UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

10,010.1
Rev. 4
8/20/15

SAMPLING VERIFICATION ACTIVITIES FOR SHIGA TOXIN-PRODUCING
ESCHERICHIA COLI (STEC) IN RAW BEEF PRODUCTS

NOTE: Although this directive is being reissued, fundamental changes in approach are not made in this revision. Agency personnel are to read Chapter I, Section III. SIGNIFICANT CHANGES below for information on the reasons for reissuance of this directive. Agency personnel are to focus on understanding the information reflected there.

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL SEPTEMBER 1, 2015

CHAPTER I - GENERAL

I. PURPOSE

A. This directive provides instructions to inspection program personnel (IPP) for collecting and submitting samples of raw beef products under FSIS's routine and follow-up sampling programs for Shiga toxin-producing Escherichia coli (STEC) and for updating the Public Health Information System (PHIS) profile information related to sampling. FSIS tests all raw beef samples collected under the routine and follow-up sampling programs for E. coli O157:H7 and Salmonella. FSIS also tests beef manufacturing trimmings from cattle slaughtered onsite for non-O157 STEC. FSIS has revised this directive to reorganize it and to simplify it to include only instructions concerning FSIS sampling and PHIS profile information related to sampling.

B. Instructions concerning STEC verification activities other than FSIS sampling are contained in a new directive, FSIS Directive 10,010.2, Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef Products. FSIS Directive 10,010.2, Chapter III, Section I, provides IPP with instructions for responding to positive results from FSIS verification testing. FSIS Directive 10,010.3, Traceback Methodology for Escherichia coli (E. coli) O157:H7 in Raw Ground Beef Products and Bench Trim, provides instructions to Enforcement, Investigations, and Analysis Officers (EIAOs) and other IPP concerning traceback investigations, new instructions for recalling product under specific circumstances, and information on high event periods (HEP).

C. IPP responsible for collecting FSIS raw beef samples and updating the PHIS profile at establishments that produce raw beef products are to be provided up to two hours of official regular (01) time to read this directive and update the profile. IPP are to designate any other scheduled tasks (i.e., blue = not opened) that they did not begin as “not performed” as a result of the time allotted for review of this issuance. IPP are to select “Higher priority task took precedent” from the justification drop-down list. IPP are to enter directive 10,010.1 in the comment text box available.

D. IPP are to follow the instructions in FSIS Directive 10,010.1, Rev. 3 until the implementation date of this directive.

NOTE: For the purposes of this directive, when the directive references “raw beef” it includes veal and not-ready-to-eat (NRTE) beef.

DISTRIBUTION: Electronic OPI: OPPD
II. CANCELLATIONS

FSIS Directive 10,010.1, Revision 3, Verification Activities for *Escherichia coli* O157:H7 in Raw Beef Products, 3/31/10

FSIS Notice 39-14, Clarification and Expansion of Sampling Eligibility Criteria for the Routine Beef Manufacturing Trimmings (MT60) and Bench Trim (MT55) Sampling Programs, 8/13/14

III. SIGNIFICANT CHANGES

A. This directive provides new instructions to IPP to:

1. Collect bench trim and other raw beef component samples based on production volume (i.e., IPP assigned to establishments with higher production volumes will receive more sample requests than IPP assigned to establishments with lower production volumes) (See Chapter I, Section IV. C. and D. and Chapter II, Section II);

2. Select the other raw ground beef components to sample using random selection (See Chapter V, Section I.A.);

3. Verify that the establishment’s PHIS profile is accurate to ensure that the establishment is eligible for raw ground beef and raw ground beef component sampling, as appropriate, by completing high priority, specific PHIS update profile tasks (See Chapter III, Section I and Attachment 1);

4. Collect raw beef samples sent to a receiving establishment to be treated with an intervention that does not achieve a full lethality (i.e., less than a 5-log reduction for *Salmonella*) at the receiving establishment where the intervention is applied, not at the originating establishment (See Chapter IV, Section IV.F.); and

5. Complete the optional updated training materials on collecting domestic and imported raw beef samples (See Chapter V, Section I.D., Chapter IX, Section II.A., and Attachment 6). This training is not required, but IPP may choose to complete it.

B. This directive provides instructions to IPP at the following types of establishments to use additional product group options in the PHIS profile to update the information on raw beef products, so that IPP at these establishments do not receive incorrect sampling tasks (see Chapter III.):

1. Establishments that portion and repackage raw ground beef products only;

2. Establishments that receive purchased beef manufacturing trimmings that are accompanied by certificates of analysis (COAs) with negative *E. coli* O157:H7 (or STEC organisms or virulence markers) test results; or

3. Establishments that receive purchased raw non-intact products (e.g., coarse grind or mechanically tenderized product) and use this product in its entirety to make raw ground beef products.

C. The directive provides and clarifies information on:

1. Raw beef product sampling eligibility (Chapter II, Figure 1);

2. When it is appropriate to collect frozen samples (e.g., when freezing is an active process that achieves a reduction in STEC and is a critical control point in the Hazard Analysis and Critical
Control Point (HACCP) plan (See Chapter IV, Section IV.D.);

3. Procedures for collecting N60 samples (See Chapter V, Section III and Attachment 2); and

4. Alternative sampling procedures for IPP to collect raw ground beef product at establishments that meet specific criteria (See Chapter IV, Section V).

IV. BACKGROUND

A. FSIS considers all raw non-intact beef and raw intact beef intended for use in raw non-intact product that is contaminated with the following STEC to be adulterated under the Federal Meat Inspection Act (21 U.S.C. 601(m)(1)): E. coli O157:H7, O26, O45, O103, O111, O121, and O145.

B. FSIS sampling verifies that an establishment’s controls or food safety procedures adequately address STEC.

C. FSIS has made changes to the sampling algorithm for scheduling the bench trim (MT55) and other raw ground beef component (MT54) sampling programs. Therefore, FSIS is replacing two project codes on September 1, 2015.

1. MT55 will have the new project code MT65; and

2. MT54 will have the new project code MT64.

D. FSIS is implementing these changes to reflect changes in the statistical design of its sampling. New project codes are needed to facilitate data analysis (e.g., to distinguish results collected and tested under the revised sampling designs) in order to evaluate program effectiveness (e.g., sample scheduling and collection rates). The MT65 and MT64 sampling projects will begin on September 1, 2015, as announced in the Federal Register Notice, Risk-Based Sampling of Beef Manufacturing Trim for Escherichia coli (E. coli) O157:H7 (80 Fed. Reg. 23761 (April 29, 2015)). FSIS is increasing the sampling task frequency in some establishments as a result of these changes.

E. FSIS requires establishments to hold or maintain control of raw beef products that FSIS has tested for STEC pending negative results.

CHAPTER II – ELIGIBILITY CRITERIA FOR FSIS STEC SAMPLING

I. DOMESTIC SAMPLING

A. IPP are to be aware that FSIS samples and tests eligible raw beef products produced under inspection, including inspected source materials that are subsequently used in retail operations conducted onsite.

B. Establishments that slaughter and further process raw beef product may be eligible for multiple FSIS STEC sampling programs. These establishments may produce ground product, beef manufacturing trimmings, bench trim, and other raw ground beef or beef patty components. These establishments may use purchased product to produce bench trim or raw non-intact products. Therefore, IPP may receive sampling tasks for MT43, MT60, MT64, and MT65 samples during the same sampling window.

C. Some slaughter establishments may produce beef manufacturing trimmings and other raw ground beef components and grind that product or produce other raw non-intact product. In this situation, IPP are to sample the trim under the MT60 sampling program, the other components under the MT64
sampling program, and raw ground beef product under the MT43 sampling program when they receive sampling requests with these codes.

D. Establishments are eligible for both the MT65 and MT60 sampling programs if they use certain types of purchased product to produce bench trim (MT 65) and source materials from their own slaughter operation to produce beef manufacturing trimmings (MT60) (see Figure 1 of this chapter).

E. Figure 1 on the following page provides a general description of eligible products for each of the routine domestic sampling programs (MT60, MT64, MT65, and MT43). IPP are to refer to this figure, as needed, when they receive routine domestic sampling tasks.

F. As noted on Figure 1, FSIS tests all raw beef samples collected under routine and follow-up sampling programs for *E. coli* O157:H7 and *Salmonella*. FSIS also tests beef manufacturing trimmings from cattle slaughtered on-site for non-O157 STEC.

**NOTE:** Trim that a sister processing establishment produces from carcasses, carcass halves, or quarters supplied by a single slaughter establishment within its corporate structure is subject to MT60 sampling at the sister processing establishment, however, it is not tested for non-O157 STEC because the trimmings are not generated from cattle slaughtered on-site.
MT 60 — Beef manufacturing trimmings
Analysed for E. coli O157:H7, Salmonella, and non-O157 STEC

- Eligible products from cattle (including veal) slaughtered onsite and
  that the establishment intends for use in raw non-intact product or
  when the intended use is unclear include:
  1. Beef parts of boneless beef of any size in boxes or in combination
     of producing slaughter establishment meets for raw non-intact use;
  2. primal cuts the producing slaughter establishment markets for raw
     non-intact use;
  3. Two-piece chunks (i.e., the blade portion and an arm roast from the
     forequarter individually packaged and placed into the same
     container); and
  4. Smaller pieces of trimmings from subprimals.

NOTE: Trim that a facility processing establishments produces from
components, carcass halves, or quarters supplied by a single slaughter
establishment within its corporate structure is subject to MT60
sampling at the facility processing establishment, however, it is not
analyzed for non-O157 STEC.

MT 43 — Raw ground beef products in establishments that grind or form patties
Analysed for E. coli O157:H7 and Salmonella

- Eligible products include products listed below that are produced from
  grinding or forming into patties using in-house or purchased source
  materials:
  1. 9 CFR 319.15(a) — chopped or ground beef;
  2. 319.15(b) — hamburger;
  3. 319.15(c) — beef patties;
  4. Other raw beef products that do not meet the standards of identity for chopped or
     ground beef, hamburger, or beef patties but are produced similarly,
     such as:
     a. raw ground beef products with added
        ingredients or seasonings (e.g.,
        beef patties with chemicals, party mixes);
     b. ground beef with one or more different
        species where beef is the
        predominant species (e.g.,
        ground beef with
        1% added pork);
     c. Not ready-to-eat (NRE) ground product
        that receives a heat treatment but is
        not fully cooked (e.g.,
        heat-treated but not fully cooked
        beef patties, chicken-laden steak type
        product, or restructured
        beef product that is heated
        treated but not fully cooked);

MT 64 — Raw ground beef components other than trimmings
Analysed for E. coli O157:H7 and Salmonella

- Eligible products from cattle (including veal) slaughtered onsite include:
  1. Other raw ground beef components produced from beef
     slaughtered onsite, including:
     a. head meat;
     b. flank meat;
     c. kidney meat;
     d. heart meat;
     e. product from advanced meat recovery systems;
     f. low temperature rendered products, such as partially defatted
        chopped beef, partially defatted beef fatty tissue, and low
        temperature rendered lean finely textured beef;
     2. Ammoniated beef products produced at slaughter and
        non-slaughter establishments.

MT 65 — Bench trim derived from cattle not slaughtered onsite
Analysed for E. coli O157:H7 and Salmonella

Bench trim is produced from cattle not slaughtered at the establishment. Eligible
bench trim includes:
  1. Purchased product the establishment uses to produce secondary trimmings and smaller
     pieces of trim as well as chuck rounds, sections, etc. Other primal or subprimals that
     are not already eligible for sampling under the MT60 beef manufacturing trimmings or
     MT64 other raw ground beef components sampling program, and that a further processor
     receives and uses to produce smaller pieces of trim or uses in their entirety to produce
     other raw non-intact product;
  2. Primal and subprimals cuts derived from purchased whole, half, or quarter carcases,
     provided the further processor intends the primal and subprimals cuts for raw non-intact
     use (e.g., entire subprimals or primal cut that the further processor grinds).

Maximum Monthly Sampling Task Frequencies for Each Routine Sampling Program: MT60, MT64, MT65, and MT43

<table>
<thead>
<tr>
<th>Eligible Product Availability</th>
<th>Small</th>
<th>Medium</th>
<th>Large</th>
<th>Very Large</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size (per day)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Note: if sampling

<table>
<thead>
<tr>
<th>Size</th>
<th>Min. Sample Size</th>
<th>Max. Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>
G. Table 1 below provides a general description for each of the domestic follow-up sampling programs (MT44, MT52, MT53, MT44T). In the event of a positive sample from any of the routine domestic sampling programs, follow-up samples will be scheduled at the establishment. The purpose of scheduling these follow-up samples is to determine whether the establishment effectively addresses STEC. IPP are to refer to this table, as needed, when they receive follow-up sampling tasks.

<table>
<thead>
<tr>
<th>Sampling Program</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MT44</td>
<td>Follow-up sampling of raw ground beef product in response to a MT43 or Agricultural Marketing Service (AMS) positive result in raw ground beef product at Federal establishments</td>
</tr>
<tr>
<td>MT52</td>
<td>Follow-up sampling at suppliers of beef manufacturing trimmings or other components from originating slaughter suppliers, in response to a MT43, MT65, or AMS ground beef positive result</td>
</tr>
<tr>
<td>MT53</td>
<td>Follow-up sampling of trim or other components at the establishment that produced product in response to a MT60, MT65, MT64, or AMS trim testing positive</td>
</tr>
<tr>
<td>MT44T</td>
<td>Follow-up sampling of raw ground beef, trim, or other component outside of projects MT44, MT53, and MT52 collected by IPP at Federally inspected establishment</td>
</tr>
</tbody>
</table>

II. SAMPLING FREQUENCIES FOR ROUTINE SAMPLING PROGRAMS

A. IPP are to be aware that FSIS has a set minimum sampling frequency for each establishment. FSIS will sample each establishment that:

1. Produces raw ground beef products at least three times per year; and

2. Produces bench trim, other raw ground beef components, or beef manufacturing trimmings at least once per year for each product.

B. If IPP do not receive the minimum number of sampling tasks, they are first to determine whether they have the necessary finished product information in the PHIS profile to generate specific sampling tasks (see Chapter III).

