do not*** open the container. Follow the instructions in FSIS Directive 7355.1 (seal it with the Container Seal, 7355-2A, and ship it back to the lab of origin for processing; complete the seal by writing "seal broken" in the "Form No." blank).

Pack the sample in this order.

1. Absorbent pad
2. Gel pack
3. Cardboard separator
4. Sample with paperwork (all in a zip-top bag)
4. Foam plug
5. Close the shipper with seal (7355-2A – Container Seal)

To ensure the product is maintained at refrigeration temperature, place the sample in a pre-chilled shipping container with an absorbent pad and frozen gel pack, even if the sample was previously refrigerated or frozen. A piece of cardboard goes on top of the gel pack to separate it from the sample. Put a small bar code sticker from Form 7355-2 at the top center of the sample form and put the form in a plastic bag. Put another small bar code sticker on each of the bagged sample units. Put the sample and form into the larger zip-top bag and affix the Identification Label (7355-2B) to the larger bag. Note that the 7355-2B is a ***label*** rather than a seal and is simply stuck on the bag. There is no need to fold over and seal the bag with the label. The zip-top bag, containing the bagged sample and the paperwork, is put into the shipper. Filler material is ***not allowed*** in the shipping container. This means that no newspaper or paper towels should be put inside the shipping container to take up empty space. The foam plug must be pushed down as far as possible to keep the sample from being tumbled inside the shipper. Put any extra unused bar codes into the box so that the lab can account for them, or put them on the Container Seal where they won't cover any written or printed information. Alternatively, if you keep a record of the sample, you can affix the extra bar code to your record. Close up the box and seal it.

For sample integrity, a Container Seal (FSIS Form 7355-2A) must be put on the shipping container in such a way that it cannot be opened without disturbing the seal.

Raw beef product samples are mailed to the laboratory on the first available day the contract carrier picks up after collecting the sample. Samples should be shipped when collected, do not wait for the establishment to complete their pre-shipment review for the product sampled.

Double-check that the lab address in PHIS is the same as on the expanded billable stamp. If these are different, your sample will be discarded. If the lab listed is different from the one on the expanded billable stamp, e-mail the lab listed and request an expanded billable stamp from that lab. You should determine if you have a billable stamp for the correct lab when you **first** schedule the sample task, **not** when you are about to mail the sample.

Check the expiration date on the expanded billable stamp. Do not use it if it is expired.

On the expanded billable stamp, enter the establishment number, shipping date (day sample box picked up by carrier) and the establishment's phone number.

Example 1: You receive a sample request task for project code MT43. You read the information in the related directives. You note the sample collection window time frame in the establishment task list. You schedule the sample in PHIS and make sure you have the proper sampling supplies and billable stamp for the lab. On the appropriate date, you notify establishment management that you will be collecting a sample today and provide the reason for taking the sample.

You ask what products are being produced. The production manager tells you that today they are producing bulk raw ground beef in 20-lb bag; raw hamburger in 2-lb tray packs, and raw beef patty mix in 40-lb boxes. In the recent past, you had sent in samples of the beef patty mix and the bulk ground beef, which were negative for *E. coli* O157:H7. To ensure you are sampling the various products, this time you select the hamburger. You inform the production manager that you'll sample the hamburger.

At the time you go to collect the sample from the packaging line, you notify establishment management. A QC person accompanies you out to the line. You wash and sanitize your hands and then pick up a package. The QC person asks why you selected that package. You tell her it was random based on time.

You realize that you won't be able to mail the sample until tomorrow morning, so you refrigerate the sample. You put it in the retain cage in the cooler and secure it with a government lock. You collect the supplier information and document the information in a MOI. The following morning, you pack and send the sample to the FSIS lab listed on the sample request form.

Step 5: Results

Access Laboratory Information Management System (LIMS)-Direct to track your sample receipt and results. LIMS-Direct is a computer application that provides sample data electronically to FSIS program personnel. LIMS-Direct reports sample status and the results of the analyses. More information is contained in FSIS Notice 46-13.

Check LIMS-Direct each day after you submitted the sample to the FSIS laboratory. If the sample was discarded, notify the establishment immediately so it can release the product.

The first lab analysis is accomplished within two days of sample receipt. It is a screening test that identifies the possible presence of *E. coli* O157:H7 or one of the six non-O157 STEC. If the screening test is negative, *E. coli* O157:H7 is not present (or below detectable levels) in the sample tested. The negative results are posted in LIMS-Direct as "Acceptable". FSIS resumes normal sampling at that establishment.

Every FSIS verification sample that the laboratory confirms **positive for *E. coli* O157:H7** goes through three stages of analysis. If the screening test is positive, the sample is potentially positive for *E. coli* O157:H7 and additional testing is necessary to confirm the result. The laboratory reports the sample result in LIMS-Direct as a "Potential Positive". In the next stage, based on further analyses that reveal more evidence to suggest that *E. coli* O157:H7 may be present in the product, LIMS-Direct reports the sample result as "Presumptive Positive". Upon further analysis and conclusive evidence that *E. coli* O157:H7 is present in the sample, the result is reported as "Confirmed Positive". The confirmatory testing is usually accomplished within 3 to 4 days of the sample receipt at the FSIS laboratory, but can sometimes take longer.

Every FSIS verification sample that the laboratory confirms **positive for one or more non-O157 STEC serogroups** also goes through three stages of analysis. If the screening test is positive, the sample is potentially positive for one or more non-O157 STEC serogroups and additional testing is necessary to confirm the result. The laboratory reports the sample result in LIMS-Direct as a "Potential Positive". In the next stage, based on further analyses that reveal more evidence to suggest that one or more non-O157 STEC serogroups may be present in the product, LIMS-Direct reports the sample result as "Presumptive Positive". Upon further analysis and conclusive evidence that one or more non-O157 STEC serogroups is present in the sample, the result is reported in LIMS-Direct as "Confirmed Positive". The O group that was found to be positive will also be reported, for example O26 or O111. The confirmatory testing usually takes 3 to 4

days after the sample receipt at the FSIS laboratory, but can sometimes take longer.

The following table compares the different testing stages for *E. coli* O157:H7 and non-O157:

Comparison between non-O157 STEC and *E. coli* O157:H7 Testing

Stage	non-O157	*E. coli* O157:H7
Potential	Sample that causes a positive reaction with both screen tests: • stage 1 - for the *stx* and the *eae* genes and • stage 2 (concurrent with stage 1) for one or more of the target serogroup genes	Sample that causes a positive reaction with the screen test
Presumptive	Sample that has typical colonies, observed on Rainbow Agar, and reacts specifically with one or more of the target serogroup antiserum	Sample that has typical colonies, observed on Rainbow Agar, and reacts specifically with O157 antiserum
Confirmed	An isolate has *stx*, *eae*, and one or more of the target serogroup genes and has been biochemically confirmed to be *E. coli*.	Biochemically-identified *E. coli* isolate that is serologically or genetically determined to be 'O157' that meets at least one of the following criteria: 1) positive for Shiga toxin production, 2) positive for Shiga toxin gene, 3) "H7"genetically determined

Presumptive positive and positive sample results are e-mailed to establishments that have an e-mail address in the PHIS establishment profile. Negative results are not e-mailed to the establishment. **Even if the establishment receives sample result notifications by e-mail, it is still your responsibility to notify the establishment when sample results are posted on LIMS-Direct**.

Note: Positive *Salmonella* results from raw ground beef samples submitted to the laboratory under project code MT43S will not have any immediate regulatory consequences. Therefore upon receiving negative *E. coli* O157:H7 results from the same sample (MT43) you are to notify the establishment that it may release any affected product on hold. If you receive the *Salmonella* results before the *E. coli* O157:H7 results, you should wait to notify the establishment until you receive the *E. coli* O157:H7 results.

Workshop I

1. When would a ground beef sample be sent to the lab for an *E. coli* O157:H7 directed sample?

    a. the day before the “use by” date
    b. just prior to packaging
    c. as soon as the contract carrier is available after the sample is collected
    d. as soon as the lot is assembled

2. Establishment management is notified that you are taking a sample

    a. when you receive the analysis result (either from LIMS-Direct or the DO).
    b. if the establishment has a good working relationship with FSIS.
    c. enough in advance to allow the establishment to hold the product, but not soon enough to allow it to alter the process.
    d. because of the Freedom of Information Act (FOIA).

