VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS
FOOD SAFETY CONSUMER PROTECTION
Meat Inspection Service
MONTPELIER, VT
Anson Tebbetts, Secretary

	MIS DIRECTIVE Adopted from FSIS Directive 10010.1	10010.1 Rev. 6	3/26/2024

SAMPLING VERIFICATION ACTIVITIES FOR SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* IN RAW BEEF PRODUCTS

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 VAAFM's routine and follow-up sampling programs for Shiga toxin-producing *Escherichia coli* (STEC). VAAFM tests all raw beef samples collected under the routine and follow-up sampling programs for seven adulterant STEC serogroups (*E. coli* O157, O26, O45, O103, O111, O121, and O145) and *Salmonella*.

B. Instructions concerning STEC verification activities other than VAAFM sampling are contained in VT Directive 10010.2, *Verification Activities for Shiga Toxin-Producing Escherichia coli in Raw Beef Products*. VT Directive 10010.2, Chapter III, Section I, provides IPP with instructions for responding to positive results from VAAFM verification testing. VT Directive 10010.3, *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, recalling product, and high event periods.

C. This directive provides instructions to IPP for sampling beef manufacturing trimming, bench trim and certain follow-up sampling projects with the cloth sample collection method instead of N60 excision sampling.

D. The Directive is being reissued to clarify that when the establishment makes ground beef patties with the same formulation as the ground beef used to make the patties (i.e., without adding additional ingredients or reducing particle size), then IPP may sample ground beef from an offline grinder instead of sampling ground beef patties (see Chapter IV Section V. D.).

E. Per 6 V.S.A. § 3305 (8), the federal meat inspection regulations and federal poultry inspection regulations of the U.S. Department of Agriculture, Title 9, Code of Federal Regulations, Chapter 3, 9 CFR §§ 300.1 et seq., together with any amendments, supplements, or revisions thereto, are adopted, for the State meat inspection program to operate in an 'equal to' status.

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

II. CANCELLATIONS

VT Directive 10,010.1, Revision 5, Verification Activities for Escherichia coli O157:H7 in Raw Beef Products

III. BACKGROUND

A. All raw non-intact beef and raw intact beef intended for use in raw non-intact product are adulterated under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(m)(1)) and 6 VSA 204 when they are contaminated with *E. coli* from one of seven serogroups (O157, O26, O45, O103, O111, O121, and O145) and the Shiga toxin (*stx*) and Intimin (*eae*) genes are present.

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

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

CHAPTER II – ELIGIBILITY CRITERIA FOR VAAFM STEC SAMPLING

I. DOMESTIC SAMPLING

A. IPP are to be aware that VAAFM samples and tests eligible raw beef products produced under inspection, before such products can be marked inspected and passed. The retail exempt processing requirements (9 CFR 303) specify that only inspected and passed product sources are to be used. Products cannot be used for retail exempt processing, whether onsite or at another facility, until it completes the inspection process, including any VAAAFM sampling of eligible raw beef products when applicable.

B. Establishments that slaughter and further process raw beef product may be eligible for multiple raw beef sampling programs. These establishments may produce ground product, beef manufacturing trimmings from cattle slaughtered onsite, and raw ground beef components other than trim. Additionally, these establishments may use purchased product intended for intact use to produce bench trim or raw non-intact products. Therefore, IPP may receive sampling requests during the same sampling window.

C. As described below and outlined in Figure 1, VAAFM has four routine raw beef sampling programs for official establishments. There are three source material sampling programs (beef manufacturing trimmings, Bench Trim and raw ground beef components other than trim) to sample intact beef intended for non-intact use or when the intended use is unclear and one sampling program to sample certain finished raw ground beef products. A brief description of each project and eligible products is included below.

   NOTE: Non-intact beef products include: ground beef; chopped beef; flaked or minced product; beef that is vacuum tumbled with solutions; beef that an establishment has mechanically tenderized by needling (including injecting with solutions), cubing, pounding devices (with or without marinade); beef that an establishment has reconstructed into formed entrees; beef with proteolytic enzymes applied; and diced beef less than ¾ inch (dial setting) in any one dimension on average.

D. **Beef Manufacturing Trimmings (BMT)**- Sampling of intact beef slaughtered onsite when the

intact product is intended for non-intact use or when the intended use is unclear. These can be beef products of any size except for carcasses, halves, and quarters. Eligible products include, but are not limited to:

1. Boneless beef of any size, in boxes, combos or other containers the producing slaughter establishment intends for raw non-intact use;

2. Two-piece chucks (i.e., the blade portion and an arm roast from the forequarter individually packaged and placed into the same container); and

3. Smaller pieces of trimmings from subprimal cuts when the beef was slaughtered on-site.

NOTE: Intact products intended for raw non-intact use or when the intended use is unclear are eligible for BMT sampling even when the meat is made non-intact at that specific establishment, or at another off-site location.

E. **Raw Ground Beef Components Other Than Trim (COMP)**- Sampling of raw ground beef components other than trim from beef slaughtered onsite when the product is intended for non-intact use or the intended use is unclear. COMP samples are collected from:

1. Head meat;

2. Cheek meat;

3. Weasand meat;

4. Heart meat;

5. Meat produced from Advanced Meat Recovery (AMR) systems;

6. Low temperature rendered product (LTRP), such as partially defatted chopped beef (PDCB), partially defatted beef fatty tissue (PDBFT), and low temperature rendered lean finely textured beef (LTRLFB); and

7. Ammoniated beef products (produced at slaughter and non-slaughter establishments).

F. **Bench Trim (BT)**-Sampling of beef not slaughtered on-site and originally intended for intact use by the slaughter establishment. The product becomes eligible for BT when some, or all of the product originally intended for intact use (typically vacuum packaged primals and subprimals) are designated for non-intact use (or the intended use is unclear) by the receiving establishment. BT samples are collected from, but are not limited to:

1. Beef of any size, prior to the non-intact process (e.g., tenderization, grinding) that the slaughter establishment intended for intact use, but is used by the receiving establishment to make a non-intact product;

2. Beef of any size that the slaughter establishment intended for raw intact but is used by the receiving establishment to make product intended for non-intact use or the intended use is unclear. For example, chucks, loins, or rounds that were not originally eligible for BMT sampling as the slaughter establishment intended the product for intact use, but the receiving establishment changed the intended use to intended for non-intact use for some or all the received product;

3. Raw ground beef components other than trim (e.g., head meat) or that the slaughter establishment intended for intact use but is used by the receiving establishment to make a non-intact product (e.g., ground beef), a product intended for non-intact use (e.g., beef for grinding) or the intended use is unclear; and

4. Primal and subprimal cuts derived from purchased whole, half, or quartered carcasses provided that the further processers intend those products for raw non-intact use (e.g., grinding or mechanical tenderization).

G. **Ground Beef (GROUND)**- Sampling of certain finished non-intact products including:

1. Those that meet the standard of identity as listed in 9 CFR 319.15.

    a. 319.15(a) chopped or ground beef;

    b. 319.15(b) hamburger; and

    c. 319.15(c) beef patties;

2. Other raw beef products that do not meet the standards of identity in 9 CFR 319.15 but are produced similarly, such as:

    a. Raw ground beef products with added ingredients or seasonings (beef patties with cherries, beef patty mixes);

    b. Ground beef with one or more different species where beef is the predominant species (e.g., finished ground product is 50% or more beef); and

    c. NRTE ground product that receives a heat treatment but is not fully cooked (e.g., char-marked heat-treated but not fully cooked beef patties, chicken fried steak type product, or breaded beef patty that is heat treated but not fully cooked.

H. Some slaughter establishments use beef manufacturing trimmings and other raw ground beef components to produce raw ground beef. In this situation, IPP are to sample the beef manufacturing trim under the BMT sampling program, the other components under the COMP sampling program, and raw ground beef product under the GROUND sampling program. IPP are not to collect the GROUND sample from the same beef lot already sampled for BMT of COMP.