1. If the information in the PHIS profile is accurate, they are to contact the Risk, Innovations, and Management Staff (RIMS) through the “Sampling” category of askFSIS to request sampling tasks.

2. If IPP made changes to the PHIS profile to generate sampling tasks, they are to contact RIMS if they have not received sampling tasks within 45 days.

C. IPP assigned to establishments with higher production volumes will likely receive more sampling tasks than IPP assigned to establishments with lower production volumes.

D. Figure 1 provides information on the maximum number of sampling tasks for each routine sampling program that IPP may receive monthly based on the establishment’s production volume. The only changes to the maximum sampling task frequencies concern the bench trim (MT65) and
other raw ground beef components (MT64) sampling programs and are a result of the design changes to those sampling programs (see Chapter I, Section IV. C. and D. and Chapter II, Section II).

NOTE: The maximum frequencies in Figure 1 only apply to routine sampling programs. In the event that follow-up sampling is necessary in response to an FSIS or AMS positive result, IPP will receive more sampling tasks than the maximum frequencies listed in Figure 1, and they are to collect the samples as requested (see Chapter VII, Section II.C.).

III. INTENDED USE AND SAMPLING ELIGIBILITY

A. The product’s intended use is a key factor in determining whether FSIS collects samples. FSIS samples products intended for use in raw non-intact product (e.g., ground, mechanically tenderized, needled, and vacuum marinated), or when the intended use is unclear.

B. IPP are not to sample product that the establishment intends for use in intact or ready-to-eat product, or product that will receive other full lethality treatment at another federally inspected establishment. If the product is to receive a full lethality treatment at another federally inspected establishment, IPP are to verify that the establishment’s hazard analysis and flow chart show that the product is intended for one of these controlled uses, and that the establishment has controls that ensure that the product is used as intended. If not, IPP are to collect the sample. Examples of full lethality treatments other than cooking can include high pressure processing and irradiation, provided that the establishment has supporting documentation that shows the treatment achieves a 5-log reduction for *Salmonella* and applies the treatment consistent with its critical operational parameters.

C. When establishments do not maintain clear records concerning the intended use of raw ground beef product, beef manufacturing trimmings, bench trim, or other raw ground beef components, IPP are to consider that these products are intended for use in the production of raw non-intact products. Such products are subject to FSIS sampling and testing for STEC.

D. If a product is subject to being sampled, IPP are to sample the product even if the establishment decides to change the product’s intended use (e.g., to cook all the product represented by the sample or to send the product to another establishment to cook the product after FSIS has collected the sample). In this situation, IPP are to proceed with submitting the sample to the FSIS laboratory for analysis.

E. IPP are to use Figure 1 to determine whether the products produced by the establishment are subject to routine FSIS sampling and testing and then are to perform the “Update Profile-Raw ground beef products” and “Update Profile- Other components” as described in Chapter III.

IV. IMPORT SAMPLING

Table 2 below provides a general description of eligible products for each of the routine import sampling programs (MT51 and MT08). Import inspection personnel are to refer to this table, as needed, when they receive sampling tasks for imported product.

<table>
<thead>
<tr>
<th>Table 2. FSIS’s Sampling Programs for Imported Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sampling Program</strong></td>
</tr>
<tr>
<td>MT51</td>
</tr>
<tr>
<td>MT08</td>
</tr>
</tbody>
</table>
products are analyzed for \textit{E. coli O157:H7} and \textit{Salmonella}.

\section*{CHAPTER III – PHIS PROFILE RESPONSIBILITIES}

\section{I. MANAGING THE PHIS PROFILE}

A. IPP assigned to establishments producing raw beef products are to look for the task “Update Profile- Raw ground beef products” on the task list and schedule it on the task calendar.

B. IPP are to determine whether the establishment produces product eligible for MT43 raw ground beef product sampling (See Figure 1 in Chapter II). IPP are then to review the establishment profile and update the profile, as needed, to make the establishment subject to MT43 sampling (See MT43 section of Table 3). IPP are to complete this task no later than 30 days after the issuance of this directive.

C. While performing the “Update Profile-Raw ground beef products” task, IPP assigned to establishments that:

\begin{itemize}
  \item 1. Portion and repackage raw ground beef products only;
  \item 2. Receive purchased beef manufacturing trimmings that are accompanied by certificates of analysis (COAs) with negative \textit{E. coli O157:H7} (or STEC organisms or virulence markers) test results; or
  \item 3. Receive purchased raw non-intact products (e.g., coarse grind or mechanically tenderized product) and use this product in its entirety to make raw ground beef products
\end{itemize}

are to use the information in Figure 1 in Chapter II and this section to determine whether the establishment produces products that are not subject to MT43 and MT65 sampling and is incorrectly receiving sampling tasks. IPP at these establishments are to delete other raw ground beef products listed in the PHIS profile, as appropriate, so that establishments will stop receiving incorrect sampling tasks.

D. IPP are to be aware that establishments that only portion and repackage raw ground beef product are incorrectly receiving MT43 sampling tasks. FSIS has added an additional PHIS product group, “portioned raw ground beef product,” to identify these establishments so that IPP assigned to these establishments will stop receiving MT43 sampling tasks after they update the PHIS profile, as described in this section.

E. IPP are to be aware that further processors that receive purchased beef manufacturing trimmings that are accompanied by COAs with negative \textit{E. coli O157:H7} (or STEC organisms or virulence markers) test results are incorrectly receiving MT65 sampling tasks. FSIS has added an additional PHIS product group, “raw ground beef product produced from source materials accompanied by COA, no bench trim” to identify these establishments, so that IPP assigned to these establishments will stop receiving MT65 bench trim sampling tasks after they update the PHIS profile, as described in this section.
F. IPP are to be aware that further processors that receive purchased raw non-intact products (e.g., coarse grind or mechanically tenderized product) and use this product in its entirety to make ground beef products are incorrectly receiving MT65 sampling tasks. FSIS has added an additional PHIS product group, “raw ground beef product from non-intact source materials, no bench trim” to identify these establishments, so that IPP assigned to these establishments will stop receiving MT65 bench trim sampling tasks after they update the PHIS profile, as described in this section.

G. IPP assigned to establishments producing raw beef products are to look for the task “Update Profile- Other components” on the task list and schedule it on the task calendar. IPP are to determine whether the establishment produces product eligible for MT64 other raw ground beef component sampling (See Figure 1 in Chapter II). IPP are to review the establishment profile and update the profile, as needed, to make the establishment subject to MT64 sampling (See MT64 section of Table 3). IPP are to complete this task no later than 60 days after the issuance of this directive.

H. These tasks are to be completed only once per active establishment. IPP are to follow the instructions in FSIS PHIS Directive 13,000.1, Scheduling In-plant Inspection Tasks in the Public Health Information System (PHIS), when scheduling their inspection tasks. IPP are to designate any unscheduled tasks that they did not complete as “not performed” as a result of the “Update Profile- Raw ground beef products” or “Update Profile- Other components.” IPP are to select “Higher priority task took precedent” as the reason code.

1. In multi-inspector/multi-shift establishments, the Inspector In-Charge (IIC) is to determine which IPP on which shift is to complete these tasks.

2. In multi-shift establishments with one IPP per shift, the Frontline Supervisor (FLS) is to determine which IPP are complete these tasks.

3. In multi-shift establishments, IPP who are not assigned to the shift in which the tasks are to be performed are to mark the task as “Not performed” and select the justification “Task assigned to another inspector.”

4. Relief IPP assigned to an establishment with one shift are to complete the task the first week they are assigned to the facility if the task has not already been completed by the assigned IPP.

I. IPP are to enter each product the establishment produces according to the product’s intended use. IPP are to enter the volume associated with the intended use and the number of days per month this product is produced.

J. IPP are to delete the same product groups that have the same intended use identified.

K. When IPP make changes to the establishment profile, they are to share the changes with establishment management during the weekly meeting. If the establishment disagrees with the changes, IPP are to update the profile with changes establishment management can substantiate (e.g., more accurate production volume information).

L. When the establishment changes the finished products it produces or the product's intended use, IPP, as part of the monthly PHIS profile task, are to follow the instructions in FSIS PHIS Directive 5,300.1, Managing the Establishment Profile in the Public Health Information System (PHIS), to update the finished products information in the PHIS profile, so that the establishment is subject to the
correct sampling tasks.

M. IPP are to follow the instructions provided in FSIS Directive 13,000.2, Performing Sampling Tasks in Official Establishments using the Public Health Information System, to cancel a sampling task when the product is intended for use in RTE product or to receive another full lethality treatment at a federally inspected establishment only (see Chapter I, Section III). IPP are to also cancel a sampling task when the product does not bear a mark of inspection because it is processed under a retail exemption, or the product is produced from cattle slaughtered under a custom exemption. Such product cannot be further processed within an official establishment.

N. In the event IPP receive a sampling task for a sampling program for which the establishment is not eligible, IPP are to indicate “Requested sample/product never slaughtered/produced” as the reason for canceling the task. IPP are to note that canceling a task and providing this justification does not ensure that IPP will not receive additional sampling tasks. If IPP receive a sampling task, and the establishment is not eligible for sampling, they are to review the establishment profile to make sure it is accurate and make necessary changes to correct the information in the profile.

O. Table 3 shows the finished product groups in PHIS that will generate specific sampling tasks. Attachment 1 provides detailed information on how finished products are to appear in the PHIS profile, so that establishments are recognized as subject to MT60, MT65, MT64, and MT43 sampling tasks, as appropriate. Attachment 1 provides information describing how to delete finished products (Figure 2) and add products (Figures 3A-3F). Attachment 1 includes screenshots showing IPP how to enter finished products so that establishments are subject to correct sampling tasks. Attachment 1 also includes screenshots showing IPP how to enter finished products that are intended for RTE (Figure 19) so that establishments are not subject to sampling tasks.

Table 3. PHIS Finished Product Groups that Generate Specific Sampling Tasks. See Attachment 1 for referenced figures.

<table>
<thead>
<tr>
<th>Sampling Program</th>
<th>Finished Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beef manufacturing trimmings (MT60)</td>
<td>Beef Manufacturing Trimmings (Figure 4)</td>
</tr>
<tr>
<td></td>
<td>Beef Trimmings from non-intact beef (Figure 5)</td>
</tr>
<tr>
<td></td>
<td>Ground Beef Product from in-house source materials (Figure 6)</td>
</tr>
<tr>
<td></td>
<td>Hamburger/Beef Patty Product (Figure 7)</td>
</tr>
<tr>
<td>NOTE: These products are produced from in-house source materials with the exception of trim produced from sister processing establishments.</td>
<td>Ground Beef combined with other species from in-house source materials (Figure 8)</td>
</tr>
<tr>
<td></td>
<td>Hamburger/Beef Patty combined with other species from in-house source materials (Figure 9)</td>
</tr>
<tr>
<td></td>
<td>Other non-intact product (fresh sausage, meat loaf, gyros, meat balls) (Figure 10)</td>
</tr>
<tr>
<td></td>
<td>Mechanically tenderized products from in-house source materials (Figure 11)</td>
</tr>
<tr>
<td></td>
<td>Trim produced by sister processing establishment (Figure 12)</td>
</tr>
<tr>
<td>Bench trim (MT65)</td>
<td>Bench Trim (trimmings from animals not slaughtered at the establishment) (Figure 13)</td>
</tr>
<tr>
<td>NOTE: These products are produced from purchased source materials.</td>
<td>Bench Trim (derived from non-intact beef not slaughtered at the establishment) (Figure 14)</td>
</tr>
<tr>
<td></td>
<td>Beef Trimming from non-intact beef (Figure 5) <strong>NOTE:</strong> IPP are to use this finished product group to identify bench trim derived from mechanically tenderized product.</td>
</tr>
<tr>
<td></td>
<td>Ground Beef Product from purchased source materials (Figure 15)</td>
</tr>
<tr>
<td>Category</td>
<td>Examples</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Ground Beef combined with other species from purchased source materials</td>
<td>(Figure 16)</td>
</tr>
<tr>
<td>Hamburger/Beef Patty combined with other species from purchased source materials</td>
<td>(Figure 17)</td>
</tr>
<tr>
<td>Hamburger/Beef Patty Product (Figure 7)</td>
<td></td>
</tr>
<tr>
<td>Other non-intact product (fresh sausage, meat loaf, gyros, meatballs, etc)</td>
<td>(Figure 10)</td>
</tr>
<tr>
<td>Mechanically tenderized products from purchased source materials</td>
<td>(Figure 18)</td>
</tr>
<tr>
<td><strong>Other raw ground beef components (MT64)</strong></td>
<td></td>
</tr>
<tr>
<td>Head Meat (Figure 20)</td>
<td></td>
</tr>
<tr>
<td>Cheek Meat (Figure 21)</td>
<td></td>
</tr>
<tr>
<td>Heart Meat (Figure 22)</td>
<td></td>
</tr>
<tr>
<td>Weasand Meat (Figure 23)</td>
<td></td>
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<tr>
<td>Ground Beef Product from in-house source materials (Figure 6)</td>
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<tr>
<td>Ammoniated Beef (Figure 24)</td>
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<tr>
<td>Advanced Meat Recovery (AMR) (Figure 25)</td>
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<tr>
<td>Low Temperature Rendered Product – Finely Textured Beef (FTB) (Figure 26)</td>
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<tr>
<td>Low Temperature Rendered Product – Partially Defatted Beef Fatty Tissue (PDBFT) (Figure 27)</td>
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<tr>
<td>Low Temperature Rendered Product – Partially Defatted Chopped Beef (PDCB) (Figure 28)</td>
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<tr>
<td><strong>Raw ground beef product (MT43)</strong></td>
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<tr>
<td>Hamburger/Beef Patty Product (Figure 7)</td>
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<tr>
<td>Ground Beef Product from in-house source materials (Figure 6)</td>
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<tr>
<td>Ground Beef Product from purchased source materials (Figure 15)</td>
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<tr>
<td>Ground Beef combined with other species from in-house source materials (Figure 8)</td>
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<td>Ground Beef combined with other species from purchased source materials (Figure 16)</td>
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<tr>
<td>Hamburger/Beef Patty combined with other species from in-house source materials (Figure 9)</td>
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<tr>
<td>Hamburger/Beef Patty combined with other species from purchased source materials (Figure 17)</td>
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**NOTE:** Establishments will not be subject to specific sampling tasks in PHIS if all of the finished product groups eligible under the sampling scheduling criteria in the PHIS profile are marked as “intended for RTE only.”

