

**TEXAS DEPARTMENT OF STATE HEALTH SERVICES
MEAT SAFETY ASSURANCE UNIT
AUSTIN, TX**

MSA DIRECTIVE	10,800.1 Rev. 1	3/3/14
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**RESIDUE SAMPLING, TESTING AND OTHER VERIFICATION PROCEDURES UNDER THE
NATIONAL RESIDUE PROGRAM FOR MEAT AND POULTRY PRODUCTS**

CHAPTER ONE – GENERAL

I. PURPOSE

A. This directive provides instructions to inspectors in charge (IIC), including Circuit Managers (CMs), on selecting animals and performing chemical residue sample collection and testing procedures in accordance with the National Residue Program (NRP) for meat, and poultry products. This directive addresses the role of IIC in the collection of animal identification (ID) and producer information, in conducting in-plant residue screening tests, and in completing residue sampling tasks using the Public Health Information System (PHIS).

B. This directive advises IIC about their responsibilities, as part of the NRP, to verify that the establishment is controlling residues in its food safety system. It also advises them on actions to take when a residue violation is suspected or identified through sampling, when a residue repeat violator is identified, and when an establishment fails to collect animal ID information or to maintain animal ID identifiable with the carcass pending FSIS residue test results.

KEY POINTS:

- *IIC select carcasses for NRP scheduled (directed) sampling from all animals that pass antemortem inspection, regardless of post-mortem disposition.*
- *Establishments that do not have an effective residue control program in place in their Hazard Analysis and Critical Control Point (HACCP) system when slaughtering cull dairy cows and bob veal calves are targeted for in-plant testing for chemical residues at an increased rate.*
- *MSA condemns an entire carcass and its parts when there is no Food and Drug Administration (FDA) or Environmental Protection Agency (EPA) established tolerance or action level for the identified chemical residue in muscle, whether the chemical residue is found in muscle, organ, or other tissue.*
- *IIC will take action in an establishment that receives animals from a producer who has been determined to have more than one (1) FSIS laboratory-confirmed residue violation within a twelve (12) month period.*
- *The Kidney Inhibition Swab (KIS™) test has replaced the Fast Antimicrobial Screen Test (FAST) in all slaughter establishments*
- *FSIS laboratories now use multi-residue screening methods on tissue samples submitted from positive KIS™ tests.*
- *The sample size for muscle tissue collected for directed livestock and poultry residue samples submitted to FSIS Laboratories has increased from one (1) pound to two (2) pounds.*

- *MSA requires livestock slaughter establishments to hold or control livestock carcasses and parts selected for FSIS directed residue testing and not to allow them to enter commerce until the FSIS laboratory reports negative or non-violative test results.*

II. SIGNIFICANT CHANGES

MSA is issuing this directive to incorporate instructions from MSA notices and other MSA directives related to residue verification and to provide instructions for completing residue verification tasks using PHIS. It also provides clarification on actions that IIC are to take when an establishment fails to provide information on the violator upon reporting of a violative residue.

III. CANCELLATIONS

FSIS Directive 10,800.1, Procedures For Residue Sampling, Testing, And Other Responsibilities For The National Residue Program, dated 7/12/07

FSIS Directive 10,220.2, Use of CAST and FAST Screening Tests for Bob Veal Calves, dated 4/9/96

FSIS Directive 10,220.3, Using the FAST Antimicrobial Screen Test (FAST) to Detect Antimicrobial Drug Residues in Swine and Cattle, dated 8/23/06

MSA Notice 54-13, Inspection Responsibilities When a Chemical Residue Does not Have an Established Tolerance, dated 8/14/13

MSA Notice 52-13, Level of In-Plant Targeted Testing For Chemical Residues in Cull Dairy Cows and Bob Veal, dated 8/12/13

MSA Notice 73-13, Instructions for Carcass Selection for the National Residue Program Scheduled Samples, dated 11/4/13

IV. BACKGROUND

A. Under 9 CFR 417.2, establishments are to conduct a hazard analysis and consider the food safety hazards that are reasonably likely to occur in their production processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level. A food safety hazard is any biological, chemical, or physical hazard that may cause a food to be unsafe for human consumption. The possible sources from which chemical food safety hazards may arise include chemical contamination, drug residues, and pesticides. Establishments are also required to maintain documentation that supports the decisions made in their hazard analysis as a part of their records under 9 CFR 417.5(a)(1).

B. IIC conduct an in-plant screening test when they suspect an animal presented for slaughter may have violative levels of antimicrobial drug residues. IIC may determine the need for this testing based on herd history, antemortem or post-mortem examination findings, and information posted on the [FSIS Residue Repeat Violator List for Use by FSIS Inspection Program Personnel](#). IIC also use in-plant screening tests to monitor producers and suppliers who have marketed animals with violative levels of antimicrobial residues to determine whether noncompliance has been addressed and corrected and to verify the performance of an establishment's HACCP system in preventing or eliminating chemical residue hazards. In addition, IIC use the in-plant screening test to determine whether further confirmatory testing of tissue samples for antimicrobial drug residues by FSIS laboratory is needed. This testing is necessary in slaughter classes with a higher incidence of violative chemical residues.

