VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS CONSUMER PROTECTION AND FOOD SAFETY Meat Inspection Service MONTPELIER, VT Chuck Ross, Secretary

		VT Dir 7355	10/1/11
	MIS DIRECTIVE		
	Adopted from FSIS Directive 7355 Rev 2		

Use of Sample Seals for Laboratory Samples and Other Applications

I. PURPOSE

This directive provides for a unified system to ensure the integrity of samples submitted to laboratories for analysis or held for incubation in the establishment as agar plates. The uniform use of sample seals and identity labels ensures that sample integrity and identity are maintained.

II. REFERENCES

9 CFR Chapter III FSIS 10,210.1, Amendment 3, FSIS Directive 7355 Rev. 2

III. DEFINITIONS

What are the terms used in this directive?

Primary Containers - These are the containers that hold the actual sample, whether it be tissue, poultry wash, egg products or swabs. A primary container may be provided to the inspector as a jar, a sterile sample bag, or sterile sample cup or may be the retail package containing the product. It could also be a plastic bag obtained from the laboratory or from the VT MIS Office.

Shipping containers - Shipping containers are usually cardboard boxes provided by the Agency for the shipment of laboratory samples. These boxes have a foam insert to protect the samples during transport and may contain a refrigerant pack to stabilize temperature during shipment.

System-generated or directed samples – These are samples requested by the VTMIS Office as part of Agency sampling programs. The submission forms for these samples are generated at the office and distributed to the inspection program personnel.

Inspector-generated samples - Inspector-generated samples are initiated by inspection program personnel.

Scheduled samples – These are samples collected as scheduled on the Inspection Procedure Schedule under O5BO1, O5BO2 and O5CO1.

IV. BACKGROUND

A. Why must laboratory samples be sealed?

VTAAFM must be sure that samples submitted for laboratory analysis and agar plates used for in-plant screening tests are secure from the time samples are collected until the appropriate official receives the test results. Samples remain under direct VTMIS control while in the establishment and while in the laboratories. During transport, however, samples and products are not under direct control of VTMIS. The sealing of laboratory samples and agar plates used for in-plant screening tests provides a measure of security whenever these items are not under direct control. Appropriate sealing of laboratory samples and agar plates should:

1. Maintain the security and integrity of samples during shipment;

2. Identify samples where identity or integrity may have been compromised (such as in cases of suspected tampering); and

3. Identify and link samples with the information required for accurate analysis and reporting of test results.

B. To which samples does this directive apply?

This directive applies to samples submitted by inspection program personnel to laboratories used to analyze regulatory samples and agar plates held for incubation in the establishment during the performance of Fast Anti-microbial Screen Test (FAST). It includes the sealing and handling of Compliance Program Investigative Samples. Compliance samples will be sealed with same Laboratory Sample Seal Packet following the same procedures detailed below for the use of VT MI84A and B.

V. SEALING PROCEDURES

A. With what are laboratory samples sealed?

VTMI 84A/B is the Laboratory Sample Container Seal. It comes as a set of seals on a strip, one large seal for the outer shipping box (MI-84A), one medium-sized strip (MI-84B) for the plastic bag containing the primary container and the form, and several small seals, all bar-coded identically to cross-reference each other. Using one sample seal set for more than one sample could jeopardize the sample identity.

B. Where do inspectors get sample packaging and sealing supplies? Request them from the VT MIS office.

C. How are the laboratory samples sealed?

All sample packages shipped to the VT Department of Health laboratory are to be sealed and identified using a three-part system. This system identifies and links the sample with the submission form and the shipping container. When properly sealed, each laboratory sample package will have three separate but identically numbered/bar-coded identification labels, as follows:

1) One small bar-coded label is affixed to the sample submission form, in the upper-right or left corner. Make sure not to cover any sample identification information, whether pre-printed on the form or provided by the inspector.

After completing the sample submission form and affixing the bar-coded label, place it inside a plastic bag to protect it from moisture during shipping (Figure 3).



Figure 3

2) The medium-sized bar-coded label, the "Vermont Meat Inspection Laboratory Sample Identification Label" (MI-84B)) is to be placed on the plastic bag containing the primary container, as follows: Insert the sample (already in the primary container) and the submission form (in a plastic bag as in step 1 above) into a re-sealable bag. Express as much of the air out of the bag as you can, and then close the bag. Fold the top of the bag over if possible, and place the

medium-sized bar-coded label so the top bag opening is sealed to the bag itself (Figure 4).



Figure 4

Make sure the bar-code number on the label on the form matches the barcode number on the label on the bag (Figure 5).