**II. SUPERVISORY RESPONSIBILITIES CONCERNING THE PHIS PROFILE**

A. Supervisory personnel are to ensure that the “Update Profile-Raw ground beef products” and “Update Profile- Other components” tasks are completed by reviewing the “Task Summary for a Circuit” PHIS report.

B. Supervisory personnel are to review the PHIS establishment profiles. Supervisory personnel are to ensure that IPP have accurately entered PHIS profile information as described in Section I of this chapter, so that establishments are recognized in PHIS as eligible for MT43 and MT64 sampling, as appropriate.

**CHAPTER IV - SAMPLE COLLECTION PREPARATION**

**I. PREPARING TO COLLECT A SAMPLE OF RAW PRODUCT FOR STEC VERIFICATION TESTING**
A. IPP are to provide enough time for the establishment to hold the sampled lot but not enough time to alter the process. To provide establishments enough time to hold the entire sampled lot, IPP are to:

1. Be knowledgeable concerning the establishment’s production practices;

2. Provide 1 day’s notice if such advance notice is sufficient for the establishment to hold the sampled lot. IPP may also provide 2 days’ notice, if necessary. The amount of time needed for establishment notification is not to impede FSIS’s ability to conduct verification activities that are representative of the establishment’s actual production practices. If less than 1 day’s advance notice would not cause a hardship for the establishment, IPP may provide less than 1 day’s notice before FSIS collects a sample for STEC testing;

3. Consider establishment requests for more than 2 days’ notice before collecting the sample based on the establishment’s product and process flow. In some cases, based on this consideration, IPP may agree that more than 2 days’ notice is necessary. For example, if an establishment makes case-ready product and requests that the inspector give it notice two days before the inspector is to take a sample, so that the establishment can adjust its production levels to fill its orders but still hold the sampled lot, then the inspector is to accommodate this request. If IPP have questions about an establishment’s basis for requesting more notice, they are to submit them through askFSIS;

4. Inform the establishment that it is responsible for supporting its basis for defining the production lot represented by the sample (i.e., the sampled lot); and

5. Inform the establishment that it is required to hold or maintain control of the sampled lot when FSIS collects samples for STEC until negative results become available.

B. IPP are to be aware that FSIS does not recognize “Clean-up to clean-up” alone as a supportable basis of distinguishing one portion of production from another portion of production.

C. IPP are to be aware that factors or conditions that may determine the sampled lot include:

1. Any scientific, statistically based sampling programs for STEC that the establishment uses to distinguish between segments of production;

2. Sanitation Standard Operating Procedures (Sanitation SOPs) or any other prerequisite program used to control the spread of *E. coli* O157:H7 cross-contamination between raw beef components during production. The following may lead to the cross-contamination between raw beef components during production:
   a. Improper sanitary dressing procedures;
   b. Insanitary product contact surfaces on equipment such as machinery and employee hand tools;
   c. Improper employee hygiene;

3. Processing interventions that limit or control STEC contamination; and

4. Beef manufacturing trimmings and raw beef components or rework carried over from one production period to another.
D. If multiple lots of raw ground beef product were produced from source materials from the same production lot from a single supplier, and some of this product was found positive for STEC, IPP are to be aware that a scientific basis is necessary to justify why any raw ground product produced at the grinder from those source materials should not be considered to be adulterated.

E. If IPP have questions concerning the establishment’s definition of or support for the sampled lot, they are to contact an Enforcement, Investigations, and Analysis Officer (EIAO) through their chain of command for assistance.

NOTE: When IPP are assigned to an unfamiliar establishment, they are to discuss sampling with the establishment during the entrance meeting. As part of this discussion, IPP are to determine how much notice to give the establishment before collecting a sample.

II. SCHEDULING SAMPLES IN PHIS

When IPP are assigned STEC sampling tasks in PHIS, they are to schedule the sampling task within the sampling window. IPP are to follow the instructions provided in FSIS Directive 13,000.2, and in the PHIS User Guide for scheduling and completing the sampling task using the PHIS.

III. ORDERING SAMPLING SUPPLIES

A. IPP are to follow the instructions provided in FSIS Directive 13,000.2, and request STEC sampling supplies at least 72 hours before the scheduled sample collection date.

NOTE: The FSIS Laboratory will not automatically send sampling supplies at the time the sample is scheduled.

B. IPP are to submit requests for N60 supply kits and additional supplies for N60 sampling to the Western Laboratory using the following Outlook mailbox:

   FSIS - Sampling Supplies – Western Lab

IV. GENERAL SAMPLING INSTRUCTION FOR ROUTINE STEC SAMPLING

A. IPP are to notify establishment management before collecting samples. IPP are to inform the establishment of the reason they are collecting the sample (e.g., routine FSIS verification testing or follow-up sampling in response to an STEC positive from FSIS or AMS testing).

B. IPP are to use a method for randomly selecting the production lot for sampling. IPP are to randomly select a day, shift, and time within the sample window after the sample collection date indicated in PHIS. IPP are to collect samples from all shifts the establishment operates and include Fridays in the random selection. There needs to be an equal chance that sampling will occur during any particular shift.

C. IPP may be assigned more than one sampling task during the same sampling window in an establishment that produces raw ground beef product, beef manufacturing trimmings, other raw ground beef or beef patty components, and trim or raw non-intact product from purchased product.

   1. IPP are not to collect a raw ground beef sample from the same lot of source materials (i.e., beef manufacturing trimmings, bench trim, or other raw ground beef components) that other IPP have already sampled.
2. If the establishment produces 1,000 pounds of product or less on a daily basis, or only on an intermittent basis, IPP are only to collect one sample. IPP are to sample beef manufacturing trimmings under the MT60 sampling program.

ANOTE: As described in Chapter III, IPP are to enter product production volumes and the number of days per month products are produced in PHIS.

D. IPP are to collect fresh and not frozen product for STEC sampling. IPP are only to collect a sample of frozen product if the establishment has a critical control point (CCP) for freezing in its HACCP plan, and freezing is an active process that achieves a reduction in STEC (e.g., a spiral freezer).

E. IPP are to collect the sample after the establishment has completed production of a lot (as defined by the establishment) and applied all antimicrobial treatments to the product to be sampled.

NOTE: Application of an antimicrobial treatment (other than a treatment that achieves a full-lethality) does not exempt the product from routine sampling.

F. HPP or irradiation can be applied in a manner that achieves full-lethality or applied so that full-lethality is not achieved. As described in Chapter II, Section III. B., if the product is to receive a full-lethality at a federally inspected establishment, IPP are to verify that the establishment’s hazard analysis and flow chart show that the product is intended for this use, and that the establishment has controls that ensure that the product is used as intended. If the product is being sent off-site to be treated with an intervention (e.g., HPP or irradiation) that does not achieve a full-lethality, IPP are to verify that the establishment’s hazard analysis and flow chart show that the product is treated with one of these interventions, the establishment has controls that ensure the intervention is applied, and the establishment does not complete pre-shipment review until these treatments have been applied. IPP are to verify, through records review, that the establishment maintains sufficient documentation to support its assertion that product receives an intervention off-site. If so, IPP are not to sample the product.

EXAMPLE: The establishment receives letters of guarantee showing that all product is treated with the intervention and maintains records documenting on-going communication with the receiving establishment to verify that all its product is being treated with the intervention.

G. IPP at the receiving establishment are to sample the product after the intervention that does not achieve a full-lethality is applied.

H. IPP are to collect a sample even if an establishment has already tested the production lot for STEC.

I. If the establishment intends to test the product for any of the adulterant STEC before completing pre-shipment review, IPP are not to wait for the establishment to receive the test results before collecting the sample. Each time IPP collect samples tested for STEC, they are to verify that establishments are holding or maintaining control of the sampled lot.

J. If an establishment does not hold or maintain control of product tested by FSIS for STEC, IPP are to write an NR because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as required in 9 CFR 417.5(c). In this situation, IPP are to immediately contact the District Office (DO).

V. ALTERNATIVE SAMPLING PROCEDURES FOR RAW GROUND BEEF PRODUCT (MT43) SAMPLING
A. General

1. Alternative sampling procedures only apply to raw ground beef product (MT43) sampling. Alternative sampling procedures are different from alternative lotting described in Section VI of this chapter. IPP are to follow the instructions below for these alternative sampling procedures when collecting a raw ground beef sample for MT43 sampling, provided that establishments meet the specific requirements applicable to each alternative sampling procedure.

2. Alternative sampling procedures include:
   a. Grinding a minimum batch of product; and
   b. Sampling a lot at the start of production.

NOTE: In the event of a positive result, IPP are to be aware that FSIS considers all same source materials used to produce the positive raw ground beef product to be positive unless the establishment has a scientific basis to distinguish production lots using same source materials (i.e., robust sampling of source materials or finished product or the application of a validated antimicrobial intervention to source materials or finished product according to the establishment’s supporting documentation).

B. Grinding a Minimum Batch of Product. An establishment may request that FSIS sample product from a minimum batch of product that represents the entire lot on a smaller grinder.

1. In this case, IPP are to verify that:
   a. The establishment has written procedures to grind a minimum batch of product that represents the establishment’s production process in a smaller, off-line grinder;
   b. The establishment has supporting documentation that describes how the minimum batch is representative of the establishment’s production process. As part of the verification that the minimum batch represents the establishment’s normal process, IPP are to ensure that the documentation includes an appropriate proportion of all types and suppliers of trim used to produce the larger production lot; and
   c. The minimum batch is not less than 50 pounds.

2. If the establishment meets the criteria in B. 1 above, IPP are to sample this minimum batch of product after randomly selecting the day, shift, and time and notifying the establishment as set out in Sections I and IV of this chapter. If the establishment does not meet the criteria, IPP are to collect the sample as described in Ch. V.

C. Sampling a Lot at the Start of Production. An establishment may request that FSIS sample a lot of raw ground beef product at the start of production.

1. In this case, IPP are to verify that the establishment has production schedules that define the specific components used at specific production times.

2. If the establishment does operate in accordance with schedules of this type, IPP are to:
   a. Randomly select a production date and time within the sample collection window on the task calendar in PHIS;
b. Select a time of production for sampling that is after the beginning of operations. If the establishment has documentation showing that it is scheduled to grind a specific lot of product at a specific production time, IPP are to allow the establishment to grind that lot of product at the beginning of operations on the day that PHIS schedules IPP for a sampling task; and

c. Verify that the establishment is not treating the source materials of the raw ground product that FSIS samples differently from other source materials used for grinding. For example, IPP are to verify that the establishment is not using interventions on the source material that it does not normally use on the ground product FSIS will sample.

3. If an establishment requests that FSIS sample raw ground beef product at the start of production, and it meets all these criteria, IPP are to collect samples at the start of production. If the establishment does not meet the criteria, IPP are to collect the sample as described in Ch. V.

VI. ALTERNATIVE LOTTING FOR RAW GROUND BEEF PRODUCT (MT43), BEEF MANUFACTURING TRIMMINGS (MT60), OTHER RAW GROUND BEEF COMPONENTS (MT 64), AND BENCH TRIM (MT65) SAMPLING

A. An establishment may request to reduce its lot size to one combo bin or some other unit (e.g., box) for samples of raw ground beef, beef manufacturing trimmings, other raw ground beef components, and bench trim on the day that FSIS collects samples.

B. In this case, IPP are to verify that the establishment:

1. Has a validated intervention for STEC at a CCP in the HACCP plan under which the beef manufacturing trimmings or other raw ground beef components are produced or requires its suppliers to have a CCP where a validated intervention is applied to the source materials used to manufacture the raw ground beef product or bench trim; and

2. Samples and tests every production lot for STEC and generally collects its samples of raw ground beef, beef manufacturing trimmings, other raw ground beef components, or bench trim across multiple combo bins or other sample units.

C. If an establishment meets the criteria in B. above, and reduces its lot size of ground product or bench trim from source materials, beef manufacturing trimmings, or other components to a single combo bin or sample unit when FSIS samples the product, IPP are to collect a sample from the single combo bin or sample unit. If the establishment does not meet the criteria, IPP are to collect the sample as described in Ch. V.

VII. GATHERING SUPPLIER INFORMATION

A. IPP are to gather information about the source materials and suppliers at the time they collect a routine raw ground beef (MT43) and bench trim (MT64) sample, as well as when they do follow-up sampling to these programs (MT44, MT44T, MT52, or MT53). Attachment 1 of FSIS Directive 10,010.3, Traceback Methodology for Escherichia coli (E. coli) O157:H7 in Raw Ground Beef Products and Bench Trim, provides IPP the supplier and source material information they are to gather at the time they collect raw ground beef and bench trim samples. This information enables FSIS to trace the raw material back to the original slaughter establishment. IPP can keep the actual label from empty packages. Establishment management can also provide information about the source materials. For imported source materials, IPP are to record the Inspection certificate number.
B. IPP are to document this information in a memorandum of interview (MOI) (see FSIS Directive 5000.1, Verifying an Establishments Food Safety System). IPP are to include "Supplier Information" in the subject line of the MOI. IPP are also to make note of any information that the establishment is unable to provide. IPP are to provide a copy of the MOI to establishment management. The information in the MOI will be available for use by IPP or EIAOs during traceback investigations as described in FSIS Directive 10,010.3.

CHAPTER V – SAMPLE COLLECTION PROCEDURES

I. GENERAL

A. The establishment may be eligible for more than one sampling program. IPP are to sample beef components, beef manufacturing trimmings, and bench trim separately and under their respective sampling codes, following the instructions provided in this Chapter. When the establishment produces multiple types of trim or components, IPP are to randomly select beef manufacturing trimmings, bench trim, and beef components and collect samples under their respective sampling codes. For a given sampling event, IPP are to collect only one type of trim or component type, whenever possible. The intent is that, through random selection, all eligible products the establishment produces that are subject to sampling will likely be selected over time. IPP are to ensure that IPP are to collect bench trim under the MT65 code even if the establishment has mixed in trim from animals slaughtered on site.