Scenario

1. You received a directed sample request on your task list for a raw ground beef or veal sample under the MT43 project code. This is the first time you have received this type of sample request.

    As a critical thinker, what do you do next?

    The instructions tell you to randomly select and aseptically collect an unfrozen two pound sample prior to freezing. The establishment receives beef trimmings and chubs of ground beef. The chubs may be added to the beef trimmings and ground, or they may be shipped without any further processing. The ground beef and beef trimmings are ground into ground beef, ground beef patties with seasoning ingredients, raw beef and pork sausage, and cooked meatloaf. The establishment has one grinder and does a complete cleaning and sanitizing of the equipment prior to the start of operations each day.

What product could you sample for the *E. coli* O157:H7 under this project?

When would you notify establishment management that you will take a sample?

What should you do after you collect and submit the sample?

FSIS Actions after a Positive FSIS or another Federal or State Entity Sample Result

FSIS Presumptive Positive Sample Result

The lab notifies the DO using BITES (Biological Information Transfer E-mail System) prior to posting the information in LIMS-Direct if the sample is presumptive positive for *E. coli* O157:H7 or one or more non-O157 serogroups, if applicable. Because the laboratory confirms most "presumptive positives", the contact person in the DO where the establishment is located alerts the establishment if the sample is "presumptive positive." This ensures that the establishment receives that important message when you are not available. The DO contact will also inform the establishment if the results are confirmed positive. Even though the establishment may already know about the presumptive positive or confirmed positive result, you are still required to notify the establishment of the presumptive positive and confirmed positive result.

Confirmed Positive Sample Result

When an FSIS laboratory or another Federal (Agricultural Marketing Service-AMS) or State entity confirms a sample is positive for *E. coli* O157:H7 or a non-O157 serogroup the DO accesses the System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS), and opens a case file for the incident. The DO enters all the supplier information you gathered into STEPS. The DO is also responsible for determining whether any of the supplying establishments were also **originating supplying slaughter establishments** that produced the source materials that were used in the raw beef product that tested positive for *E. coli* O157:H7. Follow-up samples are collected from originating supplying slaughter establishments.

With respect to supplying establishments that **are not** originating supplying slaughter establishments, the DO is to inform the IIC to collect supplier information on the source materials that went into the lot represented by the positive sample and forward the information to the DO.

Enforcement Actions Based on FSIS and Establishment Test Results

Before you can determine whether to document the positive result as a noncompliance, you need to gather information. You need to determine if the establishment has its own *E. coli* O157:H7 sampling program for its raw beef products or whether it tests for non-O157 STEC or virulence markers. If the raw beef product sample you submitted is positive for *E. coli* O157:H7 or one or more non-O157 STEC serogroups and the establishment tested the **same** product,

check the establishment's test results to determine whether it also found the sampled product positive for *E. coli* O157:H7 or one or more non-O157 STEC serogroups. If the establishment held the product or maintained control of the product (for example, the establishment moved the product off site but did not complete pre-shipment review or transfer ownership of the product to another entity) pending its own test results, and FSIS **AND** the establishment found the product positive for *E. coli* O157:H7 or one or more non-O157 STEC serogroups, you **do not** issue a noncompliance record (NR). For example, if a sample of beef manufacturing trimmings tested positive for *E. coli* O26 and the establishment tested a sample from the same lot and found it positive for *E. coli* O157:H7 you would not issue a noncompliance record because they found the product positive for a Shiga-toxin producing *Escherichia coli* (STEC) organism. Even if the type of STEC positive did not match, you would still not an issue an NR. Review previous NRs and associate this NR to the last positive, if appropriate. If the establishment has a documented procedure for diverting all product lots that are sampled by FSIS, you would not issue an NR. **However**, it is important to note that you must perform all other FSIS follow-up verifications, including **verifying that the establishment performs the appropriate corrective actions following the positive result**.

Issue an NR when FSIS finds product positive for *E. coli* O157:H7, but the establishment does not, under the appropriate HACCP Verification task, and cite §417.4(a) and §301.2 as the relevant regulations. Continuing with that HACCP Verification task, determine whether or not the establishment implements corrective actions that meet the requirements described in §417.3. Verify that the establishment has held on-site or maintained control of the affected product. In addition, if the establishment has its own testing program, review its records to determine if the establishment has found multiple *E. coli* O157:H7 positive results which would be evidence of a systemic problem. Verify the implementation of the Sanitation SOP by following the instructions in FSIS Directive 5000.4. Verify sanitary dressing procedures, if the positive result is from beef manufacturing trimming or other components produced at a slaughter establishment. If the establishment delays disposition of the positive product, you are to work with your FLS to determine how to work with the establishment to ensure proper and timely disposal of the product. When issuing the NR, review documentation to determine whether there have been previous NRs for positive product sampling, and if so consider whether it is appropriate to associate the NRs.

Establishments are expected to ship only wholesome unadulterated product. The establishment is responsible for determining what product it holds and what it determines to be affected product. (FSIS Directive 8080.1 contains more information related to affected product.) If the establishment does not control its product, then take a regulatory control action (retain product if it is available or

take a withholding action per §500.3(a) (1) if the establishment shipped the adulterated product into commerce). If any affected product has left the establishment and it is no longer under the establishment's control, notify the DO immediately. A recall may be recommended. (Documentation and enforcement will be covered in more detail in a later module.)

Establishment management must account for all affected products by identifying them and their location. The establishment must take **corrective actions** that meet one of the following requirements.

- 417.3(a) if *E. coli* O157:H7 or non-O157 (depending on the test and the result) is addressed in the HACCP plan, or
- 417.3(b) if *E. coli* O157:H7 or non-O157 (depending on the test and the result) is not addressed in the HACCP plan, or if it is addressed in prerequisite programs, or
- 417.3(b) and 416.15 if *E. coli* O157:H7 or non-O157 (depending on the test and the result) is addressed in the Sanitation SOP.

The establishment may need to conduct a reassessment of its HACCP plan or reevaluate its Sanitation SOP or prerequisite programs to meet these requirements. In addition, the establishment should reassess (§417.4(a) (3)) because something in the process has changed. Issue an NR if the establishment fails to take the appropriate corrective actions.

In addition, you will conduct follow-up sampling, per instructions later in this module. You will perform a directed Hazard Analysis Verification task to review the establishment's HACCP system. (Upon future implementation, you will also perform a PHIS Supplier Tracking task to identify suppliers.)

If product disposition is to occur off-site, verify that the establishment maintains appropriate control of the product as explained in the next section.

Off-Site Disposition of E. coli O157:H7 or non-O157 Positive Product

Raw beef products confirmed positive for *E. coli* O157:H7 or a non-O157 serogroup may be moved off-site for proper disposition, under appropriate controls. Product may be transferred to another official establishment for further processing to destroy the pathogen. Establishments may opt to dispose of the product through rendering or disposal in a landfill. Establishments may also divert product that is presumptive positive, rather than wait for a confirmation. Presumptive positive product must be controlled just like confirmed positive product. Establishments may use their own controls (company seals) or move the product under FSIS control (using USDA seals or FSIS Form 7350-1,

"Request and Notice of Shipment of MPI Sealed Meat/Poultry"). When the product is destined for a landfill or rendering operation, it moves under company controls, because FSIS representatives are not at those locations to remove USDA seals or follow up with FSIS Form 7350-1.

When the establishment moves presumptive positive or positive product off-site for disposition, verify the establishment that produced the positive product maintains appropriate control of the product at **all times**, including while it is in transit to the off-site location where the product will either be processed to destroy pathogens before entering commerce or be disposed of so it will not be used for human consumption.

When you perform a directed follow up HACCP Verification task verify that the establishment:

- Maintained records identifying the official establishment, renderer, or landfill operation that received positive product;

- Maintained control of product that was destined for a landfill operation or renderer while the product was in transit (through company seals);

  Note: If an establishment ships adulterated product to a renderer or landfill operation, you are to verify the establishment denatures the product before the product leaves the establishment (9 CFR 314.3).

