

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

FSIS NOTICE

36-21

8/31/21

CONTINUED IN-FIELD STUDY TO TEST THE CLOTH SAMPLE COLLECTION METHOD FOR BEEF MANUFACTURING TRIMMINGS

DO NOT IMPLEMENT THIS NOTICE UNTIL OCTOBER 1, 2021.

****FSIS is changing the cloth sampling method to begin using neutralizing buffered peptone water (nBPW) during shipping to the FSIS laboratories.****

I. PURPOSE

A. This notice re-issues and revises instructions to inspection program personnel (IPP), as previously described in FSIS Notice 69-20, *In-Field Study to Test a New Sample Collection Method for Beef Manufacturing Trimmings*. This notice provides updated instructions to IPP to begin using neutralizing buffered peptone water (nBPW) when shipping the cloth sample to the FSIS labs. Step-by-step instructions to use nBPW are included below in Section IX, *Sampling Procedures*.

B. This notice provides instructions to IPP on how to collect raw beef manufacturing trimmings verification samples for an in-field study. The goal of the study is to determine if a non-destructive surface sampling device, the cloth manual sampling swab – commonly referred to as the “cloth” – can replace the current N60 excision sample collection method used to take a sample under the MT60 sampling project. All establishments that typically receive MT60 sampling assignments will be included in the study.

II. BACKGROUND

A. FSIS currently collects raw beef manufacturing trimmings verification samples using the N60 excision sampling procedure as described in [FSIS Directive 10.010.1](#), *Sampling Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef Products*. The N60 excision method (MT60 project code) is a destructive sampling method that requires IPP to cut and collect thin slices from the external surface of beef tissues.

B. FSIS is conducting an in-field surface sampling study to determine the feasibility of a non-destructive surface sample collection method to collect raw beef manufacturing trimmings verification samples. To conduct this study, FSIS will be collecting the non-destructive surface sample alongside the N60 excision sample collection. The alternative sampling method should cover approximately the surface area of a standard combo bin.

1. FSIS is testing a non-destructive surface sample collection method, the cloth manual sampling swab (“cloth”); and
2. The goal is to compare the N60 excision sampling and the non-destructive cloth surface sample collection method to determine if the cloth can comparably recover organisms (fit-for-purpose). IPP

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OPI: OPPD

are to collect both N60 excision and cloth samples on the same sampled lot to allow comparison.

C. The study began on January 4, 2021, updated instructions will begin October 1, 2021, and the study is expected to continue for a minimum of 1 additional month.

D. MT60 and cloth samples will be collected and shipped together to the FSIS Field Service Laboratories. MT60 samples will be analyzed for multiple analytes. Cloth samples will be analyzed for *Salmonella* and indicator organisms only. FSIS is focusing its surface sampling analysis on *Salmonella* and indicators during the in-field study. The traditional MT60 sample will be analyzed for Shiga-toxin producing *E. coli* (STEC), *Salmonella*, and indicator organisms. STEC testing of the MT60 sample requires establishments to hold product until test results are available.

III. ESTABLISHMENT SAMPLING ELIGIBILITY AND PHIS SAMPLING TASK ASSIGNMENT

A. Establishments that produce beef manufacturing trimmings eligible for MT60 sampling—from cattle slaughtered onsite or at sister establishments as described in [FSIS Directive 10,010.1](#)—will be included in the study.

B. IPP are to ensure that the Public Health Information System (PHIS) Establishment Profile information for establishments that produce beef manufacturing trimmings is up-to-date and accurate.

C. IPP will receive PHIS tasks for the non-destructive cloth sampling method under the **MT60_CLOTH** sampling code. IPP are to schedule both the MT60 and MT60_CLOTH sampling tasks in PHIS on the same day for sample collection. Every MT60 sample will have a companion MT60_CLOTH sample that is to be collected on the same day.

D. PHIS tasks and scheduling for MT60 excision samples remain unchanged.

IV. INFORMATION SHARING WITH ESTABLISHMENT MANAGEMENT

A. At the next weekly meeting at establishments producing beef manufacturing trimmings, IPP are to share this updated notice with establishment management.