B. IPP are to collect samples of a lot according to the establishment’s lotting practices.

C. IPP are to use aseptic technique, including proper gloving technique, when collecting samples.

D. STEC Sampling of Domestic Raw Beef Products Video training is available online. See Attachment 6 for information on how to get credit for completing the optional training.

E. Attachments containing step-by-step sample collection procedures by sampling program are available. Attachment 2 provides sample collection procedures for MT60 beef manufacturing trimmings and MT65 bench trim. Attachment 3 provides sample collection procedures for MT64 other raw ground beef components. Attachment 4 provides sample collection procedures for MT43 raw ground beef product.

II. FINAL PACKAGING

A. IPP are to collect raw ground beef products in their final package whenever possible. IPP are to collect the appropriate number of packaged products so that the sample equals two pounds.

B. IPP are to place the product collected in its final packaging in the larger, non-sterile bag provided with the sampling supplies. IPP are not to use the Whirl-pak® bags when collecting products in its final packaging.

III. N60 SAMPLING METHOD

A. N60 sampling is the sample collection method IPP are to use when collecting samples of beef manufacturing trimmings and bench trim, provided the establishment produces beef manufacturing trimmings and bench trim in amounts that are large enough to be sampled using the N60 method. IPP assigned to establishments that produce beef manufacturing trimmings and bench trim of sufficient size to be sampled using the N60 method and trim too small to be sampled using the N60 method are to collect samples from the product that lends itself to N60 procedures. If the establishment commingles both types of trim, whenever possible, IPP are to collect samples from the product that lends itself to N60 procedures before commingling.
NOTE: If the establishment only produces beef manufacturing trimmings and bench trim that is too small to be sampled using the N60 method, IPP are to collect a sample by taking aseptic grab samples (see Section IV in this chapter).

B. IPP are to not to use the N60 method when collecting other raw ground beef component samples (MT64). IPP are to collect other raw ground beef component samples by taking aseptic grab samples (see Section IV in this chapter).

C. N60 sampling involves collecting 60 thin slices from the external surface of beef tissues. Each sample slice should be about 3 inches long by 1 inch wide and 1/8th inch thick, as shown below. It is important to collect thin slices because the surface of the beef carcass can be contaminated through improper sanitary dressing procedures. IPP are to collect only one sample slice from each of the 60 individual pieces of trim. IPP are not to take multiple samples from a single piece of beef manufacturing trimmings unless the production lot consists of less than 60 individual pieces. Collecting thin slices from the external surface maximizes the amount of surface area sampled, which increases the likelihood of finding pathogens if they are present.

D. IPP are to use the 3 Whirl-Pak bags when collecting samples using N60 procedures. IPP are to place 30 pieces in each of the two Whirl-Pak bags. NOTE: When cut to the correct size, 30 sample slices should fill one Whirl-Pak bag to the fill line. In the third Whirl-Pak bag, IPP are to aseptically collect samples of trim from the same production lot by using a grab sample technique. For larger trim pieces, IPP are to cut the trim piece so that it fits in the Whirl-Pak bag with at least 2-3 inches of space at the bag.

E. IPP are to randomly select one production lot according to the establishment’s lotting practices with each lot having an equal chance of being selected regardless of product location.

1. If an establishment’s specific production lot is greater than 5 containers, IPP are to select randomly 5 containers for sampling with each container having an equal chance of being selected; and

2. If the establishment’s specific production is 5 or less containers, IPP are to refer to Table 4 to determine the number of sample pieces to collect from each container.

<table>
<thead>
<tr>
<th># of containers in each specific lot</th>
<th># of sample pieces to select from each container</th>
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<tbody>
<tr>
<td>5</td>
<td>12 pieces</td>
</tr>
<tr>
<td>4</td>
<td>15 pieces</td>
</tr>
<tr>
<td>3</td>
<td>20 pieces</td>
</tr>
</tbody>
</table>
3. If the establishment reduces its lot size to one container and meets the alternative lotting in Chapter IV, Section VI. IPP are to collect samples from that container.

F. Some slaughter establishments may transfer beef manufacturing trimmings to another establishment that is in the same building as the slaughter establishment or separated from the slaughter facility by only a wall to ammoniate product. In some slaughter and fabrication establishments, product intended for use in ammoniated product may be moving on a conveyor belt directly into a second establishment. IPP are to sample the beef manufacturing trimmings at the slaughter establishment, just as if an establishment would send this product to a more distant location.

G. IPP are to use the N60 method to collect samples from primal and subprimal cuts that are used to produce mechanically tenderized products before tenderization if IPP can safely do so. When the primal and subprimal cuts used to produce mechanically tenderized product are from cattle slaughtered onsite, IPP are to sample the primal and subprimal cuts under MT60. When the primal and subprimal cuts or other source material used to produce mechanically tenderized products are from purchased product, IPP are to sample the primal and subprimal cuts or other source material under MT65.

H. IPP assigned to establishments that apply an antimicrobial and tenderize in a closed tunnel or cabinet-type system are to ask the establishment whether it has the capability and will agree to temporarily shut off the tenderizing component so that IPP can safely collect the sample after the antimicrobial treatment and before tenderization. If the establishment has this capability and agrees to do so, IPP are to collect the sample as the product exits the tunnel or cabinet after receiving the antimicrobial treatment. Once IPP collect the sample using the N60 procedures, the establishment could then run the remainder of the product that is to be treated through the tenderizer.

I. If the establishment does not have the capability to temporarily shut off the tenderizing component, or does not agree to do so, IPP are to collect the sample from the mechanically tenderized product using the N60 procedures and note in PHIS that mechanically tenderized product has been sampled.

IV. ASEPTIC GRAB SAMPLING

A. IPP are to aseptically collect grab samples and are not to use the N60 sample method when collecting other raw ground beef component (MT64) samples.

B. IPP are to aseptically collect grab samples when raw ground beef product (MT43) is not available in its final packaging, or the package is too large.

C. For aseptic grab samples, IPP are to collect a sufficient quantity of product to fill each of the three Whirl-Pak bags to the fill-line. For larger components, such as hearts, IPP are to collect one or more pieces or enough to fill each of the 3 Whirl-Pak® bags above the fill line but leaving at least 2-3 inches of space at the top of the bag when collecting MT64 samples.

V. PHIS QUESTIONS RELATED TO SAMPLE MATERIAL

A. For each sample of beef manufacturing trimmings collected in the MT60, MT52, and MT53 sampling programs, IPP are to answer the following questions in the Public Health Information System (PHIS) sampling collection task, in addition to any other questions not specific to non-O157 STEC sampling. IPP responses to the questions are important as they determine which analyses the FSIS laboratories will perform. (Only when the answer to all questions below is “yes” will the sample be analyzed for non-O157 STEC.)
B. Following some of the answer choices is guidance to assist IPP with answer selection.

1. Does the sampled lot contain beef manufacturing trimmings from cattle slaughtered only on-site?
   a. Yes
   b. No

**NOTE:** IPP that collect trim at sister processing establishments under MT60 are to answer “No” to this question so that the sample is not analyzed for non-O157 STEC at the lab.

2. Does the sampled lot contain only beef manufacturing trimmings and no other components?  
   (FOR MT52 AND MT53 SAMPLES ONLY)
   a. Yes: IPP are to select ‘Yes’ when they have verified that the entire sampled lot is composed only of beef manufacturing trimmings and does not contain any amount of other components or other material.
   b. No: IPP are to select ‘No’ when the sampled lot contains any amount of material other than beef manufacturing trimmings.

C. If IPP have concerns that an establishment is changing its lotting practices or other normal operational practices (including lot composition) to limit FSIS from testing beef manufacturing trimmings samples for the relevant non-O157 STECs, IPP are to consult their supervisory chain of command for further instructions

VI. PACKING AND SHIPPING THE SAMPLE

IPP are to use only the shipping materials provided by the laboratory and refer to FSIS Directive 7335.1, *Use of Sample Seals for Program Samples and Other Applications*, for complete instructions on the proper use of sample seals.

VII. ACCESSING TEST RESULTS

A. IPP are to obtain sample results by accessing Laboratory Information Management System (LIMS)-Direct for each sample submitted. The laboratories will report the results for all adulterant STECs (*E. coli* O157:H7 and non-O157 STEC) for each sample in LIMS-Direct.

**NOTE:** Results for *Salmonella* will continue to be displayed in LIMS-Direct under the section “Analysis Result: Non-regulatory Result” and will be displayed as being either “positive” or “negative.”

B. “Not acceptable” positive test results for adulterant STEC are reported in LIMS-Direct as soon as each analysis is completed and reviewed. If the sample confirms positive for a non-O157 STEC, LIMS-Direct will display the specific non-O157 STEC serogroups that are positive. “Acceptable” test results are not reported in LIMS-Direct until after all sample analyses are completed, and the results comply with FSIS regulatory requirements.

C. After receiving the STEC test results, IPP are to advise an establishment that is holding product that it does not need to continue to hold that product if it has tested negative for STEC. IPP are to be aware that establishments are not required to hold product when only *Salmonella* results are pending. If IPP receive *Salmonella* results before the *E. coli* O157:H7 results, they are to wait to notify the establishment until after receiving the STEC results.
D. Sample discard: If the FSIS Laboratory discards a sample submitted for STEC testing, IPP are to notify establishment management so that product may be released. IPP are to take appropriate action, based on the reason for the sample discard when applicable. IPP are to review the reason for sample discard and make the necessary adjustments in how the samples are collected, sealed, and shipped to ensure that the laboratory does not discard future samples because of improper handling or packaging.

NOTE: There may be reasons for sample discards (e.g., FedEx issues) that are beyond IPP control.

CHAPTER VI – FSIS ACTIONS IN RESPONSE TO FSIS, OTHER FEDERAL, OR STATE ENTITY STEC TEST RESULTS

I. NEGATIVE TEST RESULTS

IPP are to immediately notify the establishment of negative test results, so that the establishment can release product.

II. PRESUMPTIVE POSITIVE TEST RESULTS

When the DO receives a LIMS-Biological Information Transfer and E-mail System (BITES) notification that a sample is presumptive positive, the DO is to follow the instructions provided in FSIS Directive 10,010.3.

III. CONFIRMED POSITIVE TEST RESULTS

In the event of a confirmed positive result in raw ground beef product or trim or other components intended for use in raw non-intact product, the sampled lot is adulterated. The contact person in the DO is to immediately inform IPP assigned to that establishment and the establishment management. IPP are to follow the instructions in Chapter III, Section I of FSIS Directive 10,010.2 for responding to confirmed positive results.

IV. DO RESPONSIBILITIES IN RESPONSE TO AN FSIS CONFIRMED POSITIVE TEST RESULT

A. General

1. The DO enters information in System Tracking E.coli-O157:H7-Positive Suppliers (STEPS) based on an FSIS positive result or an AMS positive result. If another Federal or State positive result led to a recall, the DO is to enter information in STEPS based on these third party results.

2. If the DO enters one or more establishments into STEPS that are not within its District, STEPS will automatically notify the appropriate DO. The DO that receives the notification is to repeat the steps above for establishments within its District and add any additional information into STEPS.

3. IPP will only be instructed to collect follow-up samples from the establishment that produced the confirmed positive product and the originating slaughter establishments (see Chapter VII).

B. In response to a confirmed FSIS positive sample result, the DO is to:

1. Access STEPS, open a case file for the incident, and follow STEPS procedures; and

2. Direct IPP at supplying establishments to perform tasks:
a. The DO is to direct the IPP at all establishments that supplied product represented by the positive sample, including the originating slaughter establishments that were identified in STEPS, to perform directed HACCP and Sanitation SOP verification tasks per Sections V and VI of this chapter.

b. The DO is to direct the IPP at originating slaughter establishments to perform a directed Sanitary Dressing task.

3. Schedule a for-cause Public Health Risk Evaluation (PHRE) and after the completion of the PHRE take appropriate enforcement actions, if warranted, or schedule a for-cause Food Safety Assessment (FSA), as described in FSIS Directive 5100.4, Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology.

C. The DO is to take the appropriate enforcement actions (e.g., NOIE, withhold or suspend inspection, reinstate a suspension), if warranted, based on EIAO or IPP findings, as described in FSIS Directive 5100.3, Administrative Enforcement Reporting (AER) System.

V. IPP RESPONSIBILITIES AT THE ESTABLISHMENT WITH AN FSIS, ANOTHER FEDERAL, OR STATE ENTITY CONFIRMED POSITIVE TEST RESULT

A. In the event of a confirmed positive result in raw ground beef product or beef trim or other components intended for use in raw non-intact product, the sampled lot is adulterated.

B. IPP are to perform a directed HACCP Verification task for the specific production lot that tested positive and document noncompliance, where appropriate as described in FSIS Directive 10,010.2.

C. IPP that perform a traceback investigation as described in FSIS Directive 10,010.3 in response to an FSIS or another Federal or State agency ground beef or bench trim presumptive-positive result are to use the information they gathered during the traceback investigation to perform the directed HACCP Verification task. In this situation, the only HACCP regulatory requirement that has potentially not previously been verified during the traceback investigation is corrective action, so IPP are to verify that remaining HACCP regulatory requirement during the directed HACCP Verification task (see Chapter Two, Section III of FSIS Directive 10,010.2).

D. IPP are to perform a directed Sanitation SOP task and are to verify that the establishment is properly implementing its Sanitation SOP as set out in FSIS Directive 5000.1.

E. IPP are to perform a directed Beef Sanitary Dressing task as described in FSIS Directive 6410.1, Verifying Sanitary Dressing and Process Control Procedures by Off-Line Inspection Program Personnel (IPP) in Slaughter Operations of Cattle of Any Age, if the positive sample result was from product from the establishment’s own slaughter operation.

F. IPP are to collect follow-up samples as described in Chapter VII.

VI. IPP RESPONSIBILITIES ASSIGNED TO ESTABLISHMENTS THAT SUPPLIED THE SOURCE MATERIALS USED TO PRODUCE THE POSITIVE PRODUCT

A. IPP assigned to supplying slaughter and further processing establishments are to:

1. Perform a directed HACCP verification task as described in FSIS Directive 10,010.2, for the specific production lot of source materials used to produce the product that tested positive; and
2. Perform a directed Sanitation SOP task of reviewing records for the day or days that the source materials used to produce the product that tested positive.