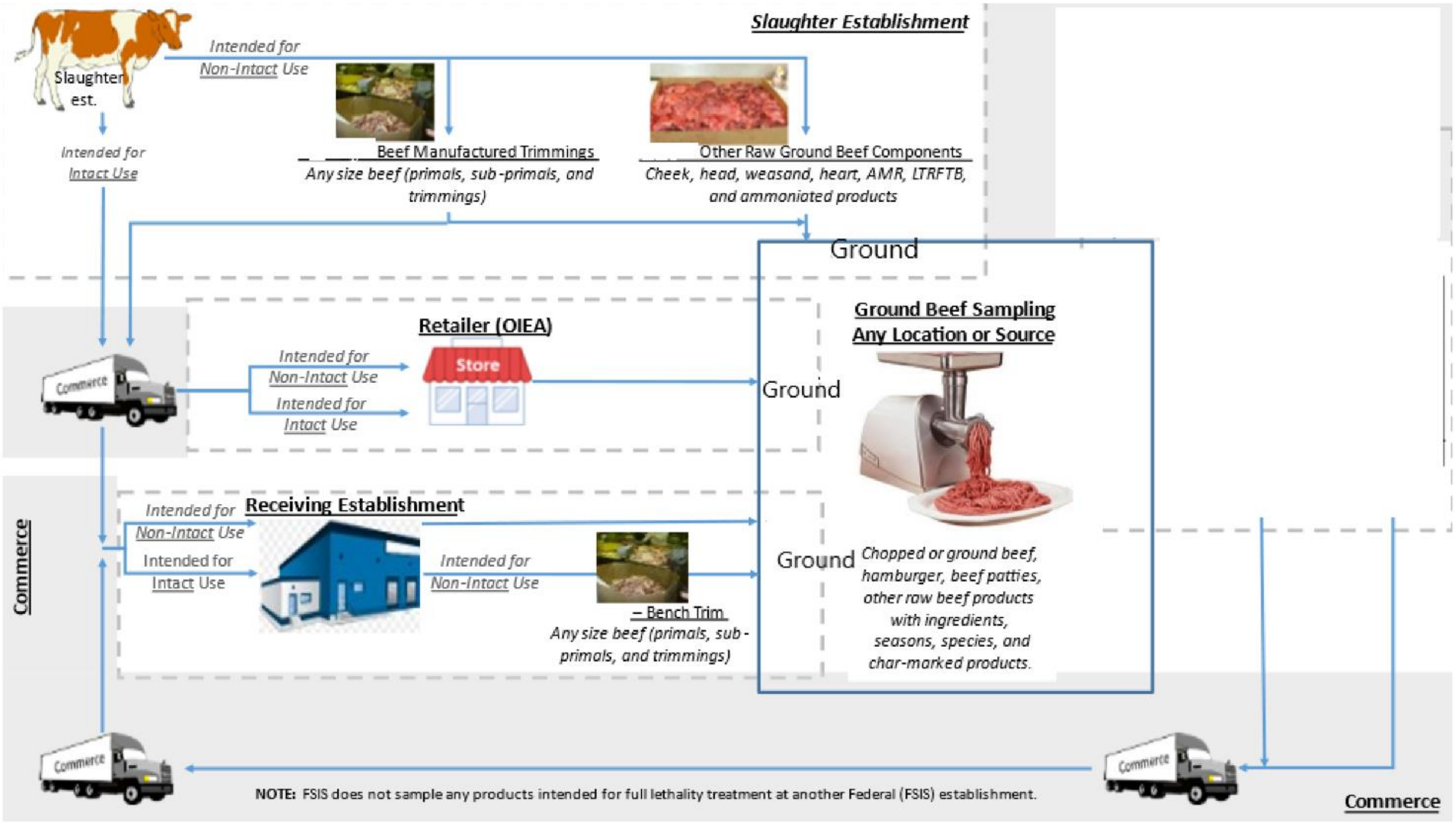
I. Establishments are eligible for both the BMT and BT sampling programs if they use certain types of purchased product to produce bench trim and source materials from their own slaughter operation to produce beef manufacturing trimmings (see Figure 1 of this chapter).

J. VAAFM tests all raw beef samples collected under routine and follow-up sampling programs for STEC and *Salmonella*.

K. The maximum number of routine sampling tasks assigned each month is included in table 1 below.

Table 1: Maximum Sampling Frequencies for Each Routine Sampling Program: BMT, COMP, BT, GROUND				
	Establishment average daily volume			
Sampling Project	≤1,100 lbs./day	1,101-50,000 lbs./day	50,001-250,000 lbs. /day	>250,001 lbs./day
Number of samples per establishment per each sampling project BMT,COMP, BT, GROUND	1/month	2/month	3/month	4/month

Figure 1. Overview of Raw Beef Sampling



sampling of ground beef at retail is not covered in this directive please see [VT Directive 8010.1 Methodology for Conducting In-Commerce Surveillance Activities.]

L. 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. Table 2 below, provides a general description for each of the domestic follow-up sampling programs (GROUND-F,BMT-F/COMP-F, BMT-F/BT-F/COMP-F/GROUND-F, Follow-up OTHER). IPP are to refer to this table, as needed, when they receive follow-up sampling tasks.

Table 2. VAAFM's Follow-up Sampling Programs for Domestic Products

Sampling Program	Description
GROUND-F	Follow-up sampling of raw ground beef product in response to a GROUND or Agricultural Marketing Service (AMS) positive result in raw ground beef produced at State establishments.
BMT-F COMP-F	Follow-up sampling at suppliers of beef manufacturing trimmings or other components from originating slaughter suppliers, in response to a GROUND or BT, or AMS ground beef positive result.
BMT-F BT-F COMP-F GROUND-F	Follow-up sampling of trim or other components at the establishment that produced product in response to a BMT, BT, COMP, AMS trim testing positive, or a GROUND positive at a combination slaughter/processing establishment.
Follow-up OTHER	Follow-up sampling of raw ground beef, trim, or other component outside of projects listed above collected by IPP at State inspected establishment.

II. SAMPLING FREQUENCIES FOR ROUTINE SAMPLING PROGRAMS

A. IPP are to be aware that VAAFM has a set minimum sampling frequency for each establishment. VAAFM 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.

3. The frequency will be based on FSIS' Guidance to the states on the average frequency of testing done at very small federal establishments. In addition, VT reserves the right to alter the frequency at any given establishment based on information from, but not limited to, inspection activity, sampling results, and food safety assessments, in order to tailor the STEC verification sampling program to address any perceived increase in risk.

4. The testing schedule for STEC raw beef and in beef manufacturing trimmings will be determined for the period of October through September, and recorded on a spreadsheet.

B. Table 1 provides information on the maximum number of sampling requests for routine sampling that IPP may receive monthly based on the establishment's production volume.

NOTE: The maximum frequencies in Table 1 only apply to routine sampling program. In the event that follow-up sampling is necessary in response to a VAAFM or AMS positive result, IPP will receive these sampling requests at a rate greater than listed in table 1 (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 VAAFM collects samples. VAAFM 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 or state-inspected establishment. If the product is to receive a full lethality treatment at another 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 (HPP) and irradiation (IR), 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 VAAFM 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 VAAFM has collected the sample). In this situation, IPP are to proceed with submitting the sample to the laboratory for analysis.

E. IPP are to use the information in Chapter II to determine whether the products produced by the establishment are subject to routine VAAFM sampling and testing and then are to perform the "Update Profile" task as needed as described in Chapter III.

CHAPTER III – PHIS PROFILE RESPONSIBILITIES

I. MANAGING THE PHIS PROFILE

NOTE: State PHIS profiles do not connect to any automatic sample request generation by PHIS

A. IPP assigned to establishments producing raw beef products are to perform the "Update Profile" task as needed and schedule it on the task calendar.

B. IPP are to determine whether the establishment produces product eligible for raw ground beef product sampling (See Chapter II). If IPP determine that raw ground beef product sampling is required, they are to review the establishment profile and update the profile, if needed.

C. IPP are also to be aware that in accordance with FSIS Directive 5300.1, *Managing the Establishment Profile in the Public Health Information System*, only finished products (those shipped from the establishment) should be entered into PHIS. Intermediary products should not be entered into PHIS. For example, if the establishment makes beef manufacturing trimmings but uses all of those trimming in-house to make ground beef, beef manufacturing trimmings should NOT be listed in the PHIS profile. Only if the establishment intends to ship some, or all, of the beef manufacturing trimming into

commerce, would beef manufacturing trimmings be entered as a finished product.

D. A "sister" processing establishment that produces trim intended for non-intact use from carcasses, carcass halves, or quarters supplied by a single slaughter establishment within the same ownership structure is eligible for BT sampling at the "sister" receiving processing establishments. IPP at the "sister" processing establishment are to follow the instructions in FSIS Directive 5300.1 to enter final products produced at the establishment when they further process received or purchased products (whether or not there is an actual financial transaction). For example, if the "sister" processing establishment produces ground beef from bench trim, the final product group is "ground beef/hamburger/beef patty product from purchased source materials intended for intact use." If the "sister" processing establishment ships bench trim as a final product, the IPP are to enter bench trim into the PHIS profile Products page and select the Product Group, "Bench Trim (trimmings from animals not slaughtered at the Est.)." IPP are not to use the raw intact beef product with Product Group "Trim produced by "sister" processing establishment."

E. IPP are to update the profile as soon as possible when there are production changes that could affect the frequency of sampling tasks. Attachment 1 provides instructions to IPP for selecting a product name and which sampling requests are associated with that name.

F. 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.

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

H. 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).

I. 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 Directive 5300.1, to update the finished products information in the PHIS profile.

J. IPP are to cancel a sampling request when the product is intended for use in RTE product or to receive another full lethality treatment at an official inspected establishment only (see Chapter II, Section III). IPP are to also cancel a sampling request 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 is not eligible for the mark of inspection nor sampling by inspection personnel. To cancel a sampling request, contact the Office so the sample schedule can be updated.

K. In the event IPP receive a sampling request for a sampling program for which the establishment is not eligible, IPP are to contact the office so the sample schedule can be updated.

L. Table 4 shows the finished product groups in PHIS that have specific sampling tasks. Attachment 1 includes a table with instructions on when IPP should enter specific finished product names into PHIS and the sampling request generated by that name. IPP are to use Table 4 and Attachment 1 when completing the PHIS profile to ensure the correct sampling tasks are assigned to the establishment.

Table 4. PHIS Finished Product Group that Generate Specific Sampling Tasks.