C. In July 2012, FSIS announced in a Federal Register Notice ([Docket No. FSIS-2012-0012](#)) the restructuring of the NRP and the process used for scheduling of chemical compounds for residue testing. To complement this new approach to sampling and sample scheduling, FSIS has implemented several multi-residue methods (MRMs) for analyzing meat and poultry product samples for animal drug residues, pesticides, and environmental contaminants in its inspector-generated

testing program. The MRMs are more efficient than the previous platform and enables FSIS laboratories to analyze each sample for more chemical compounds than was previously possible.

CHAPTER TWO - SAMPLING PROJECTS UNDER THE NRP

I. SCHEDULED (DIRECTED) SAMPLING PROGRAMS

A. Sample requests for NRP scheduled residue testing will appear as directed tasks on the establishment task list in PHIS. The sampling task provides information on when to collect the sample (collection window) and which slaughter production class to sample. IIC are to follow the instructions provided in Attachment One and in MSA PHIS Directive 13,000.2, Performing Sampling Tasks in Official Establishments Using the Public Health Information System, for accepting, scheduling, and completing a directed sampling task using PHIS. IIC are to follow the instructions for collecting tissue samples for residue testing provided in Chapter Four.

II. INSPECTOR-GENERATED SAMPLING

A. In-Plant Screening Test (KIS™ Test)

IIC are to conduct a KIS™ test on any carcass that, based on herd history or antemortem or post-mortem inspection findings, may contain a violative drug residue. IIC are to follow the instructions provided in Chapter Three for circumstances warranting a KIS™ test and Chapter Four for performing KIS™ tests and documenting the task in PHIS.

B. Inspector-Generated Tissue Samples

IIC are to collect and submit tissue samples for inspector-generated residue testing in response to a positive KIS™ test and in situations where a CM has reason to believe that a carcass or its parts may contain violative levels of one or more chemical residues, even if the KIS™ test is negative. IIC are to refer to Chapter Four for instructions on performing inspector-generated tissue sample collection and documenting the task in PHIS.

III. NATIONAL SECURITY AND OTHER SPECIAL SAMPLING

In cases involving national security, threat conditions may dictate additional sampling and verification procedures. The MSA Central Office (CO) or Circuit Manager (CM), will contact IIC with specific instructions in the event of an emergency. The CO or CM will instruct IIC regarding other special sampling situations on an as-needed basis.

CHAPTER THREE - CIRCUMSTANCES WARRANTING INSPECTOR-GENERATED SAMPLING

I. PATHOLOGIES AND CONDITIONS WARRANTING CARCASS RETENTION AND SAMPLING

A. At slaughter, IIC are to look for indications of violative chemical use or exposure and collect tissue samples for residue analysis as part of verification of the food safety system. Depending on the slaughter class involved, there are pathologies that, if found, may also indicate residue testing is appropriate.

B. The IIC is to perform a KIST™ test on any carcass suspected of containing violative levels of chemical residues and on any carcass exhibiting signs of systemic conditions (e.g., septicemia, peritonitis, pyemia). The IIC is to use professional judgment when selecting carcasses for chemical or drug residue testing based on evidence of acute or subacute disease conditions, pathological lesions, production practices, herd history, environmental exposure, and threats to homeland security. The IIC is to test animals for chemical residues when they are identified as Texas Suspect for chemical residues during antemortem inspection and when post-mortem findings may indicate antimicrobial treatment, violative chemical use or exposure, even if the carcass and its parts have been condemned.

C. The following list contains descriptions of pathologies and conditions that may warrant testing of carcasses for chemical residues. Residue testing may be appropriate when these conditions are observed. If these conditions exist, IIC are to retain carcasses for CM inspection and disposition.

NOTE: CMs may utilize the [Entry Training for the Public Health Veterinarian](#) modules on Post-Mortem Inspection and Multi-Species Dispositions for correlating with IICs on pathology and regulatory requirements for addressing each condition.

1. Mastitis – Antemortem: Signs of mastitis can vary based on the severity and duration of infection and may exhibit varying degrees of clinical signs, from pus-like or discolored discharge from the teats, redness and swelling of the udder, to no visible change in the udder. Post-mortem: Carcasses with inflammatory ventral edema in the perineal area or ventral hemorrhages and yellow serous exudates.
2. Metritis – Post-mortem: Acute inflammation, including enlargement of the uterine body; distension of the uterus with a fetid brown, red brown, or black fluid; thinning of the uterine wall and lack of evidence of normal uterine involution (e.g., no lines of contracture in the myometrium).
3. Peritonitis and surgery – Antemortem: Findings of surgical devices (e.g., suture, toggles, fistula devices) are only significant if they are associated with active peritoneal or subcutaneous inflammation. Post-mortem: Localized or diffused active peritoneal inflammation with fibrinous exudate or fetid ascitic fluid or with ventral abdominal cellulites secondary to percutaneous abomasal surgery.
4. Injection Sites – Antemortem and post-mortem: Carcasses with lesions associated with injections. Injection sites may be found in a variety of locations including the neck, shoulder, thorax, axilla, ventral abdomen (along the subcutaneous abdominal vein), flank, hindquarter, pelvic area (perirectal), and tail. Look for signs of cellulitis that is away from pressure points (e.g., tuber ischii, hip joint, stifle joint). These are typically found in the semimembranosus and semitendinosus muscle.