B. IPP assigned to supplying slaughter establishments are to:

1. Perform a directed Beef Sanitary dressing task; and

2. Conduct follow-up sampling as described in Chapter VII.

CHAPTER VII –FOLLOW-UP SAMPLING PROCEDURES

I. GENERAL

A. IPP are to collect follow-up samples in response to FSIS or Agricultural Marketing Service (AMS) positives as soon as possible after the positive results were obtained, unless the establishment stops producing any raw beef product intended for raw non-intact use. The purpose of follow-up sampling is to determine whether the establishment’s process is effectively addressing STEC.

B. IPP are to collect follow-up samples from the same type of product that tested positive, if available. If the establishment is not producing the product requested, IPP are to collect follow-up samples from beef manufacturing trimmings if the establishment is producing them.

C. In the event that the establishment does not produce the product that tested positive or beef manufacturing trimmings, IPP are to collect follow-up samples from other raw ground beef components or bench trim, if available.

D. IPP are not to wait until the establishment takes corrective actions or has confidence that its corrective actions are effective to collect follow-up samples.

E. IPP are to continue collecting samples for a follow-up sampling task until the set is complete. Specifically, IPP are to continue collecting follow-up samples until the applicable number of samples (16 or 8 consecutive negative samples, see Section II.C. of this chapter) have been collected for each follow-up sampling set triggered.

NOTE: The status of a follow-up set can be determined through a PHIS report and is included on set update alerts.

F. The Office of Data Integration and Food Protection (ODIFP) has automated the assigning of follow-up samples in PHIS. Follow-up sampling sets are generated in response to each positive from FSIS’s routine sampling programs at the establishment that received the positive result.

1. A raw ground beef positive from MT43 or AMS sampling will result in an MT44 follow-up sampling set unless the establishment is a combination slaughter/processing establishment that supplied the source materials used to produce the positive raw ground product. In this situation, PHIS will generate an MT53 follow-up sampling set.

2. A positive in beef manufacturing trimmings from MT60 or AMS sampling, bench trim (MT65), or other ground beef or raw beef patty components (MT64) will result in a MT53 follow-up sampling set.

G. FSIS also schedules follow-up sampling sets at supplying slaughter establishments in response to a positive from raw ground beef sample from MT43 or AMS sampling and a bench trim (MT65) positive.
1. Supplier follow-up sampling sets have the MT52 project code. Supplier follow-up sampling sets are discussed in more detail in Section II of this chapter.

2. In a limited situation, FSIS will schedule a follow-up sampling set for a supplying slaughter establishment in response to a positive in ammoniated product (See Section II.D. of this chapter).

H. FSIS may also schedule a follow-up sampling set (MT44T) outside these follow-up sampling projects, e.g., in response to an outbreak or recall.

I. Each positive result in a follow-up sampling set triggers another follow-up sampling set. PHIS automatically adds enough follow-up sampling tasks for IPP to collect the desired number of consecutive negatives to complete the follow-up sampling sets.

J. IIC should expect to receive a follow-up sampling set within 2 days of the positive sample result. If IPP do not receive the follow-up set within this timeframe, the IIC is to contact Risk, Innovations, and Management Staff (RIMS) through the “Sampling” category of askFSIS to request a follow-up sampling set.

K. IPP are to contact RIMS through askFSIS if they have questions concerning sampling, including whether follow-up sampling sets have the appropriate project code and number planned, and what products to collect. IPP are also to contact RIMS before canceling a follow-up sampling task to determine whether canceling the follow-up sampling task is appropriate.

L. A PHIS alert informs IPP of the components to sample based on information in the database.

II. FOLLOW-UP SAMPLING AT SUPPLIERS

A. If the originating slaughter establishments supplied more than one type of source material used in the positive ground beef or bench trim sample, PHIS will generate sampling tasks for each type of source material.

B. IPP are to collect a single follow-up sample or multiple follow-up samples at supplier establishments as assigned. PHIS does not assign follow-up sampling tasks at establishments that only bone or fabricate beef primal or subprimal cuts but do not slaughter, except for ammoniated beef trimmings (see C.4. and 5. of this section), because supplier follow-up samples target the supplying slaughter establishment.

C. If PHIS determines that an originating slaughter establishment was the only supplier, or that any of the originating slaughter establishments were suppliers that had previously been identified in STEPS within approximately 4 months (or 120 days) of the current raw ground product or bench trim positive result, PHIS assigns 16 (or 8 in response to an AMS positive or the establishment produces less than 1,000 pounds per day of the product that tested positive) MT52 follow-up sampling tasks for the originating slaughter establishments. The follow-up samples are identified for each component used in the positive raw ground beef or bench trim product.

1. If a supplier is not a sole supplier or a repeat supplier in STEPS, PHIS assigns a single follow-up sampling task for the supplier for each component used in the positive raw ground beef or bench trim product.

2. In the event of an AMS positive E. coli O157:H7 raw ground beef sample result under the AMS commodity purchase program, PHIS assigns 8 MT52 follow-up sampling tasks to the originating slaughter establishments. IPP are to collect follow-up samples of the requested source materials used to produce the ground product AMS found positive until 8 consecutive
negative samples are received, regardless of establishment size in response to an AMS positive result.

3. In combination slaughter/processing establishments, if a Federal agency other than FSIS or a State entity finds ground product positive, the results are accepted by FSIS, and the establishment produced the source materials used to produce the ground product, PHIS assigns MT53 sampling tasks to the combination slaughter/processing establishment.

   a. IPP are to collect either 8 or 16 MT53 samples, based on establishment size and the type of source materials used in the positive raw ground beef product.

   b. IPP are not to collect follow-up samples of raw ground beef product.

NOTE: Follow-up samples of raw ground beef product are to be collected from the grinders that used purchased source materials (see Section I.F.1. of this chapter).

4. If ammoniated low-temperature-rendered (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 assigns MT53 sampling tasks. IPP are to collect MT53 samples of ammoniated boneless lean beef tissue (BLBT) at the establishment that produced the ammoniated LTR product, even if that establishment is not an originating slaughter establishment.

5. If the establishment that produced the ammoniated LTR is not an originating supplying slaughter establishment, PHIS does not request MT52 sampling tasks at the slaughter establishments that produced the source materials used in the ammoniated LTR, except as provided in the D.3 of this Section.

D. If the ammoniated LTR product tests positive under the MT53 verification sampling program:

   1. IPP are to collect supplier information from the establishment that produced the ammoniated low-temperature rendered product.

   2. The DO is to enter the supplying establishments into STEPS.

   3. PHIS assigns MT52 sampling tasks the slaughter establishments that produced the source materials used in the positive ammoniated LTR product.

III. SPECIAL INSTRUCTIONS FOR FOLLOW-UP SAMPLING (MT52) OF INTACT BEEF COMPONENTS THAT WERE NOT INTENDED FOR USE IN RAW NON-INTACT PRODUCT

A. If intact product was used as a component in raw ground beef product or was sampled as bench trim that FSIS finds positive for *E. coli* O157:H7, IPP are to select a carcass (rather than the component of the carcass) at the originating slaughter establishment for follow-up sampling under the following conditions:

   1. HACCP plan records and purchase specification records for product produced at the originating slaughter establishment show that the intact product was not intended for grinding or non-intact product, and that the establishment informed purchasers that the product was not intended for grinding; and

   2. The establishment derived intact product from the carcass in a manner to minimize commingling with other product, and the establishment packaged the product separately from
other product without commingling (e.g., boneless chucks were placed on a conveyor belt and were then off-loaded for packaging without being commingled with other product).

B. IPP are to verify that that the conditions in A. above are met. If the conditions in A. above are met, IPP are to collect the samples at the originating slaughter establishment from one or more carcasses hanging in the cooler before fabrication, according to the establishment’s lotting practices.

1. IPP are not to wait until the establishment breaks the carcass down into primal and subprimal cuts to collect follow-up samples.

2. IPP are to use the N60 method to collect slices from the carcass surface from the same part of the carcass used to produce the raw ground beef product or bench trim, if known.
   a. If the location on the carcass is not known, then IPP are to sample:
      i. Inside round;
      ii. Outside round;
      iii. Navel plate;
      iv. Brisket; and
      v. Foreshank
   b. If the slaughter establishment designates more than 1 carcass as a lot, then IPP are to collect samples from more than 1 carcass as follows:
      c. IPP are to cut enough slices off the surfaces of the carcass to equal 2 pounds.

C. If both conditions in A. above are not met, IPP are to sample the intact components that were used to produce the positive raw ground beef or bench trim products using the N60 method.

D. If the FSIS sample collected is positive in B., generally only the sampled carcass is implicated because STEC contamination is generally point-source contamination that occurs sporadically as a consequence of handling during hide removal and dressing of the carcass. However, if the establishment does not prevent carcasses from being commingled or does not have adequate controls to prevent cross contamination among carcasses, it will not be able to designate a single carcass lot for sampling.
1. The establishment may decide to destroy the implicated carcass or to use it to produce products that will be processed to destroy the pathogen (e.g., by cooking).

2. Because establishments remove the head and cheek meat, weasand, hearts or offal during the slaughter process and process them separately from the rest of the carcass, FSIS will not consider these parts associated with the positive STEC result, unless there is cross-contamination, inadequate sanitary dressing procedures, or inadequate controls to prevent contamination.

CHAPTER VIII – SAMPLING OF RAW BEEF PRODUCT INTENDED FOR THE NATIONAL SCHOOL LUNCH PROGRAM (NSLP)

I. GENERAL

Establishments may produce product for the NSLP, which is administered by the Food and Nutrition Service (FNS). AMS is responsible for testing product under the NSLP.

II. IPP VERIFICATION RESPONSIBILITIES

A. IPP verify that establishments adequately address adulterant STEC by collecting samples at establishments that produce raw beef product for the NSLP, even if the establishment collects a sample to be tested for the AMS program.

1. When IPP receive a sampling task at an establishment that produces product for both the NSLP and other further processors, IPP are to prioritize sampling the non-NSLP product, if available. If only NSLP product is available during the sampling window, IPP are to collect samples from NSLP product.

2. When an establishment produces raw non-intact beef or raw intact beef intended for non-intact use for the NSLP only, IPP are to collect samples as requested. In this situation, IPP are to collect the sample even if the establishment is collecting a sample from the same production lot for AMS testing for the NSLP.

B. IPP are to review Table 6 and use the information to help them determine when to collect samples under the NSLP.

<table>
<thead>
<tr>
<th>What product is available at time of sample collection?</th>
<th>Scenario 1. Est produces products for NSLP Only</th>
<th>Scenario 2. Est produces products for NSLP and other customers</th>
<th>Scenario 3. Est produces other customer product only</th>
</tr>
</thead>
<tbody>
<tr>
<td>What product should IPP collect?</td>
<td>Response 1. Collect NSLP product</td>
<td>Response 2. Collect product for other customers, if available, and NSLP product if product for other customers is not available</td>
<td>Response 3. Collect product for other customer</td>
</tr>
</tbody>
</table>

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C. When a sample collected under the NSLP tests positive, IPP are to collect product for follow-up sampling from either NSLP product or other product. IPP are not to prioritize sampling products for other customers over NSLP product.

NOTE: Samples also collected for NSLP tests cannot substitute for those collected by FSIS for follow-up sampling.

D. When a sample collected under the NSLP tests positive, IPP are to collect 8 follow-up samples even in high volume establishments, because of the other testing that product subject to AMS sampling undergoes.

E. IPP are responsible for verifying corrective actions for a positive result for either the FSIS sample or a sample collected by the establishment for AMS testing, including appropriate disposition of the product. A positive result from either sample would mean product is adulterated, and IPP are to follow instructions regarding positive sample results.

III. DO RESPONSIBILITIES IN RESPONSE TO AN AMS CONFIRMED POSITIVE TEST RESULT

The DO is to follow the instructions provided in Chapter VI of this directive.

CHAPTER IX – IMPORTS SAMPLING

I. DEFINITIONS FOR IMPORT SAMPLING

A. PHIS makes sampling assignments for STEC based on the shipment data (process category, product category, product group) entered into PHIS. The three levels of reinspection (LOR) assigned to a type of inspection (TOI) by the PHIS are Normal, Increased, and Intensified.

B. The sampling projects for imported product tested for STEC are:

1. MT08 – the TOI and sample project for the *E. coli* O157:H7 pathogen in imported raw ground beef (including veal) product. Assigned at Normal, Increased or Intensified LOR.

2. MT51 – the TOI and sample project for the *E. coli* O157:H7 and non-O157 STEC in imported raw beef manufacturing trimmings and *E. coli* O157:H7 in other raw ground beef components. Assigned at Normal, Increased or Intensified LOR.

C. Imported raw beef product collected for STEC analysis under the MT08 and MT51 sampling programs will also be analyzed for *Salmonella*.

II. GENERAL RAW BEEF PRODUCT SAMPLING CONDUCTED AT IMPORT ESTABLISHMENTS

A. STEC Sampling of Imported Raw Beef Products Video training is available online. See Attachment 6 for information on how to get credit for completing this optional training.

B. Attachment 5 provides sample collection procedures for N60 sampling of MT51 imported frozen beef manufacturing trimmings and other frozen components.

C. When PHIS assigns an *E. coli* O157:H7 TOI for STEC analysis to a lot of imported product, import inspection personnel are to:
1. Notify the import establishment management of the reason for collecting a sample for *E. coli O157:H7* testing (normal, increased, or intensified LOR), and whether or not the sample will also be analyzed for non-O157 STEC (sampled lots that contain only beef manufacturing trimmings);

2. Follow the sampling instructions for the appropriate project;

3. When applicable, inquire whether the importer of record (IOR) will be holding the lot on-site at the official import inspection establishment or off-site under the IOR’s control. When the lot will be held off-site, import inspection personnel are to record the location in the Remarks block of the Sample Collection – Sample Management page in the PHIS; and

4. Collect samples from one specific production code or date.

D. In PHIS import inspection personnel are to:

1. From the Lab TOIs screen, click on Sample Form box. The Sample Management – Sample Collection page will appear, with the Generate a Sample tab open.