Project	Finished Product Category	Product Group	All Sampling Tasks For This Product Group
MT43	Raw ground, comminuted, or otherwise non-intact beef	Ground Beef/Hamburger/Beef Patty from in-house source materials	**Ground & BMT**
		Ground Beef/Hamburger/Beef Patty from purchased source materials accompanied by a COA, no bench trim	**Ground**
		Ground Beef/Hamburger/Beef Patty from purchased source materials intended for intact use	**Ground & BT**
		Ground Beef/Hamburger/Beef Patty from in house source material can include other ground beef component	**Ground, BMT & COMP**
		Raw ground beef product from non-intact source materials, no bench trim	**Ground**
MT60_C	Raw ground, comminuted, or otherwise non-intact beef	Beef Trimming from non-intact beef	**BMT**
		Ground Beef/Hamburger/Beef Patty from in-house source materials	**Ground & BMT**
		Ground Beef/Hamburger/Beef Patty from in house source material can include other ground beef component	**Ground, BMT & COMP**
		Mechanically tenderized products from in-house source materials	**BMT**
		Other Non-Intact Product (fresh sausage, meat loaf, gyros, meat balls, etc.)	**BMT & BT**
		Non-Intact Cuts (including Bone in and Boneless Meats)	**BMT & BT**
	Raw intact beef	Beef Manufacturing Trimmings	**BMT**
MT64	Raw ground, comminuted, or otherwise non-intact beef	Advanced Meat Recovery (AMR)	**COMP**
		Ammoniated Beef	**COMP**
		Ground Beef/Hamburger/Beef Patty from in house source material can include other ground beef component	**Ground, BMT & COMP**
		Low Temperature Rendered Product - Finely Textured Beef (FTB)	**COMP**
		Low Temperature Rendered Product - Partially Defatted Beef Fatty Tissue (PDBFT)	**COMP**
		Low Temperature Rendered Product - Partially Defatted Chopped Beef (PDCB)	**COMP**
	Raw intact beef	Cheek Meat	**COMP**
		Head Meat	**COMP**
		Heart Meat	**COMP**
		Weasand Meat	**COMP**
MT65_C	Raw ground, comminuted, or otherwise non-intact beef	Bench Trim (derived from non-intact beef not slaughtered at the Est.)	**BT**
		Ground Beef/Hamburger/Beef Patty from purchased source materials intended for intact use	**Ground & BT**
		Mechanically tenderized products from purchased source materials	**BT**
		Other Non-Intact Product (fresh sausage, meat loaf, gyros, meat balls, etc.)	**BMT & BT**
		Non-Intact Cuts (including Bone in and Boneless Meats)	**BMT & BT**
	Raw intact beef	Bench Trim (trimmings from animals not slaughtered at the Est.)	**BT**
Not Eligible	Raw ground, comminuted, or otherwise non-intact beef	Fabricated Steaks and other Non-Intact Subprimals	**Not Eligible**
		Formed Steaks	**Not Eligible**
		Portioned raw ground beef product	**Not Eligible**
	Raw intact beef	Carcass (including carcass halves or quarters)	**Not Eligible**
		Cuts (including Bone in and Boneless Meats)	**Not Eligible**
		Edible Offal	**Not Eligible**
		Other Intact	**Not Eligible**
		Primals and Subprimals	**Not Eligible**

NOTE: Establishments will not be subject to specific sampling tasks if all of the finished product category eligible under the sampling scheduling criteria in the PHIS profile are marked as "intended for RTE only."

II. SUPERVISORY RESPONSIBILITIES CONCERNING THE PHIS PROFILE

NOTE: State PHIS profiles do not connect to any automatic sample request generation by PHIS

A. 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.

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 days' 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 the establishment notification is not to impede VAAFM'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 days' notice before VAAFM 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 a notice of 2 days before taking a sample, the inspector is to accommodate this request to allow the establishment to adjust production levels to fill its orders but still hold the sampled lot. If IPP have questions about an establishment's basis for requesting more notice, they are to discuss their concerns with their supervisor;

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 VAAFM collects samples for STEC until negative results become available.

B. IPP are to be aware that VAAFM 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 STEC 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; and

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 establishment from those source materials should not be considered to be adulterated.

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

A. Sample Request Spreadsheet

1. A sample request spreadsheet is uploaded to the Sampling Schedule folder in Sharepoint in the beginning of the year, identifying of the types of scheduled samples on a monthly basis for the entire year.

2. Follow the steps below for packaging and sending the samples under seal to the laboratory.

3. If raw beef product requested for sampling is not available during the 30-day requesting window, IPP are to notify the Meat Inspection Office.

B. For samples to be tested for STEC at out-of-state laboratories:

1. The inspector will follow the SOP for Scheduling Samples on the MI-Calendar for proper notification and receipt of mailing labels.

2. Once the FedEx pick up is scheduled, you will receive the package label via email. Print out the label to be used on the outside of the package.

III. ORDERING SAMPLING SUPPLIES

A. Inspectors are to verify that proper sample supplies are present, and request any supplies needed from the Meat Inspection Office on an ongoing basis.

IIC is responsible for coordinating the sampling and assuring all samples are collected in a timely manner, and that the office is notified prior to sample collection.

B. For beef manufacturing trimmings from slaughter establishments and bench trim or any other samples going to the South Dakota Laboratory, the lab forms will be filled electronically through their on-line system. IPP should verify the requested tests are STEC and *Salmonella.*

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 VAAFM verification testing or follow-up sampling in response to an STEC positive from VAAFM or Federal testing).

B. IPP are to use a method for randomly selecting the product for sampling. IPP are to randomly select a day, shift, and time within the sample month indicated in the Sampling Spreadsheet. 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 month in an establishment that produces raw ground beef product, beef manufacturing trimmings, other raw ground beef or beef patty components, and bench trim or raw non-intact product from purchased product. A beef product is only eligible for one of the source material sampling tasks (BMT, COMP, or BT) but any source material sampled under BMT, COMP, or BT is also eligible for Ground sampling if made into eligible ground beef type products as listed in Chapter II.

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 BMT sampling program. IPP are to collect the GROUND sample on another day within the sampling month if product is available.

NOTE: 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 Hazard Analysis Critical Control Point (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 IR 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 state or federally inspected establishment, including off-site, 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, 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 and has scientific support for the specific parameters applied and log reduction achieved

1. IPP are to sample product that is sent off-site for an intervention (e.g., HPP or IR) that does not achieve a full lethality (i.e., less than a 5-log reduction for *Salmonella*) when the product is returned to the original establishment. If the product is not returned to the producing establishment after the HPP/IR treatment, IPP are to sample other product, if possible, on that day or within the sampling window. If the establishment is not producing any other eligible products during the sampling window, IPP are to cancel and reschedule the sample.

2. When the products are treated with HPP or IR for quality purposes and not to control pathogens, IPP are to perform microbiological verification sampling of the product prior to the application of the quality treatment.

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

H. 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.

I. If an establishment does not hold or maintain control of product tested by VAAFM for STEC, IPP are to write a noncompliance record (NR) because the establishment shipped product before VAAFM 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 Chief of Inspection.

V. ALTERNATIVE SAMPLING PROCEDURES FOR RAW GROUND BEEF PRODUCT SAMPLING

A. General

1. Alternative sampling procedures only apply to raw ground beef product 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 GROUND sampling, provided 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 VAAFM 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 VAAFM 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, 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 Section I and Section IV of this chapter. If the establishment does not meet the criteria, IPP are to collect the sample as described in Chapter V.

C. Sampling a Lot at the Start of Production. An establishment may request that VAAFM 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 month on the Sample Schedule spreadsheet;

    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 that day; and

    c. Verify that the establishment is not treating the source materials of the raw ground product that VAAFM 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 VAAFM will sample.

3. If an establishment requests that VAAFM 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 Chapter V.

D. When the establishment makes ground beef patties with the same formulation as the ground beef used to make the patties (i.e., without adding additional ingredients or reducing particle size), then IPP may sample ground beef as part of an alternative sampling program from an offline grinder instead of sampling ground beef patties.

VI. ALTERNATIVE LOTTING FOR RAW GROUND BEEF PRODUCT (GROUND), BEEF MANUFACTURING TRIMMINGS (BMT), OTHER RAW GROUND BEEF COMPONENTS (COMP), AND BENCH TRIM (BT) 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 VAAFM 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 Section B. 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 VAAFM 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 Chapter 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 and bench trim sample, as well as when they do follow-up sampling to these programs. Attachment 1 of VT Directive 10010.3, or VT Notice 01A-23, 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 VAAFM 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. See VT Notice 13-A for instructions on how to document in PHIS. IPP are to document this information in a memorandum of interview (MOI) (see VT 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 VT Directive 10010.3.

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 programs. 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 programs. 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 collect bench trim even if the establishment has mixed in beef manufacturing trim from animals slaughtered on site.

B. If the establishment packages product in combo bins, then IPP are to select one random combo bin from the specific production (e.g., day's production) available for sampling with one cloth for BMT and BT projects, and respective follow up sampling projects.

C. If the establishment packages product in boxes, totes, tubs, or containers other than combo bins, IPP are to use 1 cloth for *up to 5 containers* from the same lot of product for BMT and BT samples. For example, if an establishment defines its lot as 3 boxes, IPP are to swab all 3 boxes using 1 cloth, for a total of 1 cloth collected and shipped to the lab. If the lot is greater than 5 boxes or containers, IPP are to randomly select 5 boxes or containers and to swab all five boxes with one cloth.