NOTE: IIC are not to submit tissue excised from an injection site for residue testing. IIC are to collect tissues from an area away from the injection site.

5. Pneumonia – Antemortem or Post-mortem: Acute, sub-acute, and chronic active pneumonias and pleuritis, resulting from reticulo-peritonitis complex, or embolic pneumonia.
6. Pleuritis – Post-mortem: Inflammation of the pleura lining in the thoracic cavity and lungs.
7. Pericarditis – Post-mortem: fibrinous or fibrinosuppurative inflammation of the pericardium of the heart.
8. Endocarditis – Post-mortem: Inflammation of the endocardium of the heart and acute pulmonary, renal, or other embolic lesions.
9. Septicemia, pyemia or generalized disease – Antemortem and post-mortem: Animals exhibiting any of the following conditions: depression, an elevated or subnormal body temperature, hyperemic skin, congested mucous membranes, dehydration, or poor body condition, in association with an injury or inflammatory condition, such as abscesses, arthritis, pneumonia, mastitis, metritis, or diamond skin.

NOTE: Animals exhibiting any clinical or post-mortem signs of septicemia or toxemia are to be tested for residue.

10. Injury or inflammatory conditions – Ante-mortem and post-mortem: Carcasses found with conditions not resulting in condemnation such as arthritis, pneumonia, mastitis, metritis, nephritis, cystitis, or diamond skin.
11. Acute cellulitis or other acute inflammation - Post-mortem: Fibrinous or fibrinosuppurative exudate in any location on the carcass or viscera.
12. Beta-agonist use: Antemortem: Animals exhibiting clinical signs of excessive or unusually heavy muscle development or hyperexcitability. Post-mortem: Heavy muscle development or a “dark cutter.” Beta-agonist drugs, such as clenbuterol and ractopamine, may be administered to show animals to give them a competitive advantage.
13. Signs of Treatment – Antemortem and post-mortem: Signs of treatment, as indicated by leakage around jugular veins, subcutaneously, intramuscularly, or intraperitoneally, or clinical signs indicative of treatment by mouth, such as discoloration from particles found in any part of the digestive tract. These are important signs when examining veal calves for testing.

NOTE: Dairy cows may present for slaughter with fetlock or ankle bands. These bands indicate that the animal has previously received treatment for a medical condition. When observed, IIC are to correlate with the CM on when to retain these carcasses for KIS™ testing.

II. INCREASED SAMPLING FREQUENCY

A IIC are to refer to the [FSIS Residue Repeat Violator List](#) to determine whether a producer is listed as a repeat violator.

B. The IIC to increase the frequency of KIS™ testing when the establishment:

1. Has a supplier that has had more than one (1) FSIS laboratory-confirmed chemical residue violation in the previous 12 months;
2. Receives livestock from a supplier that is on the Residue Repeat Violator List;
3. Does not have a residue control program designed to control residue violations; or

4. Slaughters dairy cows or bob veal calves and does not supply the producer's name and address or some other type of credible certification that demonstrates the supplier is not on the Residue Repeat Violator List (See Chapter Five, I.E., Note, for examples of types of credible certification).

C. The IIC is to review the establishment's chemical residue control program and follow the instructions outlined in Chapter Five on verifying an establishment's control of chemical residues.

D. The IIC is to discuss the findings with the establishment at the weekly meeting and document the meeting in a Memorandum of Interview (MOI). The IIC is to provide the link to the [Residue Repeat Violator List](#) to the establishment. This list is accessible on the FSIS Web site using the following link:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry>

E. If an increased rate of testing is warranted, IIC are to:

1. Test a minimum of two (2) animals each time the establishment receives animals, and the establishment does not have controls in place that minimize the possibility that the animals have violative residues;
2. Correlate with the CM to determine whether additional sampling is necessary, up to 100% testing of the lot, based on the effectiveness of the establishment's residue control program at reducing or eliminating the occurrence of FSIS violative residue findings;
3. Continue this level of testing on all livestock from producers listed on the FSIS Residue Repeat Violator List;
4. Continue increased testing rate on all dairy cows and bob veal as long as the establishment lacks an effective control program; and
5. Use the increased testing rate for dairy cows and bob veal from any unknown source, even if the animals appear to be normal, as well as on animals with pathologies listed in Section I of this chapter. For bob veal, this increased testing rate is in addition to the rate described in 9 CFR 310.21.

F. The CM is to refer to Chapter Five for instructions on determining compliance and actions to take in situations of multiple laboratory-confirmed chemical residue violations.

III. KIS™ TESTING OF BOB VEAL CALVES

A. Bob veal calf carcasses for KIS™ testing are to be selected from apparently healthy calves, as determined by the IIC or CM, during antemortem inspection. A **bob veal** is an immature calf generally considered to be up to 3 weeks of age, or up to 150 pounds with a non-functional rumen (9 CFR 310.21(b)(1)).