**NOTE:** In the rare event that the sample was already submitted to the lab on a non-PHIS issued form because PHIS was down during intensified or increased LOR, and import inspection personnel submitted the sample outside of PHIS, import inspection personnel are to place a check in the “Has this sample already been mailed to the lab using a non-PHIS form?” box before proceeding.

2. Verify the information on the screen is correct. If the information is not correct, make the corrections before proceeding.

3. Check the appropriate “Analyses” boxes as follows for the assigned TOI:
   
   a. *E. coli O157:H7* MT08:
b. STEC MT51: (Boneless Manufacturing Trimmings)

c. *E. coli* O157:H7 MT51: (Other than Boneless Manufacturing Trimmings)

4. Enter the appropriate sample weight, and save the information.
5. After opening the Sample Collection Data tab, complete the required fields.

6. For the Production Date field, if the product code is a calendar date, select the date. If the code is not a calendar date, import inspection personnel are to type “Product Code:” in the “Remarks” block on the Sample Collection Data tab, followed by the product code, and select today’s date for the Production Date field.

7. In the Remarks block, enter any additional information that may be helpful to the lab. When the lot will be held off-site until the laboratory results are reported, import inspection personnel are to enter the name and address of the location where the IOR indicates the lot will be held. Select Save & Continue.

8. After opening the Additional Info tab opens, click on “Take Questionnaire” and, if prompted, save changes.
9. To complete and save the questionnaire, follow the on-screen prompts that appear.

10. Return to the Lab Sampling screen Data Collection Tab and select “Print Form.” Review the on-line form and, if accurate, print it.

11. Prior to clicking “Submit to Lab”, enter their title and the date, and then submit to lab.

E. Import inspection personnel are to access the Laboratory Information Management System (LIMS-Direct) to retrieve the laboratory results and provide the results to import establishment management even if the establishment receives e-mail notifications.

F. Import inspection personnel are to access PHIS to verify the results have posted to the lot in PHIS. If results do not post into PHIS within 48 hours, import inspection personnel are to submit a Foot Prints Ticket.

G. Import inspection personnel are to not perform the TOI in PHIS when notified that a laboratory sample from a lot held under an IOR’s control has been discarded and will not be analyzed by the FSIS laboratory. Import inspection personnel are to notify the official import inspection establishment so the IOR can release the product.

H. Import inspection personnel are to access PHIS to submit a 2nd sample when notified that a laboratory sample from a lot held under FSIS control has been discarded and will not be analyzed by the FSIS laboratory. Import inspection personnel are to notify the official import inspection establishment so it can notify the IOR that the lot will continue to be on hold until sample results for the 2nd sample are reported.

I. Import inspection personnel are to submit a completed FSIS Form 9770-3, “Discarded Sample Report and Findings” for samples that the FSIS laboratory reports as discards to the supervisor after completion. Import inspection personnel assigned to the import establishment from which the sample was sent are to complete the form.

J. Import inspection personnel are to initiate a refused entry in PHIS for the sampled lot if the sample reports as positive. If the lot was held off-premises, import inspection personnel are to notify import establishment management to request that the IOR return the product to the official import inspection establishment for marking and disposition. EXCEPTION: if the shipment is from Canada and was returned to Canada under the Annex J procedures referenced in FSIS Directive 9900.6, Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products, the shipment does not need to be returned for marking and disposition.

K. Import inspection personnel are to notify their supervisor immediately if import inspection personnel become aware that the IOR has not held the lot and has moved it into commerce.

L. Import inspection personnel are to verify the marking and disposition of the lot for refused entry lots, as per FSIS PHIS Directive 9900.8, Meat, Poultry, Egg Products, and Shell Eggs Refused Entry into the United States (U.S.).

III. SAMPLING PROGRAM FOR IMPORTED BEEF MANUFACTURING TRIMMINGS AND OTHER COMPONENTS (MT51)

A. Product sampled under the MT51 sampling program at official import inspection establishments may contain both beef manufacturing trimmings and other components (such as cheek meat, head meat, or other components described in this Directive). Sampled lots other than beef manufacturing trimmings are to be tested for E. coli O157:H7 and Salmonella only, while lots containing only beef...
manufacturing trimmings are also to be tested for non-O157 STEC, based on the responses to questions on the questionnaire portion of the Additional Info tab in PHIS.

B. For beef manufacturing trimmings and other raw ground beef components – Fresh (not frozen), import inspection personnel are to follow the methods described for domestic inspection.

C. To sample frozen beef manufacturing trimmings and other raw ground beef components, import inspection personnel are to select 5 containers from the lot. The containers are to have the same production code or date. Import inspection personnel are to collect 60 individual pieces from frozen beef manufacturing trimmings and other raw ground beef components as described in the Attachment 5.

D. For each sample of beef manufacturing trimmings collected in the MT51 sampling program, import inspection personnel are to answer the following question on the PHIS sample collection form. Import inspection personnel’s response to the question is important, as it determines which analyses the FSIS laboratories will perform. Only when the answer to the question in E. below is “yes” will the sample be analyzed for non-O157 STEC.

E. The question is: Does the sampled lot contain only beef manufacturing trimmings and no other components?

1. Import inspection personnel are to select ‘Yes’ when they have verified that the entire sampled lot is composed only of beef manufacturing trimmings and does not contain any amount of other components or other material.

2. Import inspection personnel are to select ‘No’ when the sampled lot contains any amount of material other than beef manufacturing trimmings.

IV. OBTAINING SAMPLE RESULTS

Import inspection personnel are to access LIMS-Direct for sample results as described for domestic samples.

V. ACTIONS TO TAKE BASED ON RESULTS

A. When a sample tests negative for *E. coli* O157:H7, the sampled lot is not subject to further testing, and import inspection personnel are to release it if it is on FSIS Hold, and all other reinspection criteria are acceptable.

B. Presumptive positive

1. When LIMS-Biological Information Transfer and E-mail System (BITES) notifies OFO import inspection management (HQ and supervisor) that a sample is presumptive positive, the supervisor is to notify import inspection personnel that the sample has a presumptive positive status. OFO RMTAS-Imports Headquarters staff is to follow the instructions provided in FSIS Directive 10,010.3.

2. Import inspection personnel are to:

   a. Notify establishment management of the presumptive positive result and are to report whether the lot is on hold by the importer of record or FSIS and the location of the lot to their supervisor;
b. Provide the supervisor with a copy of the health certificate and any other documents pertinent to the lot, including copies of the FSIS form 9540-1 and laboratory form which may be printed from PHIS;

c. If the lot is on an IOR hold, inform import establishment management that import inspection personnel are placing the product on FSIS hold. Import inspection personnel are to request that import establishment management contact the IOR to inform it of the presumptive positive, and that the product is on FSIS hold. Import inspection personnel are to report to their supervisor that the product is on FSIS hold;

d. If the lot is not on FSIS hold but is still at the import establishment, import inspection personnel are to retain the product and request import establishment management to contact the IOR to inform it of the presumptive positive result and the retention of the product. Import inspection personnel are to report to their supervisor that the product is being retained;

e. If the lot is on an IOR hold and has been moved from the official inspection establishment to an off-site location, request import establishment management to:
   i. Contact the IOR to inform it of the presumptive positive;
   ii. Inform the IOR that import inspection personnel are placing the product on FSIS hold and to stop further movement of the product; and
   iii. Request the off-site location of the product. Import inspection personnel are to report the location information to their supervisor.

f. OFO Headquarters is to notify the inspection program officials of the involved exporting country as soon as an Agency laboratory reports a presumptive positive result in order to identify whether the establishment from the exporting country has any other product from the presumptive positive lot identified in the United States.

C. Confirmed positive results

1. When a sample is confirmed positive for any adulterant STEC, import inspection personnel are to:

   a. For a lot initially on hold by the IOR, initiate a refused entry in PHIS for the sampled lot. If the lot was being held off-premises, request import establishment management to contact the IOR to inform it of the positive result and request that the lot be returned to the official import inspection establishment as soon as possible;

   b. For a lot initially on FSIS hold, initiate a refused entry in the PHIS. Import inspection personnel are to follow the refused entry procedures identified in FSIS PHIS Directive 9900.8; and

   c. Contact their supervisor who is to contact RMTAS to initiate a recall if the lot was moved into commerce. OFO DM are to follow the Recall Procedures per FSIS Directive FSIS Directive 8080.1, Recall of Meat and Poultry Products, and section D. below.

2. OFO import inspection Headquarters staff are to notify the inspection program officials of the involved exporting country as soon as a laboratory reports a positive result in order to identify
whether the foreign country has any other production lots from the lot identified exported to the United States. If any lots are identified by the foreign country from the same producer with the same production code, OFO is to:

a. Request a recall of the product if import inspection personnel passed the product under import reinspection; and

b. Refuse entry of the product if import inspection personnel have not passed the product under import reinspection.

3. OFO import inspection Headquarters is to issue an alert to import inspection personnel to refuse entry for the same lot of product with the same production codes that the foreign country presents for FSIS import reinspection after the confirmed positive result and, if needed, direct import personnel to take additional action.

D. If the product represented by the same production codes or dates that tested positive for an adulterant STEC moved into commerce by the IOR, then:

1. Import inspection personnel are to send a completed copy of FSIS Form 9540-1 and the foreign health certificate via fax (202) 720-6050 to the OFO import inspection Headquarters.

2. OFO import inspection Headquarters is to notify the head of the inspection service in the country of origin and the Foreign Agriculture Service (FAS) representative to the country from which the positive product arrived of the confirmed positive adulterant STEC sample result. OFO import inspection Headquarters is also to inform them whether FSIS will request that the IOR recall any of the applicable product in commerce. OFO import inspection Headquarters is to request that the foreign country conduct a FSA or equivalent procedure at the producing establishment and test follow-up samples from the grinding facility or the originating slaughter establishments that produced the positive product.

EXAMPLE: Raw beef product was imported from a single lot but as two separate shipments with different shipping marks. FSIS only tested one of the shipments, found it positive, and refused entry to the shipment. The products that FSIS sampled and released were in cold storage and so were not distributed. The company wanted to move that product to an official establishment for a lethality treatment. There is no HACCP plan or pre-shipment review associated with the now domestic product. The product in this example would need to move only under FSIS seal because there is not a supplying domestic establishment to control the product per the instructions in this directive.

CHAPTER X - DATA ANALYSIS

Members of the Office of Public Health Science will report the FSIS STEC laboratory test results for raw ground beef products, trim, and other raw ground beef components on FSIS’s website. The Data Analysis and Integration Staff (DAIS) within ODIFP will compute annual prevalence estimates of adulterant STEC in raw ground beef and beef manufacturing trimmings. Members of DAIS will also compare the collection rates for MT55 and MT54 sampling tasks with the collection rates for MT65 and MT64 sampling tasks and determine whether the collection rates improve as a result of the redesign of the bench trim and other raw ground beef component sampling programs.

CHAPTER XI - QUESTIONS

Refer questions regarding this directive to the Risk, Innovations, and Management Staff through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:
Subject Field: Enter **Directive 10,010.1**
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select **Sampling *E. coli* O157:H7** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**

**NOTE:** Refer to **FSIS Directive 5620.1, Using askFSIS**, for additional information on submitting questions.

[Signature]

Assistant Administrator
Office of Policy and Program Development
ATTACHMENT 1 Updating the PHIS Establishment Profile to Ensure Establishments are Eligible for MT60 Beef manufacturing trimmings, MT65 Bench trim, MT43 Raw ground beef product, and MT64 Other raw ground beef component Sampling, as Appropriate

This attachment describes how to delete finished products (Figure 2) and add products (Figures 3A-3F). Also shown are screenshots of how the establishment profile is to appear in PHIS for each finished product listed in Table 6 (Figures 4-21) to ensure that establishments are recognized by PHIS as eligible for STEC sampling programs, as appropriate.

Figure 2. How to Delete a Product in the Establishment Profile Products page. Select the trash can icon (yellow arrow) to delete the product.

Figures 3A-3F. How to Add a New Product Group in the Establishment Profile Products page. Follow the steps diagrammed in Figures 3A through 3F to add a new product group to the establishment profile. After completing each screen, be sure to click the “Save” button at the bottom of the screen.

Figure 3A. On the Products tab, select “Add a new Product Group” (yellow arrow).
**Figure 3B.** On the “Raw” tab (yellow arrow), enter the HACCP Category and HACCP Plan. For Finished Product Category, enter “Raw intact beef” (red box).

**Figure 3C.** After completing steps in Figure 3B, select the appropriate Product Group. In this example, select “Beef Manufacturing Trimmings” (yellow arrow).
**Figure 3D.** For each Product Group selected, enter the Average Daily Volume (pounds per day) (red box). For intended use in raw non-intact product (e.g., raw ground beef, mechanically tenderized product, vacuum tumbled product) or when the intended use is unclear, select “Other” (yellow arrow).
**Figure 3E.** In this example, the product group Beef Manufacturing Trimmings (red box) was added to the establishment profile.