D. If the establishment uses both combo bins and other containers (e.g., boxes), IPP are to randomly select combo bins or other containers to sample and then select the product accordingly as listed in B. and C. above.

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

F. Attachments 2, 3, 4, and 5 contain step-by-step sample collection procedures by sampling program. These attachments are also available in IPP help-raw beef sampling.

1. Attachment 2–beef manufacturing trimmings and bench trim cloth sampling instructions.

2. Attachment 3–components other than trim grab sampling instructions.

3. Attachment 4–ground beef grab sampling instructions.

4. Attachment 5– frozen trim N60 excision sampling instructions.

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 roll top bags when collecting products in its final packaging.

III. Cloth Sampling Procedure

A. IPP are to watch the cloth sampling training video on IPP help found here: Cloth Sample Collection Method. The cloth sampling video can also be found on the internet here FSIS Cloth Sampling Procedure.

B. Prior to sample collection, IPP are to complete the following steps to maintain proper temperature during sample collection and shipment:

1. Ensure nBPW is kept chilled until use by placing it in a secure refrigerator (where the supplies will remain under VAAFM control);

2. Place gel coolant packs into the freezer for at least 24 hours before sample collection; and

3. Pre-chill shipping containers by placing the pre-frozen gel pack(s) on top of the absorbent pads. The absorbent pads are used to line the bottom of the shipping containers.

NOTE: IPP are not to freeze nBPW or the sample.

B. BMT and BT Sample Procedure

1. IPP are to wash and dry hands to the mid-forearm;

2. IPP are to remove the clear, perforated plastic shrink wrap from the tube of nBPW and set the nBPW aside;

3. Prior to gloving and without touching the cloth, IPP are to drop the folded cloth onto the surface of the product using the following procedures (see photos below).

   a. Open the bag by removing the perforated strip at the top of the bag. Pull the tabs to open the wire mouth of the bag wide. Once the bag is open invert the bag to drop the cloth and allow the dry cloth to drop onto the surface of the product. If the cloth does not come out of the bag, IPP are to use one hand (on the outside of the sample bag) to push the dry cloth to the top of the sample bag and then invert again. Do not touch the cloth with bare hands.

Invert the bag, push the cloth to the top of the sample bag if needed, and allow the cloth to drop onto the surface of the combo

   b. Place the empty plastic outer bag in an upright position on a clean, sanitary surface such as a sample caddy/tote or table within suitable distance of the sampling area. This positioning will facilitate placement of the cloth back in the bag once the sampling procedure is complete;

4. Put on arm sleeves and non-sterile gloves over the sleeves. Using an alcohol-based (70% or greater) pump sanitizer (available from the office), IPP are to sanitize gloved hands and plastic sleeves simultaneously. Ensure there is no excess sanitizer on the gloved hands or forearm sleeves before touching the cloth and beginning the sampling procedure;

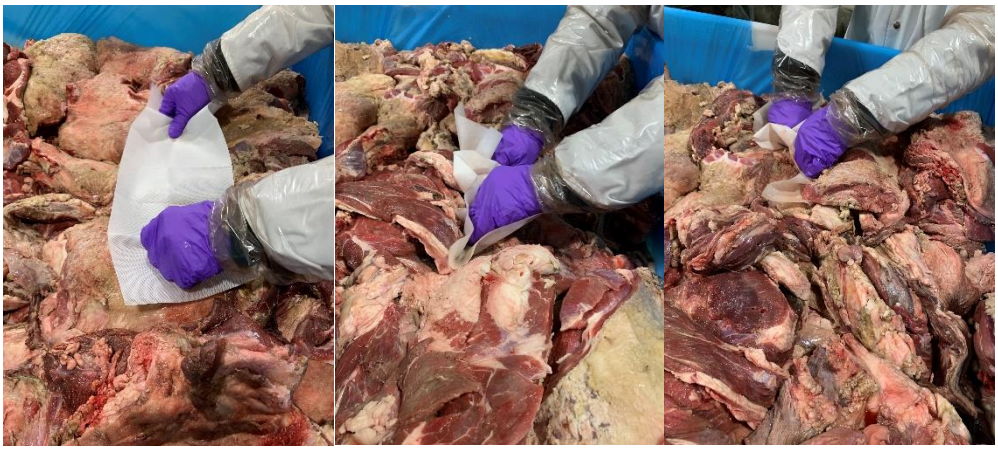
5. IPP are to maintain sanitary conditions after sanitizing gloved hands and forearm sleeves. Do not touch anything except for the cloth;

6. To perform this sampling procedure, after gloving and sanitizing as described above, IPP are to unfold the cloth, which is laying on top of the product in the combo/box;

7. IPP are to visually identify a point on the combo to begin and end the sampling procedure because IPP will move around the combo in a uniform manner to massage the entire surface of the combo;

8. Once a starting point for sampling has been identified, IPP are to tightly grasp the cloth with both hands. While using both hands, IPP are to apply downward pressure to vigorously massage the surface area of the product with the unfolded cloth;

9. IPP are to vigorously massage the surface of the beef trim, including the spaces and crevices between meat pieces, to ensure as much of the product surface area is sampled as possible;



Move uniformly around the perimeter of the combo, vigorously massaging the surface area and the space between the meat pieces

10. IPP are to use one side of the cloth to massage half of the combo;

11. At a point halfway around the combo, IPP are to flip the cloth and use the second side of the cloth to vigorously massage the remaining half of the combo until reaching the point in the combo where the sampling procedures started;

12. The total sampling time will be a minimum of 1.5 minutes per combo bin. IPP are to vigorously massage for a minimum of 45–60 seconds per side of the cloth to ensure a thorough sample collection (total sampling time of 1.5-2 minutes);

Cloth after sampling will be damp and have picked up juices and bits of meat pieces when the collection is completed

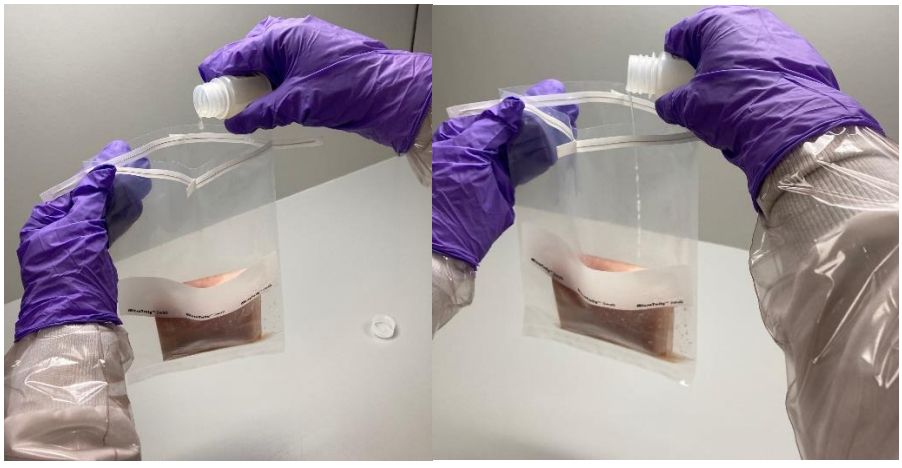
*Fold cloth along original fold lines, then **add 2 additional folds***

13. When the sampling procedure is complete, IPP are to re-fold the cloth following the original fold lines in the cloth and then add **2 additional folds** to the cloth—the 2 additional folds will assist with placing the cloth into the sample collection bag. As indicated in the photo above, the cloth is to be folded while resting on the meat product in the combo;

14. Once folded, IPP are to return the cloth to the original clear plastic sample roll top bag;

15. Next, IPP are to carefully open the nBPW tube and aseptically pour the chilled nBPW into the open bag. IPP are to ensure that the tube does not touch the inside of the bag. The tube is not to be inserted into the bag; only the buffer should contact the inside of the bag.

NOTE: IPP are to be aware that the laboratory will discard samples with the reason, *Sampling Instructions Not Followed*, if nBPW is not used.



Pour the sterile nBPW into the roll top bag

Properly folded cloth with nBPW and barcode

16. IPP are to discard the empty nBPW tube.

17. IPP are to use gentle pressure on the outside of the roll top bag to push the cloth down into the nBPW and remove excess air from the bag;

18. IPP are to close the roll top bag and roll/fold the top of the bag down at least 3 times to prevent leakage. IPP are to fold in the wire tabs to secure the bag and prevent leakage; and

19. IPP are to place at least one small, barcoded label on an individual bag.

Insert bagged cloth into a zipper lock bag for shipping

20. IPP are to package the roll top bag containing the cloth in the box for shipping.

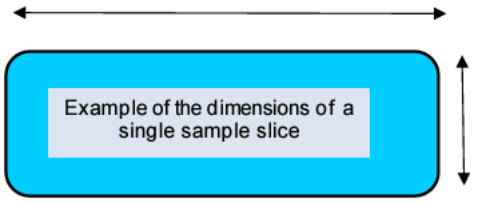
IV. N60 SAMPLING METHOD

N60 sampling is the sample collection method IPP are to use when collecting samples of beef trim at import establishments, which the State inspection program personnel will not do.