B. IPP are to inform establishment management and document in a Memorandum of Information (MOI) that:

1. MT60 sample collection procedures remain unchanged, and MT60 samples will be analyzed for STEC and *Salmonella* as described in [FSIS Directive 10,010.1](#). MT60 samples, collected utilizing the N60 sample collection procedure, will also be tested for indicator organisms. Indicator testing results will not be reported in LIMS-Direct;
2. IPP will collect cloth samples from the same lot of beef manufacturing trimmings after IPP collect an MT60 sample. Both MT60 and MT60_CLOTH samples will be shipped together and analyzed at FSIS Field Service Laboratories. Cloth samples will be analyzed for *Salmonella* and indicator organisms only. Cloth samples will not be analyzed for STEC. MT60_CLOTH results for *Salmonella* will be reported in LIMS-Direct. Indicator results will not be reported to LIMS-Direct; and
3. An instructional video of the cloth sampling procedure can be seen [here](#). IPP are to watch the video before performing the cloth sampling procedure. IPP are to also note that the addition of nBPW is not included in the instructional video, but that this is an added step that IPP are to follow.
4. As part of these newly revised MT60_CLOTH sample collection procedures, after the cloth sample has been collected, **IPP are to add nBPW** (the bottle contains 25 milliliters (mL)) **to the cloth in the Whirl Pak®** before shipping the sample to the lab.

V. SUPERVISOR RESPONSIBILITIES

- A. Field supervisors, including Supervisory Public Health Veterinarians (SPHV) and Frontline Supervisors (FLS), are to ensure that IPP that collect MT60 samples are given time to review this notice and watch the cloth sampling procedure in the instructional video as shown [here](#).
- B. Supervisors are to ensure that IPP understand that MT60 (N60) excision samples are collected first, followed by MT60_CLOTH sample collection from the same lot, and all samples are shipped to the FSIS laboratories in the same shipping box.
- C. Supervisors are to ensure that IPP understand that as part of these newly revised MT60_CLOTH sample collection procedures after the cloth sample has been collected, IPP are to add nBPW to the cloth in the Whirl Pak®, but before shipping the sample to the lab.
- D. Supervisors are to ensure that IPP understand that FSIS laboratories will discard samples with the reason, “*Sampling Instructions Not Followed*,” if nBPW is not used.

VI. SAMPLE SELECTION AND LOTTING

- A. MT60 sample collection procedures remain unchanged and IPP are to select the sampled lot as usual following the instructions in [FSIS Directive 10.010.1](#). IPP are to collect grab samples, as appropriate, per instructions in [FSIS Directive 10.010.1](#).
- B. IPP are to sample the establishment's lot as defined by the establishment.
- C. When collecting cloth samples, IPP are to use 1 cloth per lot. If the establishment defines a lot by multiple combo bins, IPP are to randomly select one of the combo bins for sampling. The intent is to, as much as possible, standardize the surface sampled.
- D. If the establishment lots product in boxes, IPP are to use 1 cloth for *up to 5 boxes*. 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.

VII. SAMPLING SUPPLIES FOR MT60 and MT60_CLOTH

- A. The FSIS laboratories will ship the sampling supplies automatically to the Inspector-in-Charge (IIC) at the establishments. IPP are to use only the sampling supplies provided by the FSIS laboratories.
- B. If IPP do not receive sampling supplies by the first day of the collection month, or need replacements for damaged or lost supplies, they are to request sampling supplies.
- C. To request sampling supplies via PHIS, IPP are to right-click a scheduled lab sampling task (e.g., “MT60”) on the Task Calendar, then select “Order Supplies” from the drop-down menu.
- D. To request sampling supplies via Outlook, IPP are to select one of the following addresses:
 - 1. SamplingSupplies-EasternLab@usda.gov;
 - 2. SamplingSupplies-MidwesternLab@usda.gov; or
 - 3. SamplingSupplies-WesternLab@usda.gov.
- E. IPP are to use the subject heading “MT60 Sampling Supplies” in the email and include the establishment name and number, the project code (MT60 or MT60_CLOTH) the IPP's contact name,

establishment number, telephone number, and a list of the supplies needed.

F. IPP will receive new shipping containers with MT60 and MT60_CLOTH sampling supplies that contain nBPW.

G. IPP are to return any unused shipping containers and sampling supplies for these projects to the FSIS Field Service Laboratories. IPP are to send a request for a pre-addressed return FedEx ground shipping label to one of the email addresses listed below.

H. When returning supplies, IPP are not to use any shipping labels included with supplies since they are labels for express delivery that are charged more than a standard ground box. IPP are to contact the lab within their region listed below and use "*Return Supplies*" in the e-mail subject heading to send unused boxes back to the laboratories.