![Image showing the addition of Beef Manufacturing Trimmings](image)

**Figure 3F.** Select the “Volumes” tab and verify that the HACCP Volumes are correct. If not, revise the volumes.

![Image showing the Volumes tab](image)
Figure 4. Beef Manufacturing Trimmings (MT60). On the “Raw” tab, for HACCP Category, select “Slaughter” or “Raw Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, select “Raw intact beef.” For Product Group, select “Beef Manufacturing Trimmings.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
Figure 5. Beef Trimming from Non-Intact Beef (MT60 and MT65). On the “Raw” tab, for HACCP Category, select “Raw - Non Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, select “Raw ground, comminuted, or otherwise non-intact beef.” For Product Group, select “Beef Trimming from nonintact beef.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
Figure 6. Ground Beef Product from In-House Source Materials (MT43, MT60, and MT64). On the “Raw” tab, for HACCP Category, select the “Raw - Non Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, select “Raw ground, comminuted, or otherwise non-intact beef.” For Product Group, select “Ground Beef Product from in-house source materials.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
Figure 7. Hamburger/Beef Patty Product (MT43, MT60, and MT65). On the “Raw” tab, for HACCP Category, select the “Raw – Non Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, select “Raw ground, comminuted, or otherwise non-intact beef.” For Product Group, select “Hamburger/Beef Patty Product.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
Figure 8. Ground Beef Combined with Other Species from In-House Source Materials (MT43 and MT60). On the “Raw” tab, for HACCP Category, select “Raw - Non Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, select “Raw ground, comminuted, or otherwise non-intact beef.” For Product Group, select “Ground Beef combined with other species from in-house source materials.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
Figure 9. Hamburger/Beef Patty Combined with Other Species from In-House Source Materials (MT43 and MT60). On the Raw tab, for HACCP Category, select “Raw-Non-Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, enter “Raw ground, comminuted, or otherwise non-intact beef.” For Product Group, enter “Hamburger/Beef Patty combined with other species from in-house source materials.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
**Figure 10.** Other Non-Intact Product (fresh sausage, meat loaf, gyros, meat balls, etc.) (MT60 and MT65). On the “Raw” tab, for HACCP Category, select “Raw - Non Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, select “Raw ground, comminuted, or otherwise non-intact beef.” Select the Product Group “Other Non-Intact Product (fresh sausage, meat loaf, gyros, meat balls, etc).” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
Figure 11. Mechanically tenderized products from in-house source materials (MT60). On the “Raw” tab, for HACCP Category, select “Raw - Non Intact” and enter the name of the establishment's HACCP plan. For Finished Product Category, select “Raw ground, comminuted, or otherwise non-intact beef.” For Product Group, select “Mechanically tenderized products from in-house source materials.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
**Figure 12.** Trim produced by sister processing establishment (MT60). On the “Raw” tab, for HACCP Category, select “Raw - Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category “Raw intact beef,” select Product Group “Trim produced by sister processing establishment.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
Figure 13. Bench Trim (Trimmings from Animals Not Slaughtered at the Establishment) (MT65). On the “Raw” tab, for HACCP Category, select “Raw - Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category “Raw intact beef,” select Product Group “Bench Trim (trimmings from animals not slaughter at est).” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
**Figure 14. Bench Trim (Derived from Non-Intact Beef Not Slaughtered at the Establishment) (MT65).** On the “Raw” tab, for HACCP Category, select “Raw Non-Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, select “Raw ground, comminuted, or otherwise non-intact beef.” For Product Group, select “Bench Trim (derived from non-intact beef not slaughtered at the est).” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
Figure 15. Ground Beef Product from Purchased Source Materials (MT43 and MT65). On the “Raw” tab, for HACCP Category, select the “Raw Non-Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, select “Raw ground, comminuted, or otherwise non-intact beef.” For Product Group, select “Ground Beef Product from purchased source materials.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
Figure 16. Ground Beef Combined with Other Species from Purchased Source Materials (MT43 and MT65). On the "Raw" tab, for HACCP Category, select “Raw Non-Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, select “Raw ground, comminuted, or otherwise non-intact beef.” For Product Group, select “Ground Beef combined with other species from purchased source materials.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
Figure 17. Hamburger/Beef Patty Combined with Other Species from Purchased Source Materials (MT43 and MT65). On the “Raw” tab, for HACCP Category, select “Raw Non-Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, select “Raw ground, comminuted, or otherwise non-intact beef.” For Product Group, select “Hamburger/Beef Patty combined with other species from purchased source materials.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
**Figure 18.** Mechanically tenderized products from purchased source materials (MT65). On the “Raw” tab, for the HACCP Category, select “Raw Non-Intact” and enter the name of the establishment’s HACCP plan. For Finished Product Category, select “Raw ground, comminuted, or otherwise non-intact beef.” For Product Group, select “Mechanically tenderized products from purchased source materials.” Enter the average daily volume and the number of days per month the product is produced. For Intended Use, select “Other.”
Figure 19. PHIS Profile example for a product that is intended for use in ready-to-eat (RTE) products at another federally inspected establishment. Do not select any other intended uses. **NOTE:** Establishments will not be subject to specific sampling tasks in PHIS if all of the finished product groups eligible under the sampling scheduling criteria in the PHIS profile are marked as “intended for RTE only.”
Figure 20. Head Meat (MT64). Under the “Raw” tab, select the “Slaughter” or “Raw Intact” HACCP Category. Select the name of the establishment’s HACCP plan. Choose the Finished Product Category “Raw intact beef.” Select the Product Group “Head Meat.” Enter the average daily volume and the number of days per month the product is produced. Select “Other” under Intended Use.
Figure 21. Cheek Meat (MT64). Under the “Raw” tab, select the “Slaughter” or “Raw Intact” HACCP Category. Select the name of the establishment’s HACCP plan. Choose the Finished Product Category “Raw intact beef.” Select the Product Group “Cheek Meat.” Enter the average daily volume and the number of days per month the product is produced. Select “Other” under Intended Use.
**Figure 22.** Heart Meat (MT64). Under the “Raw” tab, select the “Slaughter” or “Raw Intact” HACCP Category. Select the name of the establishment’s HACCP plan. Choose the Finished Product Category “Raw intact beef.” Select the Product Group “Heart meat.” Enter the average daily volume and the number of days per month the product is produced. Select “Other” under Intended Use.
Figure 23. Weasand meat (MT64). Under the “Raw” tab, select the “Slaughter” or “Raw Intact” HACCP Category. Select the name of the establishment’s HACCP plan. Choose the Finished Product Category “Raw intact beef.” Select the Product Group “Weasand meat.” Enter the average daily volume and the number of days per month the product is produced. Select “Other” under Intended Use.
Figure 24. Ammoniated beef (MT64). Under the “Raw” tab, select the “Raw- Non Intact” HACCP Category. Select the name of the establishment’s HACCP plan. Choose the Finished Product Category “Raw ground, comminuted, or otherwise non-intact beef.” Select the Product Group “Ammoniated beef.” Enter the average daily volume and the number of days per month the product is produced. Select “Other” under Intended Use.
Figure 25. Advanced Meat Recovery (AMR) (MT64). Under the “Raw” tab, select the “Raw-Non Intact” HACCP Category. Select the name of the establishment’s HACCP plan. Choose the Finished Product Category “Raw ground, comminuted, or otherwise non-intact beef.” Select the Product Group “Advanced Meat Recovery (AMR).” Enter the average daily volume and the number of days per month the product is produced. Select “Other” under Intended Use.
Figure 26. Low Temperature Rendered Product- Finely Textured Beef (FTB) (MT64). Under the “Raw” tab, select the “Raw- Non Intact” HACCP Category. Select the name of the establishment’s HACCP plan. Choose the Finished Product Category “Raw ground, comminuted, or otherwise non-intact beef.” Select the Product Group “Low Temperature Rendered Product- Finely Textured Beef (FTB).” Enter the average daily volume and the number of days per month the product is produced. Select “Other” under Intended Use.
Figure 27. Low Temperature Rendered Product- Partially Defatted Beef Fatty Tissue (PDBFT) (MT64). Under the “Raw” tab, select the “Raw- Non Intact” HACCP Category. Select the name of the establishment’s HACCP plan. Choose the Finished Product Category “Raw ground, comminuted, or otherwise non-intact beef.” Select the Product Group “Temperature Rendered Product- Partially Defatted Beef Fatty Tissue (PDBFT).” Enter the average daily volume and the number of days per month the product is produced. Select “Other” under Intended Use.
**Figure 28.** Low Temperature Rendered Product- Partially Defatted Chopped Beef (PDCB) (MT64). Under the “Raw” tab, select the “Raw- Non Intact” HACCP Category. Select the name of the establishment’s HACCP plan. Choose the Finished Product Category “Raw ground, comminuted, or otherwise non-intact beef.” Select the Product Group “Low Rendered Product- Partially Defatted Chopped Beef (PDCB).” Enter the average daily volume and the number of days per month the product is produced. Select “Other” under Intended Use.
## ATTACHMENT 2. BEEF MANUFACTURING TRIMMINGS (MT60) / BENCH TRIM (MT65)
Sample Collection Using N60 Method and Grab Sample Method

### FOR Sample Collection Using N60:
Follow the instructions provided in Steps 3 through 14.

### FOR Grab Sample Collection:
Follow the instructions provided in Step 4 – 7 and Step 15.

### Basic sampling supply kit
- 3 - Sterile Fill- Line Closure Whirl-Pak® Bags
- 1 - 13x18” Zipper Lock Bag labeled “Non Sterile”
- 1 - pair Sterile Gloves
- 3 - FedEx Billable Stamp: (EL, MWL, WL)
- 1 - FSIS Form 7355-2A/AB (sample seal set)
- 1 - 6” x 12” plastic sleeve
- 1 - Shipping Container
- 1 - Gel Coolant Pak
- 1 - Cardboard Separator
- 1 - Absorbent Pad
- 1 - Foam Plug

### N60 Supply Kit* (available upon request from the Western Laboratory)
- 1 - Caddy
- 1 - Boning Knife
- 1 - Hook
- 1 - Cut Resistant, Mesh Glove, size large: (sizes small, medium and extra-large available upon request)
- 1 - Clip
- 1 - USDA Blue N60 sample slice template (1 inch wide by 3 inches long and 1/8th inch)

* kit also includes the supplies listed in the Basic sampling supply kit

### Additional Supplies (available upon request to the Western Laboratory)
- Steel
- Sterile Drape
- Curved Boning Knife
- Forceps
- Surface Sanitizer

### NOTE:
Individual items listed on the Basic Sampling Supply and N60 Supply Kit lists are available upon request.
Upon receipt of the sampling supplies:

1. Verify receipt of all supplies needed to perform the sample collection.

2. Remove gel coolant packs from the shipping container and place them in the freezer at least 24 hours prior to sample collection. Pre-chill the shipping container.

On the day of sample collection:

1. Find a suitable workstation near the production area to place your equipment.

2. Clean and sanitize your workstation and caddy and allow them to air dry.

   If a sanitizable surface is not available near the area where you will perform the sample collection, use the sterile plastic drape to create a work surface for your sanitized sampling equipment.

3. Sanitize the knife, steel, and hook. Allow them to air dry.

   **NOTE:** Use the same sanitizing solution used by the establishment, if one is used, according to label directions. If the establishment uses only hot water, then use hot water only to sanitize your sampling equipment. If no method of sanitizing used by the establishment, then use the sanitizing solution available from the FSIS Western Laboratory.

4. Wash and dry your hands.

5. Open the sterile Whirl-Pak® bags. To open, remove the tear strip from the top, grasp the two small white tabs and pull apart. Do not touch the interior surface of the bag.

6. Position the Whirl-Pak® bag close to area where you will take the samples. The bag has a gusseted bottom so, once product is added, it will stand upright.

7. Put the mesh glove on your non-knife hand and put on the sterile gloves.
8. Aseptically collect the trimmings from one production lot. Use the sanitized hook to position and anchor a piece of meat at the top of the container.

For larger trim, you may want to use a curved boning knife and short boning hook instead of the standard hook and standard boning knife.

Collect samples from the original external surface of the carcass.

9. Use the N60 method. The N60 method involves 60 thin slices from the external surface of beef tissues. Each sample slice should be about 3 inches long by 1 inch wide and 1/8th inch thick. It is important to collect thin slices because the surface of the beef carcass can be contaminated through improper sanitary dressing procedures. To make cutting easier, score the surface of the meat in two parallel cuts. These cuts should be 1 inch apart and 3 to 4 inches long. This can make it easier to cut the sample slice to the right size.

10. Cut off a slice of the surface that is approximately 1 inch wide by 3 inches long and 1/8th inch thick. Remember to focus on thin slices from the external surface tissue. Collect only one sample slice from each of the 60 individual pieces of trim. Do not collect multiple sample slices from a single piece of trim unless the lot to be production lot consists of less than 60 individual trim pieces.

**NOTE:** It is important to keep the strips very thin and that you submit as much external surface as possible. Take care to ensure the samples contain some meat because if the entire sample is fat, the
11. Place each slice in one of the sterile Whirl-Pak® bags. Continue this process until you have collected 30 pieces in one Whirl-Pak bag.

12. Repeat steps 9 through 11 until you have collected two Whirl-Pak® bags each containing 30 slices.

**NOTE:** When cut to the correct size, 30 sample slices should fill one Whirl-Pak® bags to the fill line.

13. In the third sterile Whirl-Pak® bag, aseptically collect samples of trimmings from the same production lot by using a grab sample technique. It is not necessary to count the number of pieces or to cut the pieces to a certain dimension. Collect pieces with as much external surface as possible.

For larger trim pieces, such as chucks, cut the large trim piece so that it fits in the sample bag but make sure you leave at least 2 - 3 inches of space at the top of the bag and expel as much air out of the bag before closing it.

14. Once sample collection is complete, carefully expel
excess air from the sample bag, tightly fold over the top at least four times and then fold over the side tabs to secure the folds in place. Do not tie the ends.

15. If the available bench trim is too small for N60 sampling, aseptically collect grab samples and fill each of the 3 Whirl-Pak® bags up to the fill line. Collect pieces with as much external surface as possible.

16. Follow the instructions in Step 14 for closing and securing the Whirl-Pak® bags.
### ATTACHMENT 3. OTHER RAW GROUND BEEF COMPONENTS (MT64) ROUTINE SAMPLE COLLECTION

**ATTACHMENT 3. OTHER RAW GROUND BEEF COMPONENTS (MT64) ROUTINE SAMPLE COLLECTION**

**NOTE:** Other raw ground beef components include cheek meat; head meat; weasand meat; heart meat; product from advanced meat recovery systems (AMR); low temperature rendered products, such as partially defatted chopped beef, partially defatted beef fatty tissue; and low temperature rendered lean finely textured beef.

<table>
<thead>
<tr>
<th>Sample supply kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 - Sterile Fill- Line Closure Whirl-Pak® Bags</td>
</tr>
<tr>
<td>1 - 13x18” Zipper Lock Bag labeled &quot; Non Sterile&quot;</td>
</tr>
<tr>
<td>1 - pair Sterile Gloves</td>
</tr>
<tr>
<td>3 - FedEx Billable Stamp: (EL, MWL, WL)</td>
</tr>
<tr>
<td>1 - FSIS Form 7355-2A/AB (sample seal set)</td>
</tr>
<tr>
<td>1 - 6” x 12” plastic sleeve</td>
</tr>
<tr>
<td>1 - Shipping Container</td>
</tr>
<tr>
<td>1 - Gel Coolant</td>
</tr>
<tr>
<td>1 - Cardboard Separator</td>
</tr>
<tr>
<td>1 - Absorbent Pad</td>
</tr>
<tr>
<td>1 - Foam Plug</td>
</tr>
</tbody>
</table>

**Upon receipt of the sampling supplies:**

1. Verify receipt of all supplies needed to perform the sample collection.

2. Remove gel coolant packs from the shipping container and place them in the freezer at least 24 hours prior to sample collection. Pre-chill the shipping container.