A. IPP are to use the cloth 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 BMT. When the primal and subprimal cuts or other source material used to produce mechanically tenderized products are from purchased product arriving without a certificate of analysis (COA), IPP are to sample the primal and subprimal cuts or other source material under BT.

B. IPP are NOT to use the N60 method when collecting MT60_C beef manufacturing trim or MT65_C bench trim unless the establishment implements freezing as an intervention to reduce STEC presence. If freezing is used as an intervention, then the sample is to be collected by the N60 excision method. IPP are to collect MT64 other raw ground beef component samples by taking aseptic grab samples (see Section V in this chapter).

C. C. N60 sampling involves collecting 60 thin slices from the external surfaces of beef tissues. Each sample slice should be about 3 inches long by 1 inch wide and 1/8 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 three roll top bags when collecting samples using N60 procedures. IPP are to place 30 pieces in each of the two roll top bags.

NOTE: When cut to the correct size, 30 sample slices should fill one roll top bag to the fill line. In the third roll top 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 roll top bag with at least 2-3 inches of space at the top of 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 five containers, IPP are to select randomly five containers for sampling with each container having an equal chance of being selected; and

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

TABLE 5: Number of Sample Pieces to Collect Per Container	
# of containers in each specific lot	*# of sample pieces to select from* each *container*
5	12 pieces
4	15 pieces
3	20 pieces
2	30 pieces
1	60 pieces

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 under BMT, just as if an establishment would send this product to a more distant location.

G. 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 cloth, the establishment could then run the remainder of the product that is to be treated through the tenderizer.

H. 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 cloth and note in PHIS that mechanically tenderized product has been sampled.

V. ASEPTIC GRAB SAMPLING

A. IPP are to aseptically collect grab samples and are not to use the Cloth sample collection method or the N60 excision method when collecting other raw ground beef component samples.

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

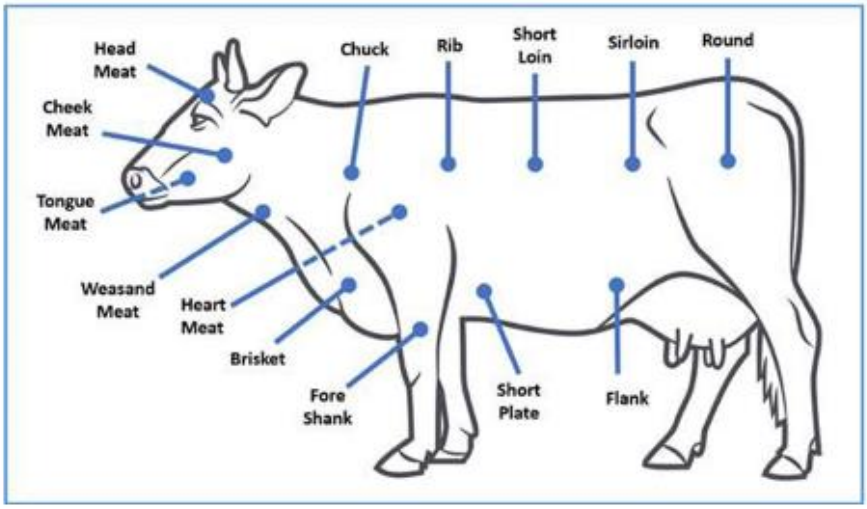
C. For aseptic grab samples, IPP are to collect enough product to fill each of the 2-3 roll top bags to the fill-line, making sure there is a **minimum of 292.5 grams (~0.64 lbs), with the ideal sample size being 325g.**
For larger components, such as hearts, IPP are to collect one or more pieces or enough to fill each of the 2-3 roll top bags above the fill line but leaving at least 2-3 inches of space at the top of the bag when collecting COMP samples, making sure there is a minimum **of 292.5 grams (~0.64 lbs), with the ideal sample size being 325g**.

VI. PHIS QUESTIONS RELATED TO SAMPLE MATERIAL

A. When IPP collect a raw beef sample, consult VT Notice 13-A for entering into PHIS. IPP are to record the primal, sub-primal, or source material used to produce the trim or non-intact product

sampled. IPP are to enter the approximate location on the carcass where source material originated from, if known.). IPP can use Figure 2 below as an aid in determining the source area of the product sampled.

Figure 2



VII. PACKING AND SHIPPING THE SAMPLE

IPP are to use only the shipping materials provided by the d refer to office and refer to VT Directive 7355.1, *Use of Sample Seals for Laboratory Samples*, for complete instructions on the proper use of sample seals.

VIII. ACCESSING TEST RESULTS

A. IPP will obtain sample results from the office. The laboratory will report the results for all adulterant STECs (*E. coli* O157:H7 and non-O157 STEC) and Salmonella to the chief or designee.

B. A master list of all samples, is kept and updated with each sample result received. Reasons for discard/invalid results are listed on the individual laboratory sample sheets. This list as well as the results are located in the Sharepoint folders for sample results.

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 STEC results, they are to wait to notify the establishment until after receiving the STEC results.

D. Sample discard: If the 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 – VAAFM ACTIONS IN RESPONSE TO VAAFM, OR FEDERAL STEC TEST RESULTS

I. NEGATIVE STEC 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 Office receives a notification that a sample is presumptive positive, the Office is to follow the instructions provided in VT Directive 10010.3.

Presumptive and Confirmed Positives:

1. Samples are initially analyzed with an STEC screen.
2. For those that screen negative, the sample is considered negative for STEC
3. To screen positive, the sample must contain the stx gene and eae gene.
   For those that screen positive, they will be tested for STEC
4. For a sample to identify as positive for STEC, the E. coli isolate must contain an stx gene, an eae gene, and genetically identify as one or more of the top seven serogroups (O26, O45, O103, O111, O121, O145, or O157)
   Typically, the *STEC* negative test results become available in 1-2 days, and confirmatory testing becomes available four to five days after the laboratory receives the sample.

Plan of Action for presumptive positive result

If the results are **presumptive positive**, the VT MPI Program will confirm the collection of the following information regarding the suppliers of the source materials used in the production of the product (9 CFR 320.1):

1. name of the supplying establishment, point of contact (name, title, e-mail address, and fax number), and phone number of supplying establishment;
2. supplier lot number; and
3. production date, name of supplied material, and any additional information to clearly identify the material used of the management of the supplying establishment.
4. IPP are to identify specifically the type of source materials the establishment used in producing the ground beef (e.g., beef trimmings, subprimal cuts, beef hearts, veal trimming, and head or cheek meat).
5. Inspection program personnel make note of any information that the establishment is unable to provide.

III. CONFIRMED POSITIVE TEST RESULTS

In the event of a confirmed positive STEC result in raw ground beef product, beef trim, or other components intended for use in raw non-intact product, the sampled lot is adulterated. The Chief or designee 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 VT Directive 10010.2, for responding to confirmed positive results.

IV. RESPONSIBILITIES IN RESPONSE TO A CONFIRMED POSITIVE TEST RESULT

A. General

1. 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 VAAFM positive sample result, the Chief is to:

1. Direct IPP at supplying establishments to perform tasks:

a. The Chief is to direct the IPP at all establishments that supplied product represented by the positive sample, including the originating slaughter establishments, to perform directed HACCP and Sanitation SOP verification tasks per Sections V and VI of this chapter.

b. The Chief is to direct the IPP at originating slaughter establishments to perform a directed Beef 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 VT Directive 5100.4, *Public Health Risk Evaluation Methodology*.

C. The Chief is to take the appropriate enforcement actions (e.g., Notice of Intended Enforcement, withhold or suspend inspection, reinstate a suspension), if warranted, based on EIAO or IPP findings, as described in VT Directive 5100.3, *Administrative Enforcement Action Decision-Making and Methodology*.

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 VT Directive 10010.3 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 actions, so IPP are to verify that remaining HACCP regulatory requirement during the directed HACCP Verification task (see Chapter Two, Section III of VT Directive 10010.2).

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

E. IPP are to perform a directed Beef Sanitary Dressing task as described in VT 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 VT Directive 10010.2 for the specific production lot of source materials used to produce the product that tested positive; and

2. Perform a directed Operation SOP task and review records for the day or days that the source materials were 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 VAAFM 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.

IPP are to be aware that follow-up sampling may involve a variety of products and sampling methodologies. In general, IPP are to collect follow-up samples from the same type of product that tested positive, if available. However, there are certain special circumstances when this is not the case, see E. 1 below. 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. For example, if head meat tested positive for STEC, then IPP are to sample head meat, if available, during follow-up sampling. If head meat is not available, IPP are to collect follow-up samples from other raw ground beef components that are available. If no other raw ground beef components are available, IPP are to sample beef manufacturing trim.

C. 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.

D. 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. IPP may collect a maximum of 2 follow-up samples per shift per day from different lots (or up to 4 samples per day at a 2-shift establishment), unless the establishment cannot continue to operate under that sampling frequency (e.g., because the establishment cannot fill orders and hold all sampled product), or the IPP's workload cannot accommodate that sampling frequency.

NOTE: The status of a follow-up set can be determined through the sample results spreadsheet on the tab created for the follow-up samples.

E. Follow-up sampling sets are generated in response to each positive from VAAFM's routine sampling programs at the establishment that received the positive result.