Figure 5 - Assure that the barcode number on the form matches the barcode number on the sample bag

3) The large bar-coded label, the Vermont Meat Inspection Laboratory Sample Container Seal (MI-84A), is to be placed on the shipping container as described in the next section. The inspector should retain a record of the seal packet used for each sample sent to the laboratory. An additional, small bar-coded label may be placed on the inspector's file copy of the submission form or on a log sheet indicating to which sample this seal corresponds.

D. How are shipping containers sealed?

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Place the packaged sample into the shipping container, with the ice-pack, if needed. Replace the foam insert lid, being sure that the insert fits entirely within the box. If the insert bulges up out of the box, the box is overfilled and a larger shipping container needs to be used. Place the large bar-coded seal (with the same identification number as the label on the form) on the shipping container as follows:

Shipping containers with self-sticking closures should have the inner flap closed. The bar-coded seal should be placed across the closed inner flap of the box parallel to the edge of the closed flap, as shown in Figure 6. The outer flap should then be closed over the seal.





Boxes without self-sticking closures should be sealed across the closed outer flaps as shown in Figure 7. The outside flaps should then be fastened shut with clear packaging tape.



Figure 7

Coolers for oversized samples should also be sealed with the bar-coded seal over the opening (Figure 8) and then securely closed with packaging tape by wrapping the tape all around the circumference of the cooler in each direction.



Figure 8

Each Pathology Sampling Kit will use one FSIS seal set. Once tissues have been placed in the jars, label the jars with the barcode label number and the serial number of the sample submission form accompanying that sample. Place the jars in the foam insert in the pathology sample box. Place the completed submission form in a plastic bag as directed in section C, and place it on top of the jars. Close the re-sealable bag containing the jars and form, making sure to remove as much air as possible. Seal bag with the medium-sized bar-coded label as previously described in section C2.

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Figure 9 – Placement of the identification label on the plastic bag inside the pathology box. Make sure the bar code on the form matches the bar code on the bag. Then seal the box with the container seal as shown in Figure 10.



Figure 10 – Correct placement of the Container Seal on the Pathology Sampling Kit.

It is very important not to overfill any of the shipping containers. The security seals are not designed to act as a closure device for the shipping containers, and if boxes are overfilled to the point that pressure is placed on self-sticking closures, it is very likely that the seal will be broken during transport.

E. How are shipping containers with multiple samples sealed?

1. If one sample consists of multiple individual primary containers, all primary containers should be placed into one re-sealable plastic bag, along with the corresponding sample submission form in its own bag, and sealed as indicated in section C.2. If all do not fit inside one bag, use a small bar-coded label to seal an additional bag, or request an extra large bag from the lab.

2. If multiple samples, each with its own sample submission form, are to be shipped in one sample shipping container, package and seal each individual sample and its own sample submission form according to section C.2. Be sure each plastic bag is sealed with the barcode seal that corresponds with the sample contained inside. Place each sealed sample package into the box, being careful to not overfill the shipping container. Only one seal (MI-84A) is needed per shipping container, even when the box contains more than one sample. All barcode numbers from samples packed in that container should be recorded on the one MI-84A container seal used.

Note: Once a component of a seal packet has been used, any unused bar codes, identification labels, or container seals from that packet should be disposed of.

It is critical that shipping containers, especially those containing heavy samples like antibiotic residue samples, some ready-to-eat samples, and multiple samples in the same box, not be overfilled. If the foam insert bulges upward, placing pressure on the closure device, place the samples back in the freezer, and request a larger box.

F. How should seals be placed to secure agar plates?

When incubators cannot be secured, seals may be placed on agar plates to detect tampering (FAST tests require the use of agar plates - petri dishes filled with sterile agar). Apply the sample seal to individual agar plates very carefully to avoid tipping or dislodging the disk or swab. Place a small Vermont Meat Inspection Laboratory Sample Identification label (MI-84B) seal across the agar plate cover and fold each end down over the plate bottom. Avoid placing the label across the bottom of the plate.

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To avoid handling the test plates, incubator doors or other enclosed areas where the plates are being incubated may be locked or secured instead of sealing plates as long as only appropriate inspection personnel have access.

H. How are Investigative samples to be sealed?

Investigative samples should be sealed with a MI-84A/B following the same procedures detailed in this directive for all other laboratory samples.

I. What happens if a non-routine sample is collected and the inspector has no seal packet available?

Rarely, a sample with potential public health significance may be collected and the inspector may not have a seal packet available for use. In those rare instances, the inspector should contact the VTMIS office. Do not send unsealed samples without first contacting the Office.

VII. SAMPLE ACCEPTANCE POLICY

What happens if the laboratory receives a shipping container with a broken or missing seal? The laboratory will notify the VTMIS office directly.

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