- Maintained control of product that was destined for an official establishment while the product was in transit (through company seals) or ensured that such product moved under FSIS control (under USDA seal or accompanied by FSIS Form 7350-1);

  Note: An instructional "For Cooking Only" statement on the container label is not a sufficient control.

- Maintained records showing that every lot of product implicated by the positive test result received appropriate disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where disposition occurred; and

  Note: Records of receipt at an official establishment, landfill operation, or renderer **are not** adequate to show that the product received appropriate disposition. Documentation (a record) from the official establishment, landfill operation, or renderer must show that the positive product was further processed to destroy *E. coli* O157:H7 or the specific product was

destroyed. For example, this record may be a record of receipt and control pending the product receiving a lethality treatment. The record should include information necessary to identify the product, the number of pounds of raw beef product received (landfill check weights), and the number of pounds of such product rendered or destroyed.
- Completed pre-shipment review for the positive product only after it has received the records described above for that particular product.

You cannot complete the HACCP Verification Task for the specific production until the establishment completes the corrective action and documentation requirements (417.3(a) or 417.3(b) and 416.15), which includes receiving documentation from the official establishment or landfill operation or renderer that demonstrates proper disposition/disposal of every lot implicated by the positive result and conducts pre-shipment review of the corrective actions.

Note: If the product is shipped to another official establishment for disposition (for example, cooking), IPP at that establishment are to verify that the receiving establishment adequately addresses the pathogen in the product as part of their ongoing verification duties.

Issue an NR if you find noncompliance while verifying the establishment's off-site product disposition corrective actions. Document the noncompliance under:

- 9 CFR 417.3(a) if *E. coli* O157:H7 or non-O157 (depending on the test and the result) is addressed in the HACCP plan,

- 9 CFR 416.15 and 417.3(b) if *E. coli* O157:H7 or non-O157 (depending on the test and the result) is addressed in the Sanitation SOPs, or

- 9 CFR 417.3(b) if *E. coli* O157:H7 or non-O157 (depending on the test and the result) is addressed in a prerequisite program.

You should contact the DO, through supervisory channels, if the determination is made, or if questions arise about whether the establishment committed the prohibited act of selling or transporting adulterated articles in commerce (no controls) that have not been inspected and passed.

Verification Activities at an Establishment Receiving E. coli O157:H7 or non-O157 Positive Product

If you are the inspection program employee at the establishment that receives raw ground beef products, beef manufacturing trimmings, or other raw ground beef components, or raw beef patty components that tested positive for *E. coli*

O157:H7, you have certain verification functions to perform to ensure the establishment adequately addresses the pathogen in the product.

When you perform a HACCP Verification task for such products, verify that the establishment:

- documents receipt of presumptive or confirmed positive product (as per §417.5),
- maintains control of the product, and
- addresses the receipt *E. coli* O157:H7 in its hazard analysis, flow chart, and HACCP plan (which includes an adequate lethality treatment to destroy the pathogen).

You are not required to be present at the establishment to verify the disposition of the raw beef product that is positive or presumptive positive for *E. coli* O157:H7 or one of the six non-O157 serogroups. You can verify that the product received proper disposition through records review.

Note: You are to verify that the establishment has supporting documentation validating the effectiveness of the lethality treatment during the Hazard Analysis Verification task.

Note: FSIS does not require establishments to re-test product for *E. coli* O157:H7 after the establishment subjects the product to a lethality treatment adequate to destroy the pathogen.

Document all noncompliance as per PHIS FSIS Directive 5000.1.

FSIS Verification Activities at Supplying Establishments when a Raw Beef Product at an Official Establishment or Retail Facility Tests Positive for E. coli O157:H7 or a non-O157 serogroup

When raw beef products are confirmed positive, FSIS will conduct verification activities at supplier establishments, including the originating supplying slaughter establishment that produced the source materials that were used to produce the positive product. The DO will contact the IIC at **each** of the supplying establishments, including the originating supplying slaughter establishments. If you are at the ***supplying establishment***, remind the establishment that the notification is to ensure that the supplier knows that it ***could be*** the source of positive product. The IIC at the supplying establishment will ensure that a HACCP Verification Task is performed to verify that the supplier met all the

HACCP regulatory requirements (monitoring, verification, recordkeeping, and corrective actions) at all CCPs in the HACCP plan for source material production lots sent to the establishment or retail facility where the positive was found. If the establishment has its own *E. coli* O157:H7 sampling program for its raw beef products, IPP are to review establishment records to determine if it has found multiple positive results which would indicate there is a systemic problem. IPP are to verify the establishment's control of its sanitary dressing procedures during the beef slaughter Sanitary Dressing task per FSIS Directive 6410.1. In addition, perform a Hazard Analysis Verification (HAV) task to review the HACCP system.

Multiple Follow-Up Sampling After an E. coli O157:H7 or non-O157 Positive Sample Result

Each time that an FSIS routine sample or another Federal or State entity's sample of raw ground beef product, ammoniated beef product, beef manufacturing trimmings, bench trim, or ground beef or raw beef patty components tests positive for *E. coli* O157:H7 or one or more non-O157 STEC serogroups, IPP will receive a directed sample task for 16 follow-up samples to sample product from the establishment that produced the positive raw beef product. IPP will also receive a directed sample task for 16 follow-up samples when FSIS follow-up samples of beef trimmings or other raw beef patty components or ground beef test positive for *E. coli* O157:H7 **OR** when an originating slaughter establishment is the **sole supplier** or **a repeat** supplier of the source materials implicated in positive sample result. IPP will automatically receive sample requests through PHIS to sample product from the establishment that produced the positive raw beef product. In addition, IPP will automatically receive sample requests as a result of a positive follow-up test of raw ground products. All follow-up sampling at originating slaughter establishments is generated by PHIS and the Policy Analysis Staff (PAS) as outlined in the next section.

For low volume establishments, (establishments that produce less than 1000 pounds per day of the product to be sampled), **8** samples need to be collected instead of 16 samples.

The type of sample requested will be based on the type of raw beef product implicated in the positive test result. The sampling project code will identify the type of raw beef product to sample.

For instance:

- Sample raw ground beef product under the MT44 project code after a MT43 project code (ground beef product) positive result;

- Sample source materials (beef manufactured trimmings, primals or sub-primals bench trim, or ground beef/beef patty components) under the MT52 project code when the originating supplying slaughter establishment is the **sole supplier** identified as a supplier of source materials for product found to be positive 120 days prior to the date of the current raw beef product positive result, i.e., **a repeat supplier** of source material that has been implicated in a positive result.

- Sample beef manufacturing trimmings, bench trim, OR other raw ground beef or raw beef patty components under the MT53 project code after a

  - MT60 project code positive result (beef trim derived from cattle slaughtered at the establishment); or

  - MT54 project code positive result (raw ground beef/beef patty component); or

  - MT55 project code positive result (beef trim derived from cattle NOT slaughtered at the establishment); or

- Sample ground beef products under the MT53 project code after a follow-up MT44 project code positive result (ground beef product); or

- Sample beef manufacturing trimmings or ground beef/beef patty components under the MT53 project code after a follow-up MT52 project code positive result (source material from the originating supplying slaughter establishments).

Sampling from production lots produced after the positive result starts as soon as possible following receipt of the follow-up sample requests. You **DO NOT** wait for the establishment to complete the corrective actions taken in response to the positive result before conducting follow-up sampling. As soon as the establishment resumes production of the product(s) to be sampled, start your sample collection of either 8 or 16 samples at the following daily and weekly frequencies.

- Sample a maximum of 2 follow-up samples per shift per day from different lots (up to 4 samples per day for a 2-shift establishment). Follow this procedure unless the establishment cannot continue to operate under that sampling frequency (for example, cannot fill orders or hold all sampled product) or your workload will not accommodate that sampling frequency. If either of these concerns arises, discuss it with FSIS supervision immediately.