1. IPP are to be aware the follow-up sample collection methodology and product to be sampled can vary. IPP are to collect the following products:

    i. If a slaughter-processing establishment has a ground beef or a BMT positive result, IPP are to collect beef manufacturing trim samples follow-up sample set using the cloth sample collection methodology.

    ii. If a slaughter-processing establishment has a components other than trim (i.e., head meat) positive result, they are to collect the same type of component (e.g., head meat) that tested positive if available, using the grab sample collection methodology follow-up sample set. If the same type of component is not available, then IPP can randomly select from any other COMP eligible products that are available for follow-up sampling.

    iii. If a downstream (processing only) establishment has a GROUND beef positive result, IPP are to collect ground beef samples using a grab sample collection methodology follow-up set assignment.

    iv. If a downstream (processing only) establishment has an BT positive result, IPP are to collect bench trim samples follow-up sample set using the cloth sample collection methodology.

F. VAAFM also schedules follow-up sampling sets at supplying slaughter establishments in response to a positive from a raw ground beef sample from ground, or a bench trim positive.

1. Supplier follow-up sampling sets are discussed in more detail in Section II of this chapter.

2. In a limited situation, VAAFM 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).

G. VAAFM may also schedule a follow-up sampling set outside these follow-up sampling projects, e.g., in response to an outbreak or recall. IPP are to be aware that follow-up samples can be variable depending on the beef commodity to be sampled and may or may not require the cloth sampling technique. Specific instructions to IPP will be provided through the office in coordination with the Chief and EIAO, if needed, on a case-by-case basis.

H. Each positive result in a follow-up sampling set triggers another follow-up sampling set.

I. IIC should expect to receive a follow-up sampling set within 2 days of the positive sample result.

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, there will be 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. Follow-up sampling tasks are not assigned 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. Assign follow-up sampling tasks for the originating slaughter establishment when:

1. The originating slaughter establishment was the only supplier, or,

2. Any of the originating slaughter establishments were suppliers that had previously been identified within approximately 4 months (120 days) of the current raw ground product or bench trim positive result.

D. There are 8 assigned follow-up sampling tasks for the originating slaughter establishments in response to a positive or if the establishment produces less than 1,000 pounds per day of the product that tested positive.

E. 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, a single follow-up sampling task is assigned for the supplier for each component used in the positive raw ground beef or bench trim product.

2. In combination slaughter/processing establishments, if a Federal agency finds ground product positive, and the results are accepted by VAAFM, sampling tasks will be assigned to the combination slaughter/processing establishment that produced the source material.

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

    b. IPP are <u>not</u> 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 STEC when sampled by VAAFM or a Federal or State entity, IPP are to collect samples of ammoniated boneless lean beef tissue 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, sampling tasks are not requested 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 verification sampling program:

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

2. Sampling tasks are assigned to the slaughter establishments that produced the source materials used in the positive ammoniated LTR product.

III. SPECIAL INSTRUCTIONS FOR FOLLOW-UP SAMPLING 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 VAAFM finds positive for STEC, 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. are met. If the conditions in A. are met, IPP are to collect the samples at the originating slaughter establishment from one or more carcasses hanging in the cooler before fabrication.

1. IPP are to contact the Chief to obtain the most up-to-date sampling procedure for follow-up sampling of carcasses.

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

C. If both conditions in A. 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 cloth sampling method.

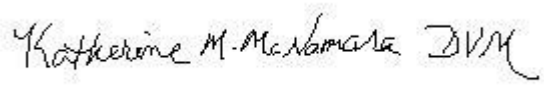
D. If the VAAFM sample collected is positive in B., generally only the sampled carcass is implicated because STEC contamination is generally point-source contamination that occurs sporadically as a consequence of handling during hide removal and dressing of the carcass. However, if the establishment 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, VAAFM 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 XI – QUESTIONS

Refer questions regarding this directive to your immediate supervisor .



Katherine McNamara, DVM
Deputy Director FSCP
VT Meat and Poultry Inspection Service

ATTACHMENT 1: PHIS Finished Raw Beef *Non-Intact* and *Intact* Finished Product Group Names		
If the establishment:	**IPP are to select this PHIS finished *non-intact* product group:**	**Sampling requests generated**
Produces and/or ships AMR product from the establishment.	Advance meat recovery (AMR)	Other Raw Ground Beef Components (ORGBC)
Produces and/or ships LTRFTB product from the establishment.	Low Temperature Rendered product-finely textured Beef (LTRFTB)	ORGBC
Produces and/or ships PDBFT product from the establishment.	Low Temperature Rendered-partially defatted beef fatty tissue (PDBFT)	ORGBC
Produces and/or ships PDCB product from the establishment.	Low Temperature Rendered-partially defatted chopped Beef (PDCB)	ORGBC
Produces and/or ships Ammoniated Beef product from the establishment.	Ammoniated Beef	ORGBC
Produces and ships raw ground beef, hamburger, or beef patty product produced from cattle slaughtered on-site (including sister establishments).	Ground Beef/Hamburger/Beef Patty from in-house source material	Beef Manufacturing Trimming, Ground Beef
Produces and ships raw ground beef, hamburger, or beef patty product produced from cattle slaughter on-site **AND** the formulation for the product may include other raw ground beef components (including sister establishments).	Ground Beef/Hamburger/Beef Patty from in-house source material that can include other ground beef components	Beef Manufacturing Trimming ORGBC Ground Beef
Produces and ships raw ground beef, hamburger, or beef patty product produced from cattle slaughtered off-site and intended for intact use (e.g., boxed beef, vacuum packaged product).	Ground Beef/Hamburger/Beef Patty from purchased product intended for intact use	Bench Trim Ground Beef Note: because the source material was intended for intact use it was not eligible for sampling at the supplier. Since the receiving establishment changed the intended use of some, or all, of the received product to intended for non-intact use, the source material becomes eligible for Bench Trim sampling.
Produces and ships raw ground beef, hamburger, or beef patty product produced from cattle slaughtered off-site but accompanied by a Certificate of Analysis (COA) showing the product was robustly sampled and tested for *E.coli* O157:H7 and/or the non O157 STEC adulterant serogroups.	Ground Beef/Hamburger/Beef Patty from purchased source material accompanied by a COA, no bench trim	Ground Beef only. Note: the COA shows that the source material was intended for non-intact use. Therefore, the source material was already eligible for sampling at the supplier.
Produces and ships raw ground beef, hamburger, or beef patty	Raw Ground Beef product from non-intact source materials-no bench trim	Ground Beef

product produced from ground beef (either coarse or finely ground) product produced at a different establishment.		Note: this name applies if the establishment reduces particle size or adds ingredient to the incoming beef. If the establishment does not reduce particle size or add ingredients to the incoming ground beef, use the name “portioned raw ground beef product” as listed below
Produces and ships raw ground beef, hamburger, or beef patty product produced from ground beef produced at a different establishment and the product particle size is not reduced and ingredients, including seasonings, are NOT added.	Portioned raw ground beef product	Portioned product is not eligible for sampling.
Produces and ships mechanically tenderized or needle injected product produced from cattle slaughtered on-site (including sister establishments).	Mechanically tenderized products from in-house source material	Beef Manufacturing Trim
Produces and ships mechanically tenderized, or needle injected produced from cattle slaughtered off-site and received without a COA.	Mechanically tenderized product from purchased source material	Bench Trim
Produces and/or ships beef trim from product that has already been made non-intact produced from cattle slaughtered on-site.	Beef Trimming from non-intact beef	Beef Manufacturing Trim
Produces and/or ships bench trim from product that has already been made non-intact produced from cattle slaughtered off-site	Bench Trim (derived from non-intact beef not slaughtered at the EST.)	Bench Trim
Produces and ships fresh beef sausage, gyros, meat load or meat balls.	Other Non-Intact Product (fresh sausage, meat loaf, gyros, meat balls, etc)	Beef Manufacturing Trim, Bench Trim
Produces and ships vacuum marinated or vacuum tumbled products.	Non-intact cuts (including bone in and boneless meats)	Beef Manufacturing Trim, & Bench Trim
Produces and ships formed steaks from any source material.	Formed Steaks	Not eligible
Produces and ships fabricated steaks from any source material	Fabricated Steaks	Not eligible

If the establishment:	IPP are to select this PHIS finished *intact* product group	Sampling requests generated
Produces and ships beef manufacturing trimming intended from cattle slaughtered on-site (or sister establishment) for raw non intact use.	Beef Manufacturing Trimmings	Beef Manufacturing Trimmings
Produces and ships carcasses, halves, or quarters.	Carcasses (including halves and quarters)	None, FSIS does not routinely sample carcasses, halves, or quarters.
Produces and ships cheek meat.	Cheek Meat	ORGBC. IPP will have to verify the intended use of the product and collect samples when intended for non-intact use or the intended use is unclear.
Produces and ships head meat.	Head Meat	ORGBC (see cheek meat above).
Produces and ships bone in and boneless beef in consumer ready packaging.	Cuts (including bone in and boneless beef)	None.
Products and ships bench trim	Bench Trim (trimming from animals not slaughtered at the Est.)	Bench Trim
Produces and ships edible offal	Edible Offal	None
Produces and ships intact products other than those listed in this list	Other intact	None
Produces and ships heart meat.	Heart Meat	ORGBC (see cheek meat above).
Produces and ships primals and subprimals	Primals/subprimals	None.
Produces and ships weasand meat	Weasand Meat	ORGBC (see cheek meat above).
Produces and ships beef manufacturing trimmings at a sister establishment	Follow the instructions in Chapter III section I, D. Do not use “Trim produced by sister establishment”	Do not use.