NOTE: Certified groups (calves) described in 9 CFR 310.21 no longer exist.

B. The number of healthy-appearing bob veal calves to sample is based on the percent of the day's estimated slaughter, as indicated in Table 1.

Table 1: Testing of Healthy-Appearing Bob Veal Calves (9 CFR 310.21)

Level of testing of healthy-appearing calves	Percent of daily slaughter heads to sample (%)
A	100
B	50
C	30
D	10
E	5
F	2

C. Upon initiation of the slaughtering of bob veal calves at the establishment, the IIC is to begin testing at Level D, as shown in Table 1.

1. The IIC is to **increase** the testing rate to the next higher level, on the following production day, when three (3) carcasses in out of 100 or less fewer tested consecutively tested have a violation for drug residue confirmed by an FSIS laboratory.
2. The IIC is to **decrease** the testing rate to the next lower level when no more than two (2) bob veal calves have a violation for drug residues confirmed by an FSIS laboratory in out of 500 bob veal calves consecutively tested, or for all bob veal calves tested over a sixty (60) working-day period.

NOTE: Only residue test results reported by FSIS laboratories from the sampling of healthy bob veal calves are used in this calculation.

D. The IIC is to retain all carcasses and parts from the bob veal calves selected for KIS™ testing until all test results are completed. The IIC may reduce inspection line speeds when, in his or her judgment, the required testing cannot be adequately performed within the time available because the establishment's compliance history dictates a need for intensified testing.

E. When a KIS™ test is positive, the IIC is to continue to retain only those bob veal calf carcasses testing positive and submit muscle, kidney and liver tissue samples to the FSIS laboratory for further residue testing, using the instructions provided in Chapter Four.

F. The IIC is to continue to perform KIS™ tests on bob veal calf carcasses that exhibit disease lesions or signs of treatment but is not to use any of these violative test results in calculating the bob veal calf residue testing rate.

IV. TESTING FOR NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)

A. Clinical and post-mortem findings that may indicate possible NSAID (e.g., flunixin and phenylbutazone) use in all livestock (particularly dairy cattle) including, but are not limited to:

1. Down/disabled livestock;
2. Any active inflammatory conditions, including mastitis, metritis, pneumonia, and peritonitis;
3. Injection sites showing marked local inflammation or necrosis; and
4. Arthritis, chronic traumatic injuries or lameness.

B. If the use of NSAIDs is suspected in any livestock, the CM is to direct IIC to collect tissue samples for KIS™ testing and submission to the FSIS laboratory for NSAID testing, using the instruction provided in Chapter Four. The IIC is to retain the carcass and its parts pending the receipt of test results.

NOTE: The KIS™ test does not detect NSAIDs. Regardless of KIS™ test results, IIC are to collect and submit samples to the laboratory for analysis for NSAIDs whenever the CM suspects NSAID use.

V. TESTING FOR BETA-AGONISTS

A. IIC are to collect tissue samples for beta-agonist testing (e.g., ractopamine [Paylean®], clenbuterol) under conditions when:

1. Livestock presented for slaughter exhibit signs of beta-agonist use or abuse, such as excessive or unusually heavy muscle development, hyperexcitability or a “dark cutter;” and
2. As requested by a State health or Agriculture official or Fair Board for selected show animals, such as the Grand Champion, or based on reports of beta-agonist use in show animals.

NOTE: The term “dark cutter” refers to muscle tissue that fails to turn the typical cherry red color when the cut surface is exposed to air and remains dark in color (ranging from dark red to almost black) during processing. Dark cutting beef is most often associated with pre-slaughter stress and has been linked to the misuse of growth promotants.

B. When the IIC suspect beta-agonist use, IIC are to tag these animals as “Texas Suspect,” perform a KIS™ test, and submit tissue samples to the FSIS laboratory for beta-agonist testing, using the instruction provided in Chapter Four. IIC are to note the request for beta-agonist testing in the Remarks box provided in the Sample Collection Data tab in the Sample Management – Sample Collection field in PHIS. The IIC is to retain the carcass and its parts pending the receipt of test results.

NOTE: The KIS™ test does not detect beta-agonist drugs. Regardless of KIS™ test results, IIC are to collect and submit samples to the FSIS laboratory for beta-agonist testing whenever the CM suspects beta-agonist use.

VI. TESTING OF SHOW ANIMALS

NOTE: For the purposes of this directive, a “lot” of show animals (cattle, hogs, sheep, goats) is defined as all animals presented for inspection each day from a single fair or livestock show that are otherwise healthy and have an equal chance of being selected for testing.