- At a minimum collect 3 samples per week unless the establishment cannot continue to operate under that sampling frequency or your workload will not accommodate that sampling frequency. If either of these concerns arises, discuss it with FSIS supervision immediately.

If the establishment is not currently producing the type of raw ground beef component requested, you are to collect a sample of another component that is available. You are to sample beef manufacturing trimmings if the establishment is producing them. If the establishment is also not producing beef manufacturing trimmings, then you are to collect a sample of another type of raw ground beef or beef patty component (for example, head meat, heart meat, or product from advanced meat recovery (AMR) systems) that the establishment intends to use in the production of raw ground beef products.

You only collect follow-up samples of beef manufacturing trimmings, bench trim, or raw ground beef components or beef patty components that the establishment intends for use in raw ground beef or other raw ground beef products. Randomly select the time to collect the sample of raw ground beef product, beef manufacturing trimmings, or raw ground beef or beef patty component from the establishment's current production. Follow the sample collection instructions (for example, 2 lb of raw ground beef product, the N60 sampling procedure for beef manufacturing trimmings, bench trim, and 2-piece chucks, 2 lbs (3 Whirl-Pak® bags) for AMR product, low temperature rendered products, and other raw beef components). Follow the instructions for notifying establishment management before taking the sample in FSIS Directive 10,010.1 and as previously covered in this handout. Schedule each sample in PHIS, document sample data on the day that sample is collected, submit the sample information electronically through PHIS and print the form to include with the sample as previously discussed.

You may submit more than one sample per shipping container if each sample is individually identified and the shipping container is large enough to hold more than one sample. Send the sample to the laboratory on the first available day the contract carrier picks up after collecting the sample.

While you are collecting follow-up samples for STEC testing, you may receive a **routine verification sample request form** for a raw beef product to be tested for *E. coli* O157:H7 and potentially non-O157 (for beef manufacturing trimmings). In this situation, continue to collect follow-up samples and make **follow-up sampling the priority**, rather than routine sampling. If your workload and the establishment's production practices allow it, collect the sample for routine testing within the allotted collection window. **Do not** collect a follow-up sample and a routine verification sample from the same product lot. If it is not possible for you to collect the routine sample, you should cancel the sample task and in

the justification, state that you did not collect the routine sample because of follow-up sampling.

While you are collecting follow-up samples for *E. coli* O157:H7 and potentially non-O157 testing under one sampling project code, you may receive follow-up sample request forms for another project code or the same (repetitive) follow-up sampling project code. For example, you may be in the process of collecting the 16 follow-up samples under project code MT52 when the 3rd sample of this set tests positive. As a result of this positive sample result, you will receive 16 follow-up samples for project code MT53. You are to collect the rest of the 16 follow-up samples from the MT52 project code as well as the 16 follow-up samples for the MT53 project code.

FSIS will continue to collect follow-up samples after a positive follow-up sample result until the FSIS laboratory finds no positive sample results in 16 or 8 **consecutive** follow-up samples. For example, if you receive forms to collect 16 follow-up samples under the MT53 project code, and the 3rd sample of this set tests positive, you will then receive 3 more follow-up sampling forms for MT53 sampling program. As a result of the positive sample result, you would collect the remaining 13 follow-up samples and the 3 new follow-up sampling forms for a total of 16 follow-up samples.

Follow-up Sampling at Supplying Establishments

Analysis of *E. coli* O157:H7 sample data collected by FSIS indicates that an establishment that has had a positive sample is likely to receive a second positive within 120 days of receiving the first positive result. In response to this finding, FSIS has implemented a follow-up sample testing protocol for establishments that supply raw beef products to establishments that have had product test positive for *E. coli* O157:H7.

The Data Analysis and Integration Staff (DAIS) generates, in PHIS, follow-up sampling tasks at supplier establishments. IPP are to collect **a single** follow-up sample or **multiple** follow-up samples. PHIS will send 16 follow-up sample request tasks if the originating slaughter establishment was the only supplier, or if an originating slaughter establishment is a repeat supplier for **each** source material used in the positive raw beef product. However, when a supplier is not the sole supplier or a repeat supplier, PHIS requests a **single follow-up** sample from the supplier for **each** source material used in the positive raw beef product.

Note: If an originating slaughter establishment was the only supplier for the raw beef product found positive for *E. coli* O157:H7, and that the same originating

slaughter establishment was also a supplier that had been identified within approximately 120 days of this raw beef product positive result, PHIS generates 16 MT52 project code follow-up sample tasks for the originating slaughter establishment identified for each component used in the positive raw beef product.

The DO informs IPP of which type source materials the establishment supplied to the beef boning, cut-up, or grinder facility, so that IPP can sample that raw beef source material from the establishment's current production. If the originating supplying slaughter establishments produced more than one source material used by the boning, cut-up or grinding establishment, PHIS will generate sample request tasks, project code MT52, for each type of source material.

When AMS notifies FSIS of a positive *E. coli* O157:H7 result for raw ground beef product sample collected under the AMS commodity purchase program, DAIG determines the originating supplying slaughter establishments. The DO is informed that AMS found a positive sample. PHIS generates 8 follow-up sample tasks for the type of ground beef product AMS found positive, regardless of establishment production volume, in response to the AMS positive result. In addition, if a sole supplier or repeat supplier supplied source materials for the ground beef product that AMS found positive, PHIS requests 8 follow-up sample tasks for the supplier of the raw beef source material regardless of the supplier's production volume.

In combination slaughter/processing establishments, if FSIS or another Federal or State entity finds a raw ground beef product positive, and the establishment produced the source materials used to produce raw ground beef product that tested positive, PHIS generates MT52 sampling program request tasks. IPP are to collect either 8 or 16 samples, based on establishment production volume, of the type of source materials used in the positive raw ground beef product. IPP **are not** to collect follow-up samples of the ground beef product.

If ammoniated LTR product was used as a component in raw ground beef products that tested positive for *E. coli* O157:H7 when sampled by FSIS or another Federal or State entity, PHIS generates either 1, 8 or 16 sample request tasks. IPP are to collect a sample of ammoniated beef trim at the establishment that produced the ammoniated low-temperature-rendered product, even if that establishment is not an originating supplying slaughter establishment.

If a sample collected under the MT52 sampling program tests positive, PHIS generates multiple follow-up sample requests under the MT53 sampling program.

Upon receipt of the MT52 follow-up sample request tasks, you randomly collect the sample of source materials (beef manufacturing trimmings, or other raw ground beef components, or raw beef patty components) indicated from the establishment's current production. Follow the sample collection instructions and the instructions for notifying establishment management before taking the sample previously covered in this handout. All samples and follow-up samples will be scheduled and documented in PHIS.

Follow-up Sampling of Ammoniated Low Temperature Rendered Products after an E. coli O157:H7 Positive Sample Result

Ammoniated LTR product is subject to the MT52 follow-up verification sampling program when it is used as a component in raw ground beef products that are sampled by FSIS under MT43 or MT44 sampling programs or by another Federal or State entity and are positive for *E. coli* O157:H7. You are to randomly collect a sample consisting of 1 lb but not more than 2 pounds of the ammoniated low-temperature-rendered product from a specific production lot.

If the establishment that produced the ammoniated LTR product is not an originating supplying slaughter establishment, e.g., a combination slaughter processing establishment, sample request forms with project code MT52 in Block 14 are not generated for the slaughter establishments that produced the source materials used in the ammoniated LTR, unless the sample of ammoniated LTR product that you submit to the FSIS laboratory lab is positive. When the ammoniated LTR product is submitted to the lab under the MT52 project code, you collect supplier information from the establishment that produced the ammoniated low-temperature rendered product and document the information in a MOI. If the sample is positive, the DO will enter the supplying establishments into STEPS. Sample requests with project code MT52 are generated for the slaughter establishments that produced the source materials used in the positive ammoniated LTR product.

Document the follow-up sampling in PHIS by recording a Directed Sampling Task. Pack the sample and complete sample request form as outlined in this handout. Send the sample to the laboratory on the first available day the contract carrier picks up after collecting the sample.