ATTACHMENT 2. Beef Manufacturing Trim, and Bench Trim SAMPLING PROCEDURES

Beef Manufacturing Trim, and Bench Trim sampling supply kit

1 – 7” x 8” (quart size) zipper lock bag;

1 – cloth in a roll top bag;

1 – pair non-sterile gloves;

3 – FedEx label (order from office);

1 – VT Form 7355-2A/AB (sample seal set);

1 – 6” x 12” plastic sleeve (for the sample form);

1 – plastic forearm sleeve;

1 – tube of sterile nBPW (The tube contains 25 mL, **Refrigerate on arrival**);

1 – shipping container;

1 or 2 – gel coolant packs;

1 or 2 – cardboard separators;

1 – absorbent pad

1 – foam plug.

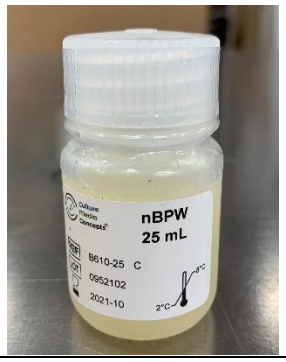
A. Prior to sample collection, IPP are to complete the following steps to maintain proper temperature during sample collection and shipment:

   a. Chill nBPW upon receipt by placing it in a secure refrigerator (where the supplies will remain under VAAFM control);

   b. Place gel coolant packs into the freezer for at least 24 hours before sample collection; and

   c. Pre-chill shipping containers by placing the pre-frozen gel pack(s) on top of the absorbent pads. The absorbent pads are used to line the

MT60_C/MT65_C sampling supply kit



tube of sterile nBPW

bottom of the shipping containers.

B. Randomly select one combo from the specific production to be sampled.

C. IPP are to wash and dry hands to the mid-forearm;

D. IPP are to remove the clear, perforated plastic shrink wrap from the tube of nBPW and set the nBPW aside.

E. Prior to gloving and without touching the cloth,

   a. Open the bag by removing the perforated strip at the top of the bag. Pull the tabs to open the wire mouth of the bag wide. Once the bag is open invert the bag to drop the cloth and allow the dry cloth to drop onto the surface of the product. If the cloth does not come out of the bag, IPP are to use one hand (on the outside of the sample bag) to push the dry cloth to the top of the sample bag and then invert again. Do not touch the cloth with bare hands.

   b. Place the opened roll top bag containing the cloth in a sanitized sample caddy (fig. 3 and 4).

F. Put on sleeves and gloves. Using an alcohol-based sanitizer (refills for pump containers available from the office), IPP are to sanitize gloved hands and plastic sleeves. simultaneously. Ensure there is no excess sanitizer on the gloved hands or forearm sleeves before touching the cloth and beginning the sampling procedure. With gloved arms facing away from product, IPP are to gently shake excess sanitizer from the gloved hands while being mindful to avoid contaminating gloves by touching non-product contact surfaces.

NOTE: IPP are to get sanitizer from the office in advance of collecting samples if needed.

Fig. 1

Fig. 2

Fig. 3

Fig. 4

G. IPP are to maintain sanitary conditions after sanitizing forearm sleeves. Do not touch anything except for the cloth;

H. To perform this sampling procedure, after gloving and sanitizing as described above, IPP are to unfold the cloth, which is laying on top of the product in the combo/box;

I. IPP are to visually identify a point on the combo to begin and end the sampling procedure because IPP will move around the combo in a uniform manner to massage the entire surface of the combo;

J. Once a starting point for sampling has been identified, IPP are to tightly grasp the cloth with both hands. While using both hands, IPP are to apply downward pressure to vigorously massage the surface area of the product with the unfolded cloth (fig. 5);

K. IPP are to vigorously massage the surface of the beef trim, including the spaces and crevices between meat pieces, to ensure as much of the product surface area is sampled as possible (fig. 6);

L. IPP are to use one side of the cloth to massage half of the combo. From the starting point of the combo, as identified by IPP, and using one side of the cloth, IPP are to move uniformly around the perimeter of the combo, vigorously massaging the surface area and the space between the meat pieces;

M. At a point halfway around the combo, IPP are to flip the cloth and use the second side of the cloth to vigorously massage the remaining half of the combo until reaching the point in the combo where the sampling procedures started (fig. 7);

N. The total sampling time will be a minimum of 1.5 minutes per combo bin. IPP are to vigorously massage for a minimum of 45–60 seconds per side of the cloth to ensure a thorough sample collection (1.5-2 minutes total sampling time);

O. When the sampling procedure is complete, IPP are to re-fold the cloth following the

Fig. 5

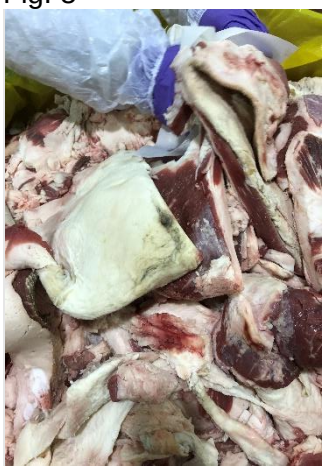


Fig. 6

original fold lines in the cloth and then add **2 additional folds** to the cloth—the 2 additional folds will assist with placing the cloth into the sample collection bag. As indicated in the photo above, the cloth is to be folded while resting on the meat product in the combo;

P. Once folded, IPP are to return the cloth to the original clear plastic sample roll top bag (fig. 8);

Q. Next, IPP are to carefully open the nBPW tube and aseptically pour the pre-chilled nBPW into the open bag. IPP are to ensure that the tube does not touch the inside of the bag. The tube is not to be inserted into the bag; only the buffer should contact the inside of the bag (fig. 8).

NOTE: IPP are to be aware that SD laboratories will discard samples with the reason, *Sampling Instructions Not Followed*, if nBPW is not used.

R. IPP are to discard the empty nBPW tube.

S. IPP are to use gentle pressure on the outside of the roll top bag to push the cloth down into the nBPW and remove excess air from the bag;

T. IPP are to close the roll top bag and roll/fold the top of the bag down at least 3 times to prevent leakage. IPP are to fold in the wire tabs to secure the bag and prevent leakage (fig. 9); and

U. IPP are to place at least one small, barcoded label on an individual bag (fig. 10).

V. IPP are to package the roll top bag containing the cloth in the box for shipping (fig. 11 and 12).

Fig. 7
Cloth after sampling will be damp and have picked up juices and bits of meat scraps when the collection is completed

Fig. 8: Adding nBPW to the cloth in the roll top bag

Fig. 9: Folded cloth in bag and barcode

Fig. 10: Insert bagged cloth into a zipper lock bag for shipping

Fig. 11: Package the sample

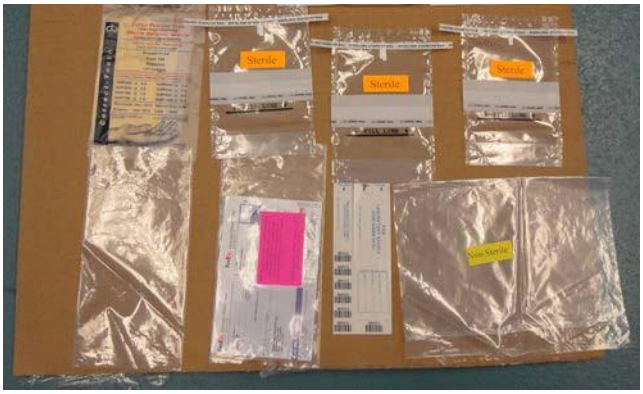
Fig. 12: Second image of a packaged sample

ATTACHMENT 3. OTHER RAW GROUND BEEF COMPONENTS 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.