A. IIC are to perform KIS™ testing whenever an establishment presents show animals, including steers, heifers, market hogs, mature sheep, and lambs for slaughter, using the instruction provided in Chapter Four, and as follows:

1. When show animals appear otherwise healthy, the IIC is to select animals at random from the entire lot of show animals for testing at the following frequency:

Table 2: Number of Show Animals to Choose for KIS™ Testing per Lot Size

Number of Livestock Animals Per Lot	Number of Animals Tested
1-10	1
11-50	2
51-100	3

- When show animals appear unhealthy or are suspected of having antibiotic residues (e.g., injection sites, evidence of a disease process), IIC are to tag the animals as “U.S. Suspect” and perform a KIST™ test. IIC are to follow the instructions provided in Chapter Four on actions to take based on the KIST™ test results.

NOTE: Live animal testing performed at fairs does not change MSA requirements for show animal testing.

B. IIC are to refer to Chapter Four for instructions on tissue sample collection and submission for inspector-generated residue tests.

- For beta-agonists testing of show animals, submit samples to the Western Laboratory (WL) and select the “CG_SHOW_WL” task from the drop -down menu in the Sample Management window of PHIS.
- For antibiotics and sulfonamides testing of show animals, submit samples to the Midwestern Laboratory (MWL) and select the “CG_SHOW_MWL” task from the drop-down menu in the Sample Management window of PHIS.

VII. TESTING ANIMALS AT A HERD LEVEL

A. IIC are to select animals within a livestock herd for targeted residue testing whenever they suspect that animals within a herd have been treated with a veterinary drug at levels that may exceed tolerances or if they suspect that a herd may have been exposed to an environmental contaminant (e.g., heavy metals, pesticides) at levels of public health concern. IIC are to refer to Table 3 for guidance in determining the number of animals to test based on herd size.

Table 3: Number of Herd Animals to Select for KIST™ Testing By Herd Size

Number of Livestock Animals Per Lot	Number of Animals Tested
1-10	1
11-50	2
51-100	3
100+	4

- If IIC suspect an antimicrobial drug, they are to perform a KIST™ test. If the test is positive, IIC are to submit the appropriate tissue samples to the FSIS Midwestern Laboratory for confirmation.
- If IIC suspect a chemical exposure other than to an antibiotic, they are to collect tissue samples and submit them to the appropriate FSIS laboratory for testing.

B. IIC are to retain carcasses selected for residue testing pending results reporting from the FSIS laboratory.

C. IIC are to inform the establishment that in the event the laboratory detects a residue at a violative level, MSA may request a recall of the carcasses from the entire herd.

VIII. LIVESTOCK USED FOR RESEARCH

A. Livestock used for research are not eligible for slaughter unless the livestock meet the criteria listed in 9 CFR 309.17. The operator of the establishment, the sponsor of the investigation, or investigator is

required to submit data or summary evaluations of data that demonstrates the use of the research product will not result in adulterated products from the research animals. The agencies responsible for granting approval for the use of livestock for research include the FDA; USDA Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS); the EPA; FSIS; and MSA.

B. Written approval is required prior to the time of slaughter, as defined in 9 CFR 309.17 (a)(2).

CHAPTER FOUR – IIC RESPONSIBILITIES FOR COLLECTING SAMPLES

I. GENERAL INFORMATION

A. Only IIC are authorized to collect tissue samples for FSIS residue sampling programs. Under the direction of a CM, IIC are to collect kidney, liver, and muscle tissues from animals whenever there is reason to suspect that a violative level of chemical residue is present or when PHIS assigns a directed residue sampling task to the establishment's task list.

B. IIC are to ensure sample integrity when collecting, preparing, and packaging samples for chemical residue testing.

C. For KIS™ test and any other inspector-generated sampling, IIC are to retain the carcass and its parts, unless otherwise subject to condemnation, pending test results. If the KIS™ test is positive, IIC are to continue to retain the carcass and parts (if not already condemned) and submit kidney, liver, and muscle tissues for further analysis to the appropriate FSIS laboratory. IIC are to document the retain tag number in PHIS for any inspector-generated sample submitted.

D. For directed residue sampling of livestock, IIC are to verify that the establishment holds or controls livestock carcasses selected for testing pending the test results. For directed residue testing of poultry, IIC are to continue to recommend that establishments hold the specific poultry carcasses selected for residue testing pending the test results.

E. IIC are to follow the instructions provided in Attachment One and MSA PHIS Directive 13,000.2 for accepting, scheduling, and completing the residue sampling task using PHIS.

II. ORDERING SAMPLING SUPPLIES FOR RESIDUE TESTING

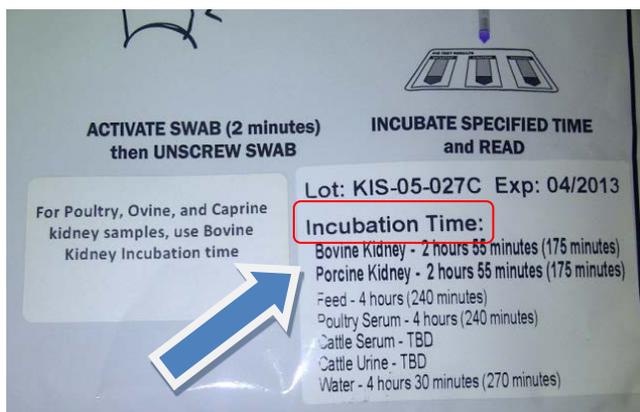
A. IIC are to use only sampling supplies provided by MSA laboratories when conducting residue testing.