Follow-Up Sampling at the Originating Supplying Slaughter Establishments for Intact Raw Beef Products <u>not</u> Intended For Use in Raw Ground Beef Products

When an establishment used intact product, (for example, primals or sub-primals) as source materials in a raw ground beef product that FSIS finds

positive for *E. coli* O157:H7, you are to **select a carcass** at the originating supplying slaughter establishment for follow-up sampling under project code MT52 rather than the raw ground beef component, e.g., beef trimmings, AMR product, head meat, etc., from the carcass if the originating slaughter establishment can demonstrate:

- Through HACCP production records and purchase specifications that the intact beef product used as a raw ground beef component **was not intended** for grinding or non- intact product, and the establishment had informed purchasers of this intent, and

- That the intact product was derived from beef carcasses in a manner to minimize commingling with other raw beef cuts and product was packaged separately and not commingled with other beef cuts prior to packaging (e.g., bone-in loins or boneless rounds were placed on a conveyor belt and were then off-loaded for packaging without being commingled with other beef cuts). You must be able to verify that the product was handled as stated above through records review or direct observation.

The two conditions are meant to show that the supplying establishment intended the product for use in intact product, e.g., steaks and roasts. If both conditions **are not** met, you are to continue to sample the beef trimmings or primals or sub-primals that were used to produce the positive raw ground beef products using the **N60 sampling procedures.** If both of these conditions **are** met, you aseptically collect enough tissue slices from the external surface off the carcass to equal 2 pounds. The slices are to be very thin (approximately 1/8 inch thick). Follow the instructions for sampling large components, sanitize the caddy, knife, and hook before collecting the samples and use sterile gloves and sterile Whirl-Pak® bags.

Cut the slices from:

- the surface of the **same part of the carcass** (e.g., chuck, loin, round, etc.) that the establishment used in producing the positive raw ground beef product sample, when possible.

- the carcass while the carcass is hanging in the cooler before fabrication, when possible.

  Note: If it is not possible to do either of these things, contact the Risk and Innovations Management Staff (RIMS) through askFSIS at http://askfsis.custhelp.com/. RIMD personnel are to cc the appropriate district personnel on their reply.

Document the follow-up sampling PHIS. Pack the sample and complete the sample request form as outlined in this handout. Send the sample to the laboratory on the first available day the contract carrier picks up after collecting the sample.

If the follow-up sample result for the carcass is positive for *E. coli* O157:H7, then only the sampled carcass is implicated because *E. coli* O157:H7 contamination is generally point-source contamination that occurs sporadically as a consequence of handling during hide removal and dressing of the carcass. The establishment will need to take corrective actions for that carcass. The establishment may decide to destroy the implicated carcass or to use it to produce products that will be processed to destroy the pathogen (for example by cooking or irradiation). Head and cheek meat from that carcass which was removed from the skull during the slaughter process is not implicated by the positive result. You should verify the establishment's control of its sanitary dressing procedures per FSIS Directive 6410.1.

FSIS Actions after a Positive E. coli O157:H7 or non-O157 Follow-Up Sample Result

Access LIMS-Direct to track your follow-up sample receipt and results. Respond to discarded samples, negative results, presumptive positive results, and confirmed positive results as previously described in your handout. The actions FSIS takes in response to *E. coli* O157:H7 positive FSIS follow-up samples are the same actions FSIS takes for an *E. coli* O157:H7 or non-O157 positive FSIS routine verification sample.

When an FSIS generated follow-up sample is found positive for *E. coli* O157:H7 or one or more of the six non-O157 serogroups and the establishment's sample for the same lot is also positive, you should not issue an NR provided that the establishment held the product represented by sample (or maintained control of the product) pending its own test results. You need to verify that the establishment takes corrective actions that meet the requirements in §417.3.

When an FSIS generated follow-up sample is found positive and the establishment either did not test the product lot or did not find the pathogen, you will issue an NR under the appropriate HACCP Verification Task citing §417.4 and §301.2 as the relevant regulations. Review previous NRs and associate this NR to the last positive, if appropriate. As soon as possible after the establishment has implemented its corrective actions, perform the HACCP Verification Task for the specific production that tested positive. Determine whether or not the establishment implements corrective actions that meet the requirements described in §417.3.

If disposition of the positive product is to occur off-site, verify that the establishment has met all corrective action requirements, e.g., maintained control of product during transportation, has records identifying who received the product and showing proper disposition or disposal, and has conducted a pre-shipment review after receiving the disposition or disposal records as described in the **Off-Site Product Disposition** section earlier in this handout. If you find noncompliance, document it in accordance with Directive 5000.1. Notify the DO through supervisory channels when the establishment has not properly moved the positive product off-site.

DO and EIAO Responses to Positive Results

The District Office (DO) will schedule a Food Safety Assessment (FSA) at an establishment within 30 days after being notified that FSIS or another Federal Agency or State entity has found a raw beef product positive for *E. coli* O157:H7. The follow-up sampling results will provide objective data that an EIAO will use in formulating an Agency position when conducting the FSA. In addition, the DO is to schedule an EIAO to conduct an FSA at establishments identified in STEPS as sole suppliers of positive *E. coli* O157:H7 ground beef product and establishments in the STEPS database more than once in the past 120 days identified as a multiple supplier except if the establishment applied a full lethality treatment to the implicated source material.

The DO and EIAOs will consider the results of follow-up sampling and take the appropriate enforcement actions (e.g., issue an NOIE, withhold or suspend inspection, reinstate a suspension), if warranted. Below are factors the DO and EIAOs consider when making a determination about whether to stop collecting follow-up samples and to take a suspension or withholding action:

- the establishment is failing to implement proposed corrective actions;
- the establishment's corrective actions that the establishment is implementing are ineffective;
- the establishment has recurring sanitary dressing noncompliances that render its corrective actions ineffective (see FSIS Directive 6410.1); or
- the establishment does not have support for decisions made in its HACCP plan or hazard analysis (see FSIS Directive 5000.1).

Establishment-Generated Sampling

Some establishments have their own sampling and testing programs for *E. coli* O157:H7, non-O157 STEC or virulence markers. Establishments are not **required** to sample and test their raw beef products or raw materials for *E. coli* O157:H7 or non-O157 STEC or virulence markers. What establishments are required to do is to conduct a hazard analysis and support the decisions they make in their hazard analysis. Sampling and testing is one way to support decision-making.

Establishments may address their sampling programs in the HACCP system, in either the HACCP plan, Sanitation SOP, or in a prerequisite or other supporting program. Even if these programs are not addressed in the HACCP system, establishments are still required to share records and analyses results with FSIS.

No establishment that produces raw ground beef products or beef manufacturing trimmings and raw ground beef and beef patty components **intended to be used in non-intact product** is exempt from FSIS verification testing for *E. coli* O157:H7, even when the establishment has its own robust testing program for *E. coli* O157:H7, non-O157 STEC or virulence markers.

Pre-shipment Review - FSIS has taken the consistent position that establishments can conduct pre-shipment review when the product is at locations other than at the producing establishment provided that the product does not leave the control of the producing establishment. Some establishments analyze samples for *E. coli* O157:H7 while they are moving the product, but the product is still under the establishment's control. FSIS is providing establishments the flexibility to move their product before pre-shipment review when the establishment is conducting testing for *E. coli* O157:H7 and maintains control of the product (e.g., through company seals or FSIS control).

Review of Establishment Data - Based on the regulatory requirements of 9 CFR 417.2(a)(1)(2) and 9 CFR 417.5(a)(1), FSIS believes that the results of any testing that the establishment performs that may have an impact on the establishment's hazard analysis are subject to FSIS review and must be available to IPP upon request, including records from prerequisite programs. FSIS Directive 5000.2 states that, ***on at least a weekly basis***, you must review the results of any testing and of any monitoring activities the establishment performed that may have an impact on the hazard analysis. There is a task in PHIS, "Review of Establishment Data" to document the performance of this review. Based on review of establishment records, if you have concerns about the design of testing, monitoring, or verification activities outside of a HACCP plan, or concerns about results from such activities, procedures, or prerequisite

programs, contact the Policy Development Staff (PDS) or raise the concern through supervisory channels. When records show that the establishment tests beef trim and raw ground beef components for *E. coli* O157:H7, but **never** finds any positives, you are to contact the DO. In addition, when establishment testing records show **multiple** positive results for *E. coli* O157:H7, non-O157 or virulence markers that may be evidence of a systemic problem, you are to contact the DO. It may be determined that an EIAO needs to conduct a food safety assessment to assess such factors as what the test results reveal about food safety and whether the design of testing, procedures, or prerequisite programs are adequately supported by the decisions made in the hazard analysis.