Sample supply kit

3 - Sterile Fill- Line Closure roll top Bags
1 - 13x18" Zipper Lock Bag labeled
1 - pair non-sterile Gloves
3 – FedEx label (order from Office)
1 – VT Form 7355-2A/AB (sample seal set)
1 - 6" x 12" plastic sleeve
1 - Shipping container
1 or 2 - Gel Coolant
1 or 2 – Cardboard Separators
1 - Absorbent Pad
1 - Foam Plug



Upon receipt of the sampling supplies:

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

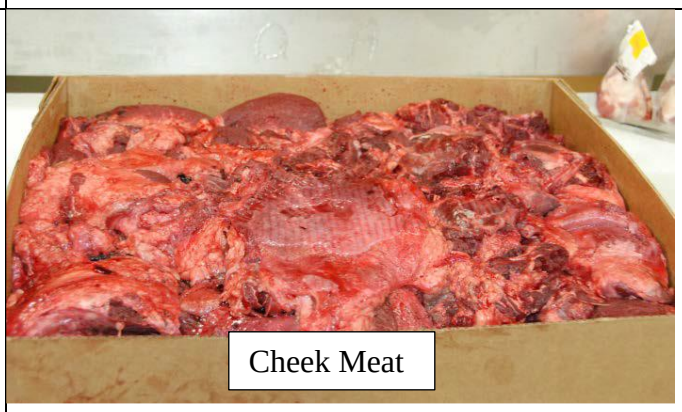
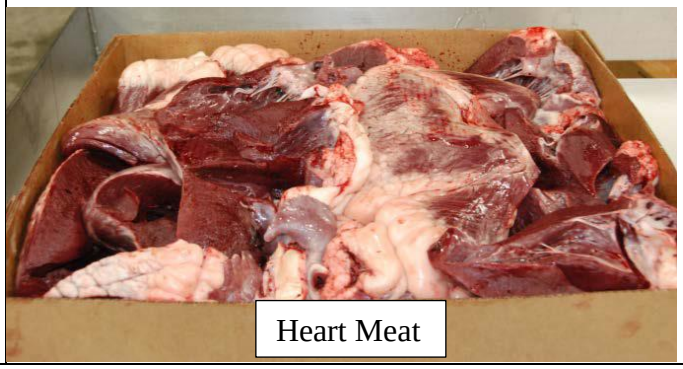
2. Remove gel coolant packs from the shipping container and place them in the freezer at least 24 hours prior to sample collection. Pre-chill the shipping container.

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 roll top 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 roll top 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 cut-resistant glove on your non-knife hand and put on the non-sterile gloves. **NOTE:** It is not necessary to put on a cut-resistant 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 roll top bags. You will <u>not</u> use the N60 or cloth sampling methods to collect other component samples. If trimming of the component is needed, IPP are to wear a cut resistant glove. a. When sampling smaller component types (such as AMR product or low temperature rendered products), aseptically collect grab samples and fill each of the 3 roll top bags <u>up to the fill line</u>.	 Cheek Meat  Heart Meat

b. For aseptic grab samples, IPP are to collect enough product to fill each of the 2-3 roll top bags to the fill-line, making sure there is a minimum of 292.5 grams (~0.64 lbs), with the ideal sample size being 325g.

c. For larger components, such as hearts, IPP are to collect one or more pieces or enough to fill each of the 2-3 roll top bags above the fill line but leaving at least 2-3 inches of space at the top of the bag when collecting COMP samples, making sure there is a minimum of 292.5 grams (~0.64 lbs), with the ideal sample size being 325g.

9. Expel as much air out of the bags, tightly fold over the top at least three times. Do not overfill bags. Fold over the side tabs to secure the folds in place. Do not tie the ends.

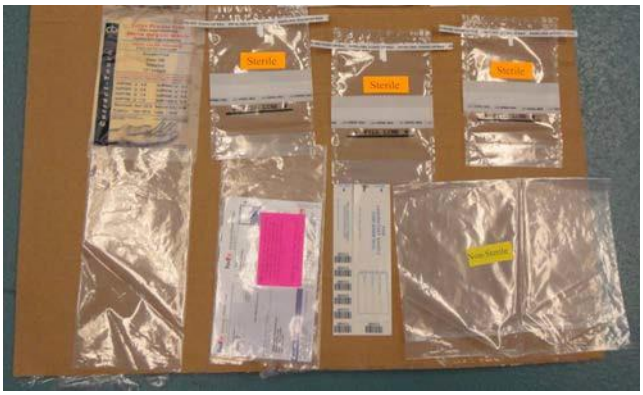
ATTACHMENT 4. RAW GROUND BEEF PRODUCTS ROUTINE SAMPLE COLLECTION IN FINAL PACKAGING AND BY GRAB SAMPLE

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

3 - Sterile Fill- Line Closure roll top Bags
1 - 13x18" Zipper Lock Bag
1 - pair non-sterile Gloves
1 - FedEx label (order from Office)
1 - VT Form 7355-2A/AB (sample seal set)
1 - 6" x 12" plastic sleeve
1 – Shipping Container
1 or 2 - Gel Coolant Pak
1 or 2 - Cardboard Separator
1 - Absorbent Pad
1 - Foam Plug



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 2 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 roll top 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, and a slack filled package is unavailable. 3. Wash and dry your hands. 4. Open the sterile roll top 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 roll top 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 on the non-sterile gloves and sanitize them, allowing sanitizer to air dry before touching the product. 7. Aseptically collect grab samples of raw ground beef.	
8. Collect a sufficient quantity of raw ground beef to fill each of the three roll top bags to the fill-line. Do not under-fill or overfill the bag.	

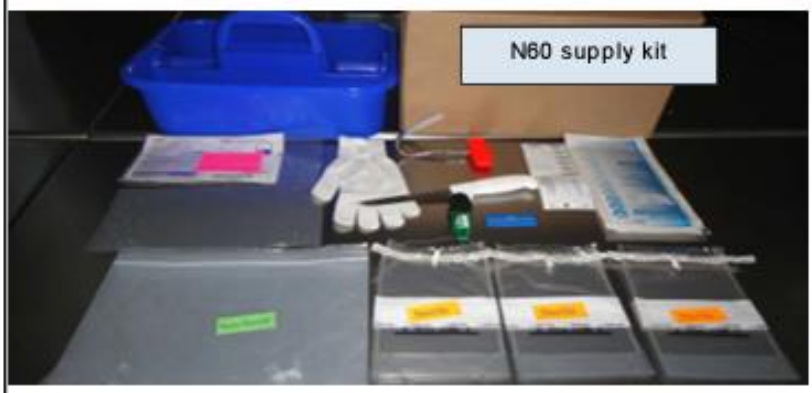
9. Once sample collection is complete, carefully expel excess air from each roll top sample bag, tightly fold over the top at least three times and then fold over the side tabs to secure the folds in place. Do not tie the ends.	

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 roll top 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 or 2 - Gel Coolant Pak
1 or 2 - Cardboard Separator
1 - Absorbent Pad
1 - Foam Plug


Basic Sample supply kit

N60 Companion Supply Kit*
(available upon request from the Western Laboratory)
1 - Caddy
1 - Boning Knife
1 - Hook
1 - Cut Resistant 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)


N60 supply kit

* 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

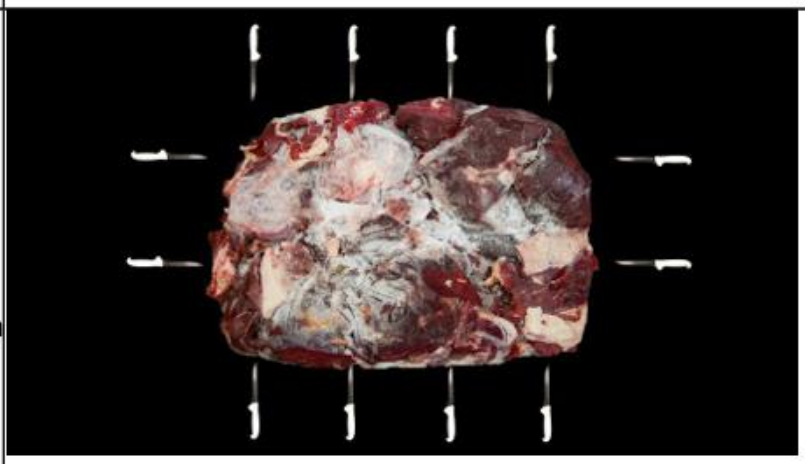
Additional supplies

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 sanitizing solution available from the MMSC.	 

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 roll top 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 roll top 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 cut-resistant 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 1/8 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.	

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.

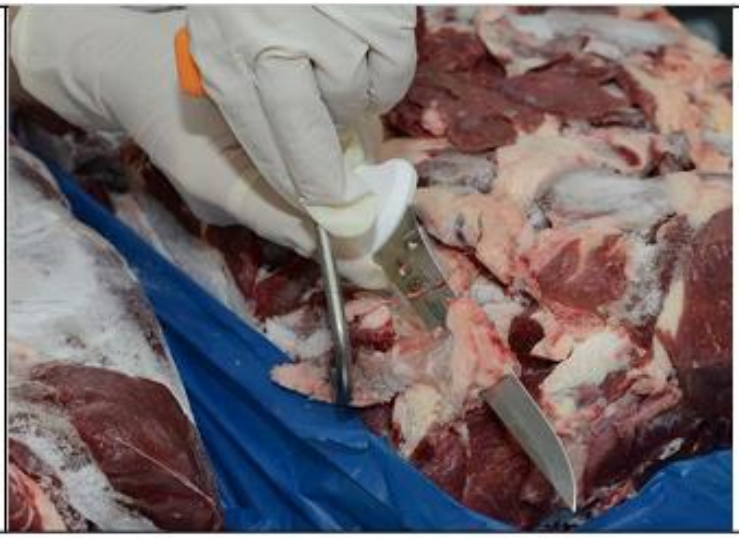


Photo showing the correct sample size for each N60 piece when compared next to the template.

13. Place each slice in one of the sterile roll top bags. Continue this process until you have collected 30 pieces in one roll top bag.

14. Repeat steps 10 through 13 until you have collected two roll top bags each containing 30 slices.

NOTE: When cut to the correct size, 30 sample slices should fill one roll top bags to the fill line.

15. In the third sterile roll top 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 three times and then fold over the side tabs to secure the folds in place. Do not tie the ends.