B. IIC are to submit requests for KIS™ test supplies to the CO. The following KIS™ test supplies are available from the FSIS Midwestern Laboratory:

1. Digital Dry Block Heater (tests up to 20 units);
2. KIS™ Tests (in packets of 25 tests);
3. Negative Controls (four (4) tablets - approximately one (1) month, as each reconstituted tablet is good for five (5) days when stored at proper temperatures);
4. 15 ml Tube of De-ionized or Distilled Water (or equivalent);
5. Timer;
6. Transfer Pipettes (in packs of 25 – approximately one month) or equivalent device for delivering 1 ml of water; and
7. Test Tube Rack (or equivalent device, to hold KIS™ tests).

NOTE: Upon receipt of KIS™ test supplies, IIC are to check the label on the KIS™ test package for the correct test incubation time based on the slaughter class and sample source (see Figure 1). IIC should note that incubation times may vary between different lots.

Figure 1. Image of a KIS™ test swab package with incubation time label



C. For directed residue samples, IIC can request sampling supply through PHIS by right-clicking on the scheduled residue sampling task on the Task Calendar and select “Order Supplies”. A screen will open and display the project code and the FSIS Laboratory that will fill the sample supply request. IIC should include any additional information regarding their request in the “Comments” box provided and then click “submit request” to place their order.

D. For directed and inspector-generated tissue sample (not KIS™ test supplies), IIC may also submit requests for sampling supply to any of the three FSIS Laboratories via Outlook, using one of the following e-mail addresses:

Eastern Laboratory (SamplingSupplies-EasternLab@fsis.usda.gov),
 Midwestern Laboratory (SamplingSupplies-MidwesternLab@fsis.usda.gov), or
 Western Laboratory (SamplingSupplies-WesternLab@fsis.usda.gov)

IIC are to include the following information in their e-mail request for supplies:

1. The sampling project code;
2. The establishment number and establishment name;
3. The IIC’s name and contact phone number; and
4. The specific supplies needed.

NOTE: In order to ensure delivery of the requested sampling supplies, the establishment’s physical street address (no P.O. Box number) must be entered in PHIS in the "Laboratory Sample Supplies Address" field, under the "General" tab in the Establishment Profile. FSIS laboratories use this address information to ship sampling supplies. Omission or inaccurate entry of this information may result in unnecessary delays in the receipt of sampling supplies. [MSA PHIS Directive 5300.1](#) provides instruction on how to enter establishment address information into PHIS.

III. COLLECTING ANIMAL IDENTIFICATION AND SUPPLIER INFORMATION

A. IIC are to obtain all man-made animal identification (ID) from the establishment for animals selected for KIS™ testing and for all directed and inspector-generated tissue samples submitted to FSIS laboratories for chemical residue testing. IIC are to document all alphanumeric information from all types of ID tags that are present on the animal selected for sampling. IIC are to refer to the [Animal Identification:](#)

Examples of Official Ear Tags document for examples of animal ID tags. Types of animal ID include, but are not limited to:

1. Livestock market or sale barn backtags,
2. Producer ear tags,
3. Feedlot identification tags,
4. Canadian tags,
5. Vaccination (e.g., calf-hood “Bangs” or Brucellosis) tags, and
6. Any special ID used on cattle imported from Mexico and presented for slaughter.

NOTE: IIC are to record any tattoo numbers present on swine selected for chemical residue testing if there is no other type of animal ID information available for the selected animal.

B. IIC are to request from the establishment the producer information for those animals that are KIS™ test positive and for all directed and inspector-generated tissue samples submitted to FSIS laboratories for residue testing (including samples for special residue sampling projects, such as the Dioxin Survey). However, if this information is not known at the time of sample collection, IIC are to enter the establishment’s name and address into PHIS as the producer into PHIS and submit the tissue samples for testing. IIC are not to hold these samples or delay their submission to the laboratory pending receipt of producer information.

C. If producer information on a violative result is later determined, IIC are to submit the information to the Policy Development Staff (PDS) by e-mail to residue@fsis.usda.gov, by fax to 1-402-344-5008, or by phone at 1-800-233-3935. IIC are to include the establishment name, establishment number, establishment phone number, the laboratory form number for the violative residue result, and the producer information in their correspondence to PDS. (See Chapter Five, I.E.)

D. IIC are to maintain the animal ID information identifiable with the carcass and hold all collected identification tags until KIS™ test results report as negative. If the KIS™ test results are positive or if samples are submitted for other analyses, IIC are to document all animal ID information in the appropriate data fields in the Sample Collection – Sample Management page in PHIS.

E. For carcasses selected for chemical residue testing that are also subject to blood sample collection for the USDA APHIS brucellosis or tuberculosis surveillance sampling programs, IIC are to record the animal ID information in PHIS and submit the animal ID tags with the blood sample to the designated State testing laboratory.