If the Establishment Rejects Product From Suppliers - An establishment may sample raw beef products for *E. coli* O157:H7, non-O157 STEC or virulence markers when they are received and hold the production lot pending the sample result. If the product is presumptive positive or positive for *E. coli* O157:H7 or non-O157, the establishment considers the product to be adulterated, does not accept the production lot, and returns the lot to the supplying establishment using FSIS Form 8140-1, "Notice of Receipt of Adulterated or Misbranded Product" under appropriate controls (e.g., company seals or FSIS seals). After the establishment notifies you that it has rejected the production lot, collect the supplier information. You need to notify the DO (9 CFR 320.7) and include the supplier information in your e-mail. The DO is to notify the IIC at the supplying establishment that rejected product is being returned and have IPP at the establishment conduct a HACCP Verification task on the affected lot of product.

Note: The Agency recognizes that it is probable that, despite the ongoing processing interventions for controlling *E. coli* O157:H7 and non-O157 STEC, some establishment samples of beef manufacturing trimmings and raw ground beef and beef patty components may test positive for *E. coli* O157:H7 or one or more of the six non-O157 STEC serogroups tested for by FSIS. These positives may be random events caused by normal process variation, or may have an identifiable, assignable cause that can be acted upon as part of corrective actions. Establishment verification testing should occur at a frequency to help determine the difference between acceptable process variation and assignable cause variation in the testing results associated with beef manufacturing trimmings and raw ground beef and beef patty components. Through this statistical analysis, the establishment will be able to justify whether corrective actions to address an assignable cause are appropriate and sensible.

If the Establishment Performs Only Screening Tests - If review of the establishment's *E. coli* O157:H7 and/or non-O157 sampling program reveals it is only performing screening tests and not further analyzing "potential positive" test

results to determine whether *E. coli* O157:H7 or non-O157 is isolated from the product, e.g., presumptive positive or confirmed positive, you are to verify that the establishment appropriately addresses the product as if the product is positive for *E. coli* O157:H7 or non-O157. The establishment cannot perform a second screening test for *E. coli* O157:H7 or non-O157 on the product and find it negative. Performing additional screening tests does not negate the original positive screening test. A screening test is not a conclusive (specific) test for the pathogen.

The establishment is not obligated to notify FSIS when it receives a presumptive positive or a positive sample result, but it **must take corrective actions** that meet the requirements of §417.3 **each time** a presumptive positive or a positive result is obtained. The establishment must also maintain appropriate control for any product that is presumptive positive or confirmed positive for *E. coli* O157:H7 or one of the six non-O157 STEC serogroups that is shipped to another establishment, or to a landfill or renderer for appropriate disposition.

FSIS Actions - When you are aware that there was a presumptive positive or positive result in establishment testing, you must:

- Conduct a HACCP Verification Task to verify the establishment's corrective actions (§417.3(a) or (b)), and

- Issue an NR **only** if the establishment fails to implement the corrective actions that meet the requirements of §417.3(a) or (b).

Note*: The HACCP Verification Task cannot be completed until pre-shipment review is completed, which includes the establishment's review of disposition documentation.*

Some establishments may opt to divert the product to another official establishment for cooking when they receive a ***presumptive positive*** in their testing program, or to a landfill or renderer for disposal. However, the establishment is still obligated to meet ***all*** parts of §417.3. It is still required to have proper control of the product while it is in transit for disposition. It also must maintain documentation of appropriate disposition.

When product that is ***presumptive positive or confirmed positive*** for *E. coli* O157:H7 is transported to another official establishment, renderer, or landfill operation for appropriate disposition, the establishment sending the product must:

- maintain records identifying the official establishment, renderer, or landfill operation that receives the presumptive positive or positive product,

  ***NOTE**: If the product is analyzed while in transit, the establishment must maintain records identifying the official establishment to which the product is being sent.*

- maintain control of product (company controls or FSIS controls),

- maintain records that indicate product received proper disposition, and

- complete pre-shipment review only after it has all disposition records for that particular product.

If you are aware that presumptive positive or positive product is in transit, verify the controls. If you find noncompliance with the establishment's handling of presumptive or confirmed positive product, contact the District Office.

Example 2
An establishment has its own testing program for *E. coli* O157:H7 for its raw hamburger patties. The establishment has not included it as a verification activity in its HACCP plan. In the last test, the result was positive. The establishment always holds product pending results. The establishment does not need to inform you of its positive result, but the establishment must implement corrective actions that meet the requirements of 9 CFR 417.3(b). You must verify that the establishment took the necessary corrective actions to meet these requirements, by performing a HACCP verification task. You should become aware of the positive from your weekly review of the establishment's sampling results, or from reviewing corrective action records, or observing corrective actions the establishment takes.

Example 3
An establishment has its own testing program for *E. coli* O157:H7 in its beef trim. The testing is part of the verification of the overall HACCP plan. The establishment analyzes the samples while the product is in transit, but still under the establishment's control (**not** in commerce). When a negative result is received, the establishment completes the pre-shipment review, and product is released into commerce.

The last test result was positive. The establishment must implement corrective actions that meet all four requirements of 9 CFR 417.3(a).

Whether the establishment brings the product back to the establishment for disposition, diverts it for further processing at another official establishment, or sends it to a landfill or renderer, the establishment must demonstrate control of the adulterated product until that product receives proper disposition. The establishment must receive documents proving proper disposition. Only **after** proper disposition of the product is documented should the establishment complete the pre-shipment review for that specific production.

Example 4
The establishment has a finished product sampling program as part of its verification of the HACCP plan for raw ground beef product. Its last sample was presumptive positive.

The establishment diverted the product to cooking at its own in-plant cooking operation. It identified all affected product and cooked it separately from its other products. The company used a HACCP plan that had been designed specifically for product known to contain *E. coli* O157:H7 and which contains a CCP for lethality that was validated to eliminate *E. coli* O157:H7. Records demonstrating the positive product received proper disposition are available.

The establishment identified the source of the presumptive positive *E. coli* O157:H7 contamination as coming from a new supplier. Establishment management required the supplier to demonstrate that validated antimicrobial interventions are implemented in its process, sample and test its product for *E. coli* O157:H7 and provide a Certificate of Analysis (COA) with each shipment before purchasing any other products from that supplier. The establishment includes this certification as a HACCP verification.

Summary

Currently, several STEC serogroups – *E. coli* O157:H7 and six non-O157 STEC (O26, O111, O121, O45, O145, O103) are a public health concern associated with raw beef products. Therefore, FSIS is analyzing beef manufacturing trimmings, bench trim, other raw ground beef components and ground beef for *E. coli* O157:H7. FSIS is also currently analyzing beef manufacturing trimmings for six non-O157 STEC in addition to *E. coli* O157:H7.

If you are assigned to a beef establishment you may perform sampling for food safety concerns.

When an FSIS sample for a raw beef product is confirmed positive for *E. coli* O157:H7 or one or more of the six non-O157 STEC, and the establishment has not found the same product to be positive, issue an NR for HACCP noncompliance, verify the establishment's corrective actions, check appropriate decision-making documents, assist as needed in any recall, and conduct a HACCP Verification task on the specific production that tested positive. You cannot complete the task until the establishment has taken corrective actions and the product has received proper disposition (including completing a pre-shipment review). If the establishment maintained control of the product and sampled it, and both the establishment and FSIS samples were found positive for *E. coli* O157:H7 or a non-O157 STEC serogroups, you are NOT to issue a Noncompliance Record. You must verify that the establishment's corrective actions meet the requirements in §417.3.