1. Eastern Lab – Atlanta (85), Raleigh (80), Philadelphia (60), Jackson (90)
SamplingSupplies-EasternLab@usda.gov
2. Midwestern Lab – Des Moines (25), Springdale (35), Chicago (50)
SamplingSupplies-MidwesternLab@usda.gov
3. Western Lab – Alameda (05), Denver (15), Dallas (40)
SamplingSupplies-WesternLab@usda.gov

VIII. MT60 and MT60_CLOTH SAMPLING SUPPLIES

A. The sampling instructions for MT60 sampling procedure remain unchanged and are to be performed prior to MT60_CLOTH sampling. All the necessary sampling supplies for MT60 and MT60_CLOTH sampling will be in the same shipping box.

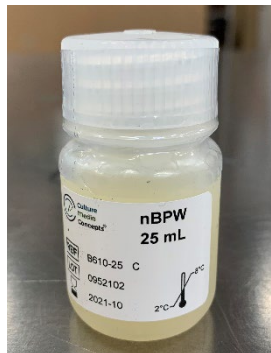
B. The box will include the following shipping supplies for both sample collection methods:

1. MT60 sampling supply kit
 - a. 3 – sterile fill-line closure Whirl-Pak® bags;
 - b. 1 – 13" x 18" zipper lock bag;
 - c. 1 – pair non-sterile gloves;
 - d. 3 – FedEx billable stamp: (Eastern Lab, Midwestern Lab, Western Lab);
 - e. 1 – FSIS Form 7355-2A/AB (sample seal set);
 - f. 1 – 6" x 12" plastic sleeve (for the sample form);
 - g. 1 – shipping container;
 - h. 2 – gel coolant packs;
 - i. 2 – cardboard separators;
 - j. 1 – absorbent pad;
 - k. 1 – foam plug; and

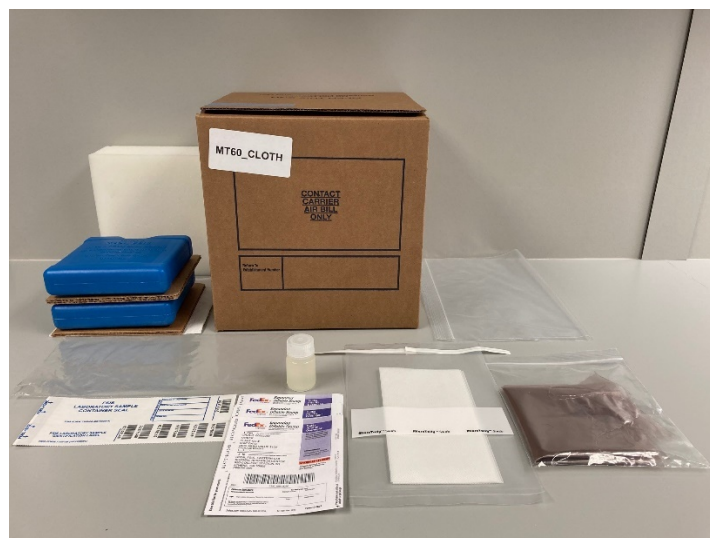
- I. 1 – caddy (only available upon request; request through Western Lab, if needed; see FSIS Directive 10,010.1 for instructions).

2. MT60_CLOTH sampling supply kit

- a. 1 – 13" x 18" zipper lock bag (for packaged cloth);
- b. 1 – cloth in a Whirl Pak® Bag;
- c. 1 – 6" x 12" plastic sleeve (for sample form);
- d. 1 – FSIS Form 7355-2A/AB (sample seal set);
- e. 1 – plastic forearm sleeved glove set; and
- f. 1 – tube of sterile nBPW (the bottle contains 25 mL).



Tube of sterile nBPW



MT60_CLOTH Sampling Kit Example

C. IPP are to only use the supplies provided for the specific sampling procedure being performed. Additional cardboard separators and gel coolant packs may be included with the sample supplies depending upon the time of the year and can be requested by IPP from one of the FSIS laboratories, if needed. Sample supplies that are not provided in the shipping container or that are not sent from any of the three FSIS laboratories for this project are not to be used.

D. Sample supplies are not to be shared or split with the establishment. However, if the establishment is interested in doing its own analysis, IPP are to be aware the establishment may use its own supplies to collect a sample at approximately the same time and point of production as the routine FSIS MT60 and MT60_CLOTH samples.