**On the day of sample collection:**

1. Find a suitable workstation near the production area to place your equipment.

2. Clean and sanitize your workstation and caddy and allow them to air dry.

   If a sanitizable surface is not available near the area where you will perform the sample collection, use the sterile plastic drape to create a work surface for your sanitized sampling equipment.

3. Wash and dry your hands.

4. Open the sterile Whirl-Pak® bags. To open, remove the tear strip from the top, grasp the two small white tabs and pull apart. Do not touch the interior surface of the bag.

5. Position the Whirl-Pak® bag close to area where you will take the samples. The bag has a gusseted bottom so, once product is added, it will stand upright.
6. Put the mesh glove on your non-knife hand and put on the sterile gloves.

**NOTE:** It is not necessary to put on a mesh glove prior to gloving if the sample collection will not require any cutting of beef components to facilitate their placement in the sample bags.

7. Randomly select one component type the establishment produces. Do not include multiple component types in a sample, whenever possible.

8. When sampling raw ground beef components other than trim, you may need to cut these components (e.g., head meat, cheek meat, weasand, or heart) into smaller pieces to fit into the Whirl-Pak® bags. You will not use the N60 sampling method to collect other component samples.

   a. For larger components, such as hearts, collect one or more pieces or enough to fill each of the 3 Whirl-Pak® bags above the fill line but leaving at least 2-3 inches of space at the top of the bag.

   b. When sampling smaller component types (such as AMR product or low temperature rendered products), aseptically collect grab samples and fill each of the 3 Whirl-Pak® bags up to the fill line.
9. Expel as much air out of the bags, tightly fold over the top at least four times. Do not overfill bags. Fold over the side tabs to secure the folds in place. Do not tie the ends.
**ATTACHMENT 4. RAW GROUND BEEF PRODUCTS (MT43) ROUTINE SAMPLE COLLECTION IN FINAL PACKAGING AND BY GRAB SAMPLE**

IPP are to collect raw ground beef product in its final package, whenever possible. When product is not available in its final package or the package is too large, IPP are to aseptically collect grab samples as described in steps 3-9.

### Sampling supplies for raw ground beef sampling

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 - Sterile Fill-Line Closure Whirl-Pak® Bags</td>
<td>1</td>
</tr>
<tr>
<td>13x18” Zipper Lock Bag labeled ”Non Sterile”</td>
<td>1</td>
</tr>
<tr>
<td>1 - pair Sterile Gloves</td>
<td>1</td>
</tr>
<tr>
<td>3 - FedEx Billable Stamp: (EL, MWL, WL)</td>
<td>1</td>
</tr>
<tr>
<td>1 - FSIS Form 7355-2A/AB (sample seal set)</td>
<td>1</td>
</tr>
<tr>
<td>1 - 6” x 12” plastic sleeve</td>
<td>1</td>
</tr>
<tr>
<td>1 - Shipping Container</td>
<td>1</td>
</tr>
<tr>
<td>1 - Gel Coolant Pak</td>
<td>1</td>
</tr>
<tr>
<td>1 - Cardboard Separator</td>
<td>1</td>
</tr>
<tr>
<td>1 - Absorbent Pad</td>
<td>1</td>
</tr>
<tr>
<td>1 - Foam Plug</td>
<td>1</td>
</tr>
</tbody>
</table>

### Upon receipt of the sampling supplies:

1. Verify receipt of all supplies needed to perform the sample collection.
2. Remove gel coolant packs from the shipping container and place them in the freezer at least 24 hours prior to sample collection. Pre-chill the shipping container.

### On the day of sample collection:

1. Find a suitable workstation near the production area to place your equipment.
2. Clean and sanitize your workstation and caddy and allow them to air dry. If a sanitizable surface is not available near the area where you will perform the sample collection, use the sterile plastic drape to create a work surface for your sanitized sampling equipment.
### A. Collecting a Raw Ground Beef Sample in Its Final Package

1. When collecting ground beef in its final packaging, collect the appropriate number of packaged products so that the sample equals two pounds.
   
   For example, if raw ground beef is packaged in 1 lb. chubs, then collect two – 1 lb. chubs.

2. Place the product collected in its final packaging in the larger, non-sterile bag provided with the sampling supplies. Do not use the Whirl-pak® bags.

### B. Collecting a Raw Ground Beef Grab Sample

**NOTE:** Use this method to collect raw ground beef product samples if it is not available in its final packaging or the package is too large.

3. Wash and dry your hands.

4. Open the sterile Whirl-Pak® bags. To open, remove the tear strip from the top, grasp the two small white tabs and pull apart. Do not touch the interior surface of the bag.

5. Position the Whirl-Pak® bag close to area where you will take the samples. The bag has a gusseted bottom so, once product is added, it will stand upright.
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.</td>
<td>Put on the sterile gloves.</td>
</tr>
<tr>
<td>7.</td>
<td>Aseptically collect grab samples of raw ground beef.</td>
</tr>
<tr>
<td>8.</td>
<td>Collect a sufficient quantity of raw ground beef to fill each of the three Whirl-Pak® bags to the fill-line. Do not under-fill or overfill the bag.</td>
</tr>
<tr>
<td>9.</td>
<td>Once sample collection is complete, carefully expel excess air from each Whirl-Pak® sample bag, tightly fold over the top at least four times and then fold over the side tabs to secure the folds in place. Do not tie the ends.</td>
</tr>
</tbody>
</table>
## ATTACHMENT 5. SAMPLE COLLECTION USING N60 METHOD FOR IMPORTED FROZEN BEEF MANUFACTURING TRIMMINGS AND OTHER FROZEN COMPONENTS (MT51)

### Basic sampling supply kit
- 3 - Sterile Fill-Line Closure Whirl-Pak® Bags
- 1 - 13x18” Zipper Lock Bag labeled “Non Sterile”
- 1 - pair Sterile Gloves
- 3 - FedEx Billable Stamp: (EL, MWL, WL)
- 1 - FSIS Form 7355-2A/AB (sample seal set)
- 1 - 6" x 12” plastic sleeve
- 1 - Shipping Container
- 1 - Gel Coolant Pak
- 1 - Cardboard Separator
- 1 - Absorbent Pad
- 1 - Foam Plug

### N60 Supply Kit* (available upon request from the Western Laboratory)
- 1 - Caddy
- 1 - Boning Knife
- 1 - Hook
- 1 - Cut Resistant, Mesh Glove, size large:
  (sizes small, medium and extra-large available upon request)
- 1 - Clip
- 1 - USDA Blue N60 sample slice template (1 inch wide by 3 inches long and 1/8th inch)

* kit also includes the supplies listed in the Basic sampling supply kit

### Additional Supplies (available upon request to the Western Laboratory)
- Steel
- Sterile Drape
- Curved Boning Knife
- Forceps
- Surface Sanitizer

### NOTE:
Individual items listed on the Basic Sampling Supply and N60 Supply Kit lists are available upon request.
**Upon receipt of the sampling supplies:**

1. Verify receipt of all supplies needed to perform the sample collection.

2. Remove gel coolant packs from the shipping container and place them in the freezer at least 24 hours prior to sample collection. Pre-chill the shipping container.

**On the day of sample collection:**

1. Find a suitable workstation near the production area to place your equipment.

2. Clean and sanitize your workstation and caddy and allow them to air dry.

   If a sanitizable surface is not available near the area where you will perform the sample collection, use the sterile plastic drape to create a work surface for your sanitized sampling equipment.

3. Sanitize the knife, steel, and hook. Allow them to air dry.

   **NOTE:** Use the same sanitizing solution used by the establishment, if one is used, according to label directions. If the establishment uses only hot water, then use hot water only to sanitize your sampling equipment. If no method of sanitizing used by the establishment, then use the sanitizing solution available from the FSIS Western Laboratory.
4. Select the number of containers of frozen product the same lot. The containers selected should all have the same production code or date. If available, randomly select five (5) containers to sample.

Take the containers of frozen product to the area where the sample collection will be performed.

5. Remove the frozen block of product from its container and place it in the area designated for sample collection.

If it is not possible to remove the frozen product from its container (such as a combo bin full of frozen product), then the container should be staged to expose the top surface of the frozen block.
6. Wash and dry your hands.

7. Open the sterile Whirl-Pak® bags. To open, remove the tear strip from the top, grasp the two small white tabs and pull apart. Do not touch the interior surface of the bag.

8. Position the Whirl-Pak® bag close to area where you will take the samples. The bag has a gusseted bottom so, once product is added, it will stand upright.

9. Put the mesh glove on your non-knife hand and put on the sterile gloves.

10. Aseptically collect the samples using the sanitized hook and knife. Cut off a slice of the surface that is approximately 1 inch wide by 3 to 4 inches long by 1/8th inch thick.

   Remember to focus on thin slices from the external surface tissue.

   **NOTE:** It is important to keep the strips very thin and that you submit as much external surface as possible. Take care to ensure the samples contain some
meat because if the entire sample is fat, the fat can interfere with the sample analysis.

11. Collect the appropriate number of samples from each frozen block based on the number of containers available from the specific lot.

From each of the 5 containers, collect samples from 12 locations distributed evenly around the surface of the frozen block. Sample as much of the surface area as possible. The diagram shows how to collect a sample at every 30-degree point of the surface the entire frozen block.

<table>
<thead>
<tr>
<th># containers in each specific lot</th>
<th># samples to collect from each container</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>1</td>
<td>60</td>
</tr>
</tbody>
</table>

12. Keep the slices very thin and ensure that samples contain some meat and are not all fat tissue.

**NOTE:** Fat can interfere with sample analysis.
13. Place each slice in one of the sterile Whirl-Pak® bags. Continue this process until you have collected 30 pieces in one Whirl-Pak bag.

14. Repeat steps 10 through 13 until you have collected two Whirl-Pak® bags each containing 30 slices.

NOTE: When cut to the correct size, 30 sample slices should fill one Whirl-Pak® bags to the fill line.
15. In the third sterile Whirl-Pak® bag, aseptically collect samples of trimmings from the same production lot. It is not necessary to cut the pieces to a certain dimension. Collect pieces with as much external surface as possible.

For larger trim pieces, such as chucks, cut the large trim piece so that it fits in the sample bag but make sure you leave at least 2 - 3 inches of space at the top of the bag and expel as much air out of the bag before closing it.

16. Once sample collection is complete, carefully expel excess air from the sample bag, tightly fold over the top at least four times and then fold over the side tabs to secure the folds in place. Do not tie the ends.
ATTACHMENT 6. HOW TO ACCESS THE OPTIONAL VIDEO TRAINING COURSES: STEC SAMPLING OF DOMESTIC RAW BEEF PRODUCTS and STEC SAMPLING OF IMPORTED RAW BEEF PRODUCTS

Passing Score: 70%
CFL will upload final grades to AgLearn
Unlimited re-takes

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<thead>
<tr>
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<th>Log into Inside FSIS</th>
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<td>Click on Login Using your USDA eAuthentication Level 2 Credential</td>
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After reading the Security Warning page, enter your User ID and Password. Remember, passwords are case-sensitive and must be entered exactly as it was established.

- Finally, click the User ID & Password LOGIN button.
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<tr>
<td><strong>2</strong></td>
<td><strong>Locate the Course</strong></td>
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<td>- A new page opens <em>INSIDE FSIS</em> homepage.</td>
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<td>- Scroll down on the page until you see <em>Employee Services</em> then click on <em>Training</em> link.</td>
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<td>- Scroll down on the page, and find <em>Featured CFL Courses and Programs</em> (the link is near the bottom of the page.)</td>
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<td>- <strong>STEC Sampling of Domestic Raw Beef Products</strong> Video training</td>
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<td>- <strong>STEC Sampling of Imported Raw Beef Products</strong> Video training</td>
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<tr>
<td><strong>3</strong></td>
<td><strong>Complete the Course</strong></td>
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<td>- Watch the video, if you want you can replay the course. When you feel ready to take the quiz, exit the screen.</td>
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<td>- Click on <strong>STEC Sampling of Domestic Raw Beef Products or STEC Sampling of Imported Raw Beef Products Quiz</strong>, to begin the exam. Good Luck!</td>
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</table>

Before watching the video, you will need to Turn Off Pop Up Blocker. Click Tools > Pop Up Blocker> Turn Off Pop Up Blocker> Yes.
4  Additional Instructions

- Before you click Submit, make sure you “Save” your answers to a file.
- Next, open your Outlook and attach the answer file to an email to FSISAgLearn@fsis.usda.gov.
- Add a subject and message then click send.
- Re-activate your Pop Up Blocker. Click on Tools> Pop Up Blocker> Turn On Pop Up Blocker> Yes.

5  Print Certificate of Completion

After passing the quiz and AgLearn has recorded your results, you’re ready to print a Certificate of Completion.

- Go to AgLearn at www.aglearn.usda.gov
- Click on the Login button
- After reading the Security Warning page, enter your User ID and Password. Remember, passwords are case-sensitive and must be entered exactly as it was established.
Print Certificate of Completion (continued)

After passing the quiz and AgLearn has recorded your results, you’re ready to print a Certificate of Completion.

- Go to AgLearn at [www.aglearn.usda.gov](http://www.aglearn.usda.gov)
- Click on the Login button
- After reading the Security Warning page, enter your User ID and Password. Remember, passwords are case-sensitive and must be entered exactly as it was established.
- Next, click the User ID & Password LOGIN button.
- A new page opens on the screen, look for the Learning Status column then click Completed Work icon.
Print Certificate of Completion (continued)

- A new page opens on your screen, called *Completed Work*.
- On the page, you will see a simple table, take your mouse and hover over the course labeled *STEC Sampling of Domestic Raw Beef Products* or *STEC Sampling of Imported Raw Beef Products*.
- Next, a small box appears on your screen, take your mouse and click the *Print Certificate* button.
- Print the certificate and save it as a record.