If you find regulatory noncompliance, e.g., the establishment fails to take corrective action in accordance with §417.3, while performing the HACCP Verification Task, document it on an NR (as per FSIS Directive 5000.1). If you find that the establishment moved positive product without the necessary controls, or if you find that the establishment does not have records documenting proper disposition of the positive product moved off-site, contact your DO through supervisory channels.

As new technologies and methods of producing products are developed, and as new pathogens emerge that affect meat and poultry food safety, FSIS will adjust its efforts to continue being a public health agency. New or different microorganisms may be added to the list of those for which the Agency currently tests. It will continue to be the responsibility of the in-plant inspection force to verify that establishments meet their food safety obligations.

Workshop II

1 Which products, when confirmed positive for *E. coli* O157:H7 are considered adulterated?

a. Mechanically tenderized beef steak
b. PDBFT for use in raw beef patties
c. Beef trimmings for use in grinding
d. Beef sub-primals boned for use in raw ground beef
e. Raw ground veal patties

2. If the establishment sends presumptive positive product for *E. coli* O157:H7 to a landfill, what are the requirements to do so?

3. If the establishment sends presumptive positive product for a non-O157 STEC such as *E. coli* O26 to a landfill, what does the CSI do?

Scenarios

1. The establishment where you are assigned slaughters and fabricates beef. It samples its own beef trimmings as a prerequisite program. On Thursday afternoon, as part of the Review Establishment Data task, you decide to review these records. You go to the office where the records for the prerequisite program are kept and review the sampling results. You notice that on Monday morning, the beef trim tested from the previous Wednesday was confirmed positive for *E. coli* O157:H7. What are your responsibilities in this scenario?

2. Last week, you submitted a sample of the establishment's raw ground beef patties to the FSIS lab. Three days ago you notified the establishment that the sample was presumptive positive. Today, when you arrived at the establishment, the establishment manager told you that he'd been informed by the District Office that the sample was confirmed positive. What are your responsibilities in this scenario?

PHIS Hands-on Activities

Managing Workload

Objective:

- Use task calendar functions to manage your workload.
- Review tasks by priority on the task calendar.
- Reschedule, remove or cancel tasks based on priorities.
- Use calendar functions to view another inspector's work, reschedule tasks when covering for another inspector.

Scenario:

- As a result of a positive *E. coli* O157:H7 finding at Groveton Meats, Robert Barclay will schedule follow-up sampling tasks.
- Due to the time needed to do these tasks, Robert Barclay will review his schedule and reschedule lower priority tasks.
- Since Open Beef was identified as the sole supplier to Groveton Meats, IIC Phyllis Isaacs directs Robert Allen and Jeb Morwork to re-arrange tasks at Open Beef based on priority.
- Jeb and Robert will schedule sampling tasks and other directed tasks associated with the positive finding.

Exercise #1 Groveton

Because of their low priority and the time needed for the *E. coli* O157:H7 positive result, Robert Barclay reschedules tasks as follows. In addition, he will schedule directed tasks.

Robert Barclay at Groveton Task Name	**Action**
General Labeling	Remove from schedule
Food Defense - Water Systems	Remove from schedule
Net Weight	Re-schedule for any date next week
Pre-Operational Record Review	Add a directed task today
Operational SSOP Record Review	Add a directed task today
MT44 Sample Request	Add two tasks for today

1. Log in to PHIS and Select User Robert Barclay.
2. Select Task Calendar from the navigation menu.
3. From the Task Calendar, scroll to the calendar section. Filter the calendar by Inspector **Robert Barclay** and the establishment **Groveton Meats.**
4. View Robert Barclay's planned tasks.
5. Right-click on Barclay's General Labeling task and click **Remove**.
6. Right-click on Barclay's Food Defense - Water Systems task and click **Remove**.
7. Right-click on Barclay's Net Weight task and click **Edit**. Change the scheduled date to **any date next week**.
8. Scroll up to the Task List section.
9. Find the task **Pre-Operational Record Review** in the task list for February. Click the **Add** link in the **Directed** column. Add 1 task for today and use **Response to Alert Notification** for the reason.
10. Find the task **Operational SSOP Record Review** in the task list for February. Click the Add link in the Directed column. Add 1 task for today and use Response to Alert Notification for the reason.
11. Find the task **MT44 Sample Request** in the task list for February, and then click the "Add" button in the assign column. Next use the calendar icons to set the "Collection Date" and Parcel Pick Up Date" for today and click "Save". Add two sample requests today.
12. Scroll down to the calendar view and ensure that the tasks have been added to the calendar.
13. Sign Out of PHIS.

Exercise #2a Robert Allen at Open Beef

Robert Allen is asked to shuffle tasks based on priority. Because Open Beef was the sole supplier and originating slaughter establishment for Groveton's lot which had the positive result, Allen has a list of follow-up tasks to perform, including sampling.

Robert Allen at Open Beef Task Name	**Action**
MT52 Sample Request	Schedule 2 sample tasks today
Pre-Operational Record Review	Schedule a directed task today
Operational SSOP Record Review	Schedule the routine task as directed for next working day
Storage Areas	Remove
General Labeling	Remove
MSS, PDBFT, PDPFT, PDCB, PDCP, AMRS	Remove
MT60 – Routine Testing of Domestic Raw Beef Manufacturing Trimmings	Reschedule for 2/24
Pre-operational SSOP Review and Observation	No change

1. Log in to PHIS and Select User **Robert Allen.**
2. Select Task Calendar from the navigation menu.
3. Scroll to the task list. Filter by Establishment = Open Beef
4. Filter the type of task by Lab Sampling and find the task MT52 Sample Request in the task list for February, then click the “Add” button in the Assign column. Next use the calendar icons to set the “Collection Date” and “Parcel Pick Up Date” for today and click “Save”. Schedule two samples for today.
5. Find the task **Pre-Operational Record Review** in the Domestic task list for February. Click the Add link in the Directed column. Add 1 task for today and use Response to Alert Notification for the reason.
6. Find the task **Operational SSOP Record Review** in the task list for February. Click the Add link in the Directed column. Add 1 task for **the next working (active) day on the schedule** and use Response to Alert Notification for the reason.
7. Scroll to the calendar view. Filter the calendar by Inspector Robert Allen and the establishment Open Beef. Ensure that the two sampling tasks and the two sanitation record review tasks have been added to the calendar on the correct dates.
8. View Robert’s planned tasks.
9. **Remove** the following tasks:

a) Food Defense - Storage Areas

b) General Labeling

c) MSS, PDBFT, PDPFT, PDCB, PDCP, AMRS

10. To **reschedule the routine sampling task, right click on MT60** and select Cancel/Reschedule. From the Lab Sample Cancel or Reschedule screen, select **Reschedule this task**. Select 2/24 for the Collection and Pickup Dates and click **Save**.

11. Sign out of PHIS.

Exercise #2b Jeb Morwork at Open Beef

Jeb Morwork is another CSI assigned to Open Beef. He helps Robert Allen by making more room on Robert's schedule, taking some of the necessary tasks, and reassigning some of Robert Allen's tasks to himself as follows:

Jeb Morwork at Open Beef Task Name	**Action**
Directed Slaughter HACCP Verification	Schedule the directed task for today
Beef Sanitary Dressing	Schedule the routine task as directed for today
Livestock Humane Handling Verification	Schedule routine task for today
Generic *E. coli*	Re-assign from Robert Allen to himself
Livestock Zero Tolerance	Re-assign from Robert Allen to himself

1. Sign into PHIS and Select User **Jeb Morwork.**

2. Select **Task Calendar** from the navigation menu.

3. Scroll to the Task List.

4. Find the directed task **Slaughter HACCP Verification** in February. Click the Add link in the column. Add 1 task for **today** and use Response to Alert Notification for the reason.