IV. CONDUCTING IN-PLANT SCREENING TESTS (KIS™ TESTS)

A. Under the direction of the CM, IIC are to conduct a KIS™ test on any livestock carcass where there is reason to believe the carcass may contain a violative drug residue, based on herd or flock history or ante mortem or post-mortem inspection findings. Although the KIS™ test cannot detect non-antimicrobial drugs, such as NSAIDs (e.g., flunixin, phenylbutazone), IIC are to conduct a KIS™ test when they suspect a violative level of either an antimicrobial drug (e.g., penicillin) or other compound.

B. IIC are to refer to Chapter Three for descriptions of pathological conditions and situations that may warrant retention and testing of carcasses. IIC are to retain the carcass while performing the KIS™ test. IIC are to record pathology findings in the appropriate manner in the PHIS.

C. The CM is to ensure that IIC designated to conduct the KIS™ test, including IIC that are new hires and those who have changed assignments and not previously received training in KIS™ testing, receive training on how to perform the test .

1. Training materials available include the “Performing the KIS™ Test” CD-ROM and the KIS™ Test Instructions booklet. The [KIS™ Test Instructions booklet](http://www.fsis.usda.gov/wps/wcm/connect/0a89eec9-ea8c-4ac0-9435-a5e7f108a42b/KIS_Booklet_0710_2.pdf?MOD=AJPERES) is available as a related document to this Directive and is also available at the FSIS website using the following link:
http://www.fsis.usda.gov/wps/wcm/connect/0a89eec9-ea8c-4ac0-9435-a5e7f108a42b/KIS_Booklet_0710_2.pdf?MOD=AJPERES
2. The designated IIC are to review the training materials. Upon completing the review, the IIC are to log onto [AgLearn](#) and affirm completion of the KIS™ test training.

D. IIC assigned to livestock slaughter establishments are to record the results of KIS™ tests in the Daily Disposition Record page in the Animal Disposition Reporting (ADR) function in PHIS. IIC are to refer to Attachment One for instructions on recording KIS™ test results in PHIS.

E. IIC are to refer to Table 4 for information on actions to take based on KIS™ test results.

TABLE 4. Further Action By IIC Based on KIS™ Test Results

What is the KIS™ Test Result?	Does the CM suspect a non-antimicrobial chemical residue may be present in the carcass?	What further action is the IIC to take?
Positive	No	Submit one (1) lb. each of muscle, kidney, and liver tissue to the PHIS-assigned FSIS Laboratory.
	Yes	Submit one (1) lb. each of muscle, kidney, and liver tissue to the PHIS-assigned FSIS Laboratory and provide a brief description of the clinical and pathological findings that prompted the suspicions.
Negative	Yes	
	No	Release the carcass and its parts to the establishment.

F. If the IIC submits tissue samples for pathology and residue testing on the same carcass, the IIC are to reference the pathology form number in the “Remarks” section of the Sample Collection Data tab in the Sample Collection - ADR Sample Management window in PHIS.

G. In circumstances where a carcass and its parts have been condemned based on post-mortem findings, IIC are still to collect and submit liver, kidney, and muscle tissue samples for inspector-generated residue testing and document the carcass as “Condemned” in the Sample Collection – ADR Sample Management window in PHIS. IIC do not need to retain a condemned carcass and its parts pending residue test results.

H. IIC are to package, secure, and ship the samples to the FSIS laboratory using the instructions provided in Section VII of this Chapter.

V. CONDUCTING INSPECTOR-GENERATED RESIDUE SAMPLING OTHER THAN THE KIS™ TEST

A. In addition to circumstances when a KIS™ test result is positive, IIC are to collect and submit tissue samples for inspector-generated residue testing when an animal presented for slaughter may have violative levels of drug residues based on herd or flock history, information from the RVIS residue violator list, or antemortem or post-mortem examination findings. IIC are to refer to Chapter Three for instruction on circumstances that warrant inspector-generated sampling.

B. IIC are to create inspector-generated residue sampling tasks through the Daily Disposition page of the Animal Disposition Reporting function of PHIS. IIC are to refer to Attachment One for instructions on how to schedule and complete inspector-generated sampling tasks in PHIS.

C. IIC are to retain the carcass and its parts pending residue test result reporting. IIC are to enter the retain tag number into PHIS and indicate that the carcass and parts are “Retained” in order to elevate the sample analysis priority.

D. For inspector-generated residue testing, IIC are to collect and submit the following tissues for analysis:

1. Livestock (except sheep and goats): one (1) pound each of muscle, kidney, and liver tissues.
2. Sheep and goats: one (1) pound of muscle tissue, one (1) pound of liver tissue and both kidneys.
3. Poultry: one (1) pound of muscle tissue and the kidneys and livers collected from six (6) poultry carcasses.

E. IIC are to package, secure, and ship the samples to the FSIS laboratory using the instructions provided in Section VII of this chapter.

VI. CONDUCTING DIRECTED RESIDUE SAMPLING TASKS

A. IIC receive notification of directed residue testing as a task added to the establishment’s task list in PHIS. IIC are to follow the instructions provided in Attachment One for accepting, scheduling, and completing directed residue sampling tasks using PHIS.