IX. SAMPLING PROCEDURES

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

1. Pre-chill nBPW upon receipt by placing it in a secure refrigerator (where the supplies will remain under FSIS 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 two pre-frozen gel packs 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. MT60 Excision Sampling Procedure

1. The sampling instructions for the MT60 sampling procedure remain unchanged. IPP are to follow the instructions in [FSIS Directive 10,010.1](#); and
2. IPP are to collect the MT60 sample and MT60_CLOTH sample from the same lot on the same sample collection day to allow comparison for this in-field study.
 - a. IPP are to collect the MT60 sample (or grab sample, if needed) first; and
 - b. IPP are to collect the MT60_CLOTH sample once the MT60 sample collection procedure is completed. IPP are to use 1 cloth per lot to sample the establishment's lot as described in Section VI, *Sample Selection and Lotting*.

C. MT60_CLOTH Sample Procedure

1. IPP are to first collect the MT60 sample as described above per instructions in [FSIS Directive 10,010.1](#);
2. IPP are to wash and dry hands to the mid-forearm;
3. IPP are to remove the clear, perforated plastic shrink wrap from the tube of nBPW and set the nBPW aside;
4. 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. To access the cloth, 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. Once the cloth is at the top of the bag, invert the bag, and allow the dry cloth to drop onto the surface of the product. Do not touch the cloth at this time;

- 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 reaching distance of the sampling area. This positioning will facilitate placement of the cloth back in the bag once the sampling procedure is complete;



Push the cloth to the top of the sample bag, invert the bag, allow the cloth to drop onto the surface of the combo

5. Put on sleeved gloves. Using an alcohol-based spray sanitizer (available from the FSIS Material Management Supply Center FSIS-80-B, FSIS-80-C, or FSIS-80-GAL then add to FSIS-80-Spray Bottle with funnel), 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;

NOTE: IPP are to order sanitizer from the FSIS Material Management Supply Center in advance of collecting samples.

6. IPP are to maintain sanitary conditions after sanitizing gloved hands and forearm sleeves. Do not touch anything except for the cloth;
7. 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;
8. 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;
9. Once a starting point for sampling has been identified, IPP are too 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;
10. 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

11. 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;
12. 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;
13. The total sampling time will be a minimum of 1.5–2 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;



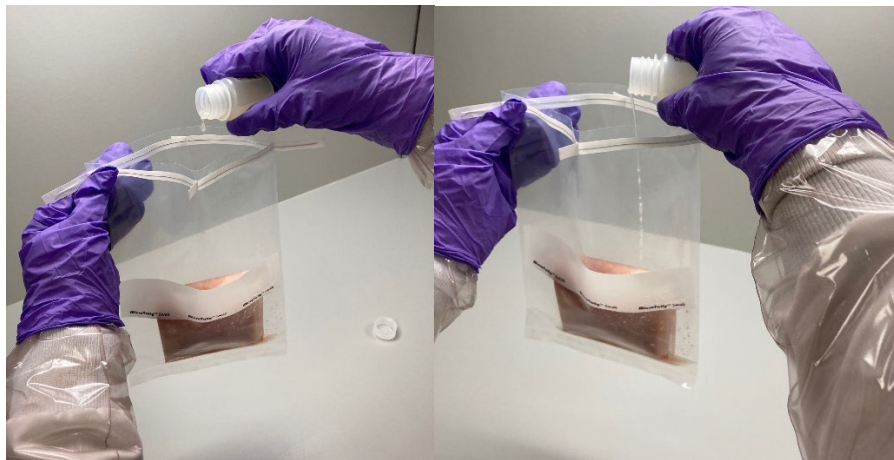
Cloth after sampling will be damp and have picked up juices and bits of meat scraps when the collection is completed



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

14. 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;
15. Once folded, IPP are to return the cloth to the original clear plastic sample Whirl Pak® bag;
16. 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.

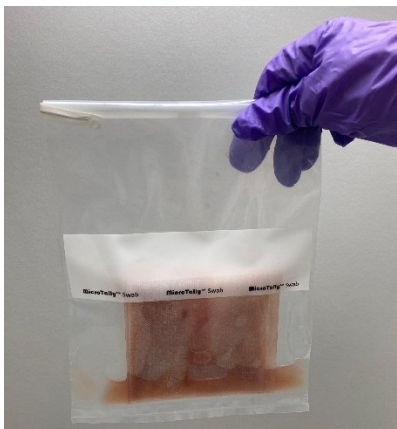
NOTE: IPP are to be aware that FSIS laboratories will discard samples with the reason, *Sampling Instructions Not Followed*, if nBPW is not used.