5. Find the task **Beef Sanitary Dressing** in the task list for February. Click the Add link in the Directed column. Add 1 task for **today** and use Response to Alert Notification for the reason.
6. Find the **Livestock Humane Handling** task for **February.** Schedule this as a routine task for **today.**
7. Scroll down to calendar view and ensure that the three tasks you just scheduled have been added to the calendar on the correct date.
8. Filter the calendar by Inspector **Robert Allen** and the establishment **Open Beef.** Now **Jeb** is looking at **Robert's** tasks.
9. Right-click on Robert's scheduled task **Generic *E. coli*** and select **Edit**. Notice that the task is now assigned to **Jeb**. Click **Save**.
10. Right-click on Robert's scheduled task **Livestock Zero Tolerance** and select **Edit**. Notice that the task is now assigned to **Jeb**. Click **Save**.
11. Ensure that Robert's tasks have been reassigned to Jeb. Filter the calendar by Inspector Jeb Morwork, then Robert Allen, then All, to see the tasks.
12. Sign out of PHIS.

Review - PHIS Fundamentals

When logging in to PHIS for the first time during the work day, IPP should:

1. Review Alerts
2. Review Task List for New Directed Tasks
3. Review Current Task Schedule
4. Add any New Directed Tasks to Calendar
5. Adjust Scheduled Tasks as necessary

ATTACHMENT 1

Resources

There are several directives and notices associated with microbial sampling of raw beef products. The FSIS website provides the current versions.

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations

FSIS Directives

5000.1	Verifying an Establishment's Food Safety System
5000.2	Review of Establishment Data by Inspection Program Personnel
7355.1	Use of Sample Seals for Laboratory Samples and Other Applications
7700.1	Irradiation of Meat and Poultry Products
8080.1	Recall of Meat and Poultry Products
10,010.1	Verification Activities for *Escherichia coli* O157:H7 in Raw Beef Products
10,200.1	Accessing Laboratory Sample Information via LEARN (to be revised)
10,210.1	Unified Sampling Form
10,230.2	Procedures for Collecting and Submitting Domestic Samples for Microbiological Analyses
13,000.2	Performing Sampling Tasks in Official Establishments Using the Public Health Information System

FSIS Notices

	Additional Analysis For Salmonella Under the Routine and Follow-Up Sampling Programs for Shiga Toxin-Producing Escherichia Coli (STEC)
13-14	Collecting Supplier Information at the Time of Sample Collection for *Escherichia coli* (*E. coli*) O157H:7 in Raw Ground Beef Products and Bench Trim
03-14	Documenting Sample Source When Collecting Samples for Shiga Toxin-Producing *Escherichia Coli* (STEC) Verification Testing
01-14	Verification Activities for Non-O157 Shiga Toxin-Producing *Escherichia Coli* (Non-O157:H7 STEC) under MT60, MT52, and MT53 Sampling Programs
81-13	Clarification and Expansion of Sampling Eligibility Criteria for the Routine Beef Manufacturing Trimmings (MT60) and Bench Trim (MT55) Sampling Programs
69-13	Containers for use when Collecting Raw Beef Samples for Shiga Toxin-Producing *Escherichia coli* (STEC) and *Salmonella* Testing

47-13	Verification Testing for Non-O157 Shiga toxin-producing *Escherichia coli* (Non-O157 STEC) under MT60, MT52, and MT53 sampling programs
46-13	LIMS-Direct to Replace LEARN for Sampling Data Reporting See also: LIMS-Direct User Guide
19-13	Sampling of Low Production Volume Raw Ground Beef Establishments for *Salmonella*
07-13	Control of Agency Tested Product for Adulterants
58-12	Scheduling and Submitting Lab Samples in PHIS
27-12	Changes In Sampling Frequency For *E. coli* O157:H7 Testing of Beef Manufacturing Trimmings (MT60)
22-12	Sampling Of Raw Beef Product Intended For The National School Lunch Program
21-12	Randomly Selecting Beef Trim to be Collected Under the Beef Manufacturing Trimmings (MT50) Sampling Program

Industry Compliance Guides

http://www.fsis.usda.gov/Regulations_&_Policies/Compliance_Guides_Index/index.asp

- Compliance Guideline Controlling Met and Poultry Products Pending Products Pending FSIS Test Results http://www.fsis.usda.gov/PDF/Compliance_Guide_Test_Hold_020113.pdf
- Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7
- Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers (http://www.fsis.usda.gov/PDF/Compliance_Guide_Est_Sampling_STEC_0512.pdf)

FSIS Microbiology Laboratory Guidebook
http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook/index.asp

Background information on the STEC sampling methods
http://www.fsis.usda.gov/PDF/Mlg_5B_02.pdf

Articles

Law, D. A Review: Virulence factors of Escherichia coli O157 and other Shiga toxin-producing *E. coli*. Journal of Applied Microbiology 2000, 88, 729-745

Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, Jones JL, and Griffin PM. 2011. Foodborne illness acquired in the United States – major pathogens. Emerg Infect Dis. 17(1):7-15.

ATTACHMENT 2

Discard Reasons

Several discard reasons that may apply to raw samples are listed here. Your frontline supervisor has access to this information and monitors the number of discarded samples. You should review the sample and paperwork before submitting them to the lab to ensure these mistakes are not made.

Delayed Shipment *(FedEx doesn't get sample to the lab in 24 hour time frame)*
Missing Date
Sample Container Leaking
Sent to Wrong Lab
Temperature Too High
Container Damaged
Insufficient Sample
Collected Outside Scheduled Time Frame
Shipped on Friday w/o Saturday Delivery label
No Form Received with Sample
Laboratory Problem
No Gel Packs/Coolants in Sample Box
Sample Container Leaking
Collection Date Not Day Prior to Sample Receipt
Sample ID # on Bag does not match ID # on Form
Security Seal Missing or Not Intact
No Accredited Lab Tests Performed
Headquarters/ PDS/DO Discard
Sampling Instructions Not Followed

ATTACHMENT 3 Sample Analysis Form

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

Form ID:100006478

SAMPLE ANALYSIS REQUEST FORM

-- For Lab Use Only--

Place Sample Seal Label Here

100006478

COLLECTION INFORMATION

1. SAMPLE FORM ID:	100006478	7. ESTABLISHMENT ID:	M38
2. PROJECT CODE:	MT43	8. ESTABLISHMENT NAME:	Groveton Meats, LLC
3. SAMPLE SOURCE:	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	9. COLLECTION DATE:	07/02/2013
4. ANALYSIS:	E. coli O157:H7	10. SHIPMENT DATE:	07/02/2013
		11. COLLECTOR NAME:	Robert Barclav
		12. COLLECTOR PHONE:	(555) 555-5555
5. ASSIGNED LAB:	Midwestern Laboratory	(St. Louis,MO)	
6. DISTRICT/CIRCUIT:	35 - Springdale, AR		

PRODUCT INFORMATION

13. PRODUCT NAME:	Ground Beef
14. PRODUCTION DATE:	07/01/2013
15. LOT NUMBER:	9225B
16. IS PRODUCT HELD:	Yes

17. COLLECTION REMARKS:

18. QUESTIONNAIRE *(If Applicable)*

SIGNATURE: _____ **TITLE:** _____ **DATE:** _____

FOR LABORATORY USE ONLY

Date Received	Analyst Code	Receipt Temperature	Not-Analyzed Code	Not-Analyzed Explain

PAGE 1 OF 2

FSIS FORM 8000 - 18 (12/17/12)

Training Example Only

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

Form ID: 100006478

SAMPLE ANALYSIS REQUEST FORM

Time of sample collection (HHMM):	:	0910
Was plant management notified of this sample collection?	:	Yes
Check one:	:	Aseptically collected (Whirlpak bag)
Is the submitted sample beef or veal?	:	Beef
How many pounds or product are represented by this sample? Enter numbers only.	:	9999
Pounds of ground beef this establishment produces on a typical/average day (all shifts) - select one:	:	1) More than 250,000 lbs.
Establishment contact person's name:	:	Jeff Irvine
Establishment contact phone number:	:	(555) 555-5555
Where is product held?	:	On-site

SIGNATURE: _____ TITLE: _____ DATE: _____

FOR LABORATORY USE ONLY

Date Received	Analyst Code	Receipt Temperature	Not-Analyzed Code	Not-Analyzed Explain

PAGE 2 OF 2

FSIS FORM 8000 - 18 (12/17/12)

Training Example Only