Pour the sterile nBPW into the Whirl Pak® bag

17. IPP are to discard the empty nBPW tube.
18. IPP are to use gentle pressure on the outside of the Whirl Pak® bag to push the cloth down into the nBPW and remove excess air from the bag;
19. IPP are to close the Whirl Pak® 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

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



Folded cloth in bag and with barcode



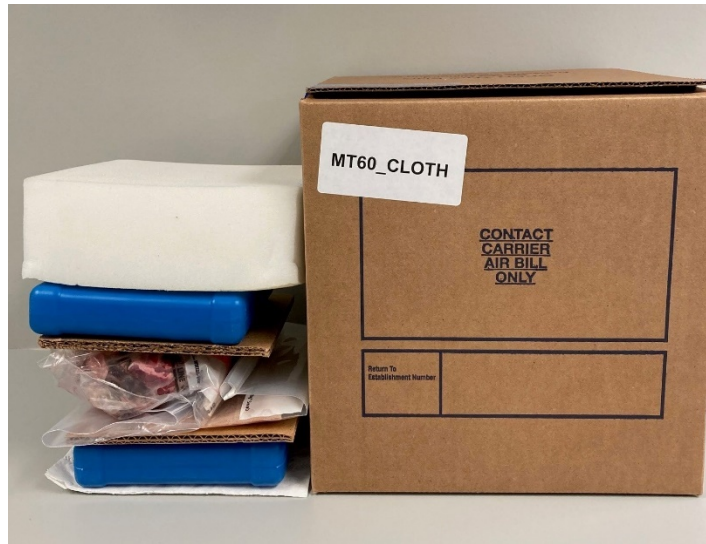
Insert bagged cloth(s) into a zipper lock bag for shipping

X. SAMPLE SHIPPING

A. IPP are to return the MT60 sample and the cloth sample to the respective field laboratory together in the same shipping sample box. MT60 samples have one set of sample seals and sample form. MT60_CLOTH samples have a separate, unique set of sample seals.

B. For sample shipment, IPP are to:

1. Pre-chill shipping containers by placing a pre-frozen gel pack at the bottom of the container and on top of the absorbent pad; refer to Section IX, C. *Cloth Sampling Procedure*;
2. Place one of the included cardboard separators on top of one of the gel packs;
3. Place the bagged and sealed MT60_CLOTH sample in a 13" x 18" zipper lock bag and close it;
4. Place the bagged MT60_CLOTH sample, along with the bagged MT60 sample, inside the insulated sample shipping box as soon as possible, place a cardboard separator on top of the sample, add a pre-frozen gel pack, and finally add the foam plug to the box;



How to pack beef manufacturing trimmings and the cloth to ensure that the sample maintains the correct temperature during shipping

5. Sample temperatures must be properly maintained during collection and shipment. IPP are to avoid storing shipping containers near heaters or in areas exposed to excessive heat. Proper use of the packing materials provided for sample collection will help ensure that an appropriate temperature is maintained during shipping; and

NOTE: If the cloth does not meet the acceptable criteria for sampling when received, it will be discarded. The routine excision MT60 sample will still be analyzed if it is received within acceptable parameters.

6. Ship the sample via overnight FedEx courier the same day the sample is collected, when possible. Samples collected prior to FedEx arrival are to be shipped the same calendar day the samples were collected. IPP are to hold the sample overnight if they collect a sample after FedEx has picked up. For example, MT60 and MT60_CLOTH samples collected from late production or second shifts are to be held overnight under refrigeration and sent by overnight courier the next calendar day. Samples collected on Friday are to be scheduled, collected, and shipped the same day for arrival at the laboratory on Saturday. IPP are not to ship a sample on Saturday or the day before a Federal holiday.

XI. DATA ANALYSIS

The FSIS Office of Public Health Science (OPHS) and Office of Planning, Analysis, and Risk Management (OPARM) will analyze the data collected in the in-field sample collection study to assess if the cloth (MT60_CLOTH) surface sampling method is fit-for-purpose and an effective replacement for the current N60 (MT60) verification sample collection method.

XII. QUESTIONS

Refer questions regarding this notice to your supervisor or as needed to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, complete the [web form](#) and select Sampling as the Inquiry Type.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.

A handwritten signature in black ink, appearing to read "Rachel A. Edelstein". The signature is fluid and cursive, with the first name "Rachel" being the most prominent part.

Assistant Administrator
Office of Policy and Program Development