B. IIC are to notify establishment management when scheduling a directed residue sample. IIC are to provide enough time for the establishment to hold the sampled carcass.

C. To collect a directed residue sample, IIC are to:

1. Select from all animals that have passed antemortem inspection on the day designated for scheduled sampling for the livestock class indicated on the sample request;
2. Randomly select carcasses at the kill floor stage, regardless of post-mortem disposition. IIC are not to select animals condemned on antemortem because these animals are not permitted into the slaughter facility;
3. Collect and submit the following tissues for analysis from the carcass selected for directed sampling:

- a. Livestock (except sheep and goats): two (2) pounds of muscle tissue and one (1) pound each of kidney and liver tissues.
 - b. Sheep and goats: two (2) pounds of muscle tissue, one (1) pound of liver tissue and both kidneys.
 - c. Poultry: two (2) pounds of muscle tissue and the kidneys and livers collected from six (6) poultry carcasses.
4. Package, secure, and ship the samples to the FSIS laboratory using the instructions provided in Section VII of this chapter.
- a. For samples that are collected and shipped on the same day, IIC are to submit tissue as fresh, refrigerated samples (not frozen) on gel coolant packs.
 - b. For samples that cannot be shipped on the same day as collected, IIC are to freeze the samples overnight and ship them on the next available shipping day.

D. If the same carcass that is randomly selected for directed residue testing also warrants sample submission because of a KIS™ test result, IIC are to perform both sampling tasks for that carcass and cross-reference the samples in PHIS. IIC are to divide available tissue, when necessary, to submit with both forms when the tissue is limited (e.g., one bob veal kidney or one-half bob veal liver with each form).

1. For the scheduled sample that is also KIS™ test positive, IIC are to cross reference the samples by entering into the remarks box, under the Sample Collection Data tab, “KIS™ test positive” and also enter the retain tag number in this box.
2. For the KIS™ test positive sample submission, IIC are to cross reference the samples by entering in the remarks box, “Also submitted for a scheduled sample on form # (provide form #)”.
3. IIC are to ensure that they enter the retain tag number into the data field on both sample forms.

E. IIC are to inform the establishment that livestock carcasses selected for directed residue testing are to be held or controlled until the FSIS laboratory reports the results. IIC are to continue to recommend that an establishment hold any poultry carcass selected for residue testing pending the test results.

NOTE: Only the sampled livestock or poultry carcass and its parts are typically held or controlled by the establishment, because for chemical residues, lots are typically determined on a single carcass basis during the slaughter operation, unless there is evidence of flock or herd application of the treatment.

F. When an establishment decides to voluntarily condemn a carcass from a healthy-appearing animal that has been selected for directed residue testing, IIC are to indicate in PHIS that the establishment elected to destroy the carcass. IIC are to indicate that the carcass was “Passed and discarded by establishment” in the Sample Collection Data tab in the Sample Collection - Sample Management window in PHIS.

VII. SAMPLE PACKAGING AND SHIPPING

A. IIC are to use only the shipping materials provided by the laboratory and refer to [FSIS Directive 7355.1](#), Use of Sample Seals for Program Samples and Other Applications, for complete instructions on the proper use of sample seals.

1. FSIS Form 7355-2A/2B (FSIS Laboratory Sample Container Seal) comes as a set of seals on a strip, one (1) large seal (7355-2A) for the outer shipping box, one (1) medium-sized strip (7355-2B)

for the plastic bag containing the primary container and the form, and several small seals, all bar-coded identically to cross-reference each other.

2. IIC are to use one (1) sample seal set (FSIS Form 7355-2A/2B) for each sample. IIC are to refer to [FSIS Directive 7355.1](#) for instruction on the use of sample seal sets when shipping multiple samples, each with its own sample submission form, in one (1) shipping container.

B. At least one (1) day prior to packing and shipping the sample, IIC are to pre-chill the shipping container in a refrigerator or freezer and place the gel coolant packs in the freezer.

C. Upon collection of the tissue samples, IIC are to:

1. Place each type of tissue collected in a separate sample bag. Do not commingle them even if they are from the same carcass. Expel excess air from the bag prior to closure. Close the bag using the zipper lock closure. If a zipper lock bag is not available, close the top of the bag by twisting the top of the bag and securing it with several loops of rubber band. Then fold the twisted end over and secured again with several loops of rubber band. Place each bagged tissue specimen in a second bag with a label identifying the tissue.
2. Using one (1) FSIS Form 7355-2A/2B, Laboratory Sample Container Seal set, apply one (1) small barcode label to each double-bagged tissue specimen. Repeat steps 1 and 2 for each tissue sample collected.
3. Affix one (1) small bar-coded sample label from FSIS Form 7355-2A/2B sample seal set to the completed and signed printed sample form. Affix the bar-coded label in the space provided at the top center of the form.
4. If the sample will be shipped on the same day as the collection day, place the bagged tissue specimen in a secure refrigerator and allow a sufficient amount of time for chilling, if time permits, prior to packing the sample in the shipping container. If the sample cannot be shipped on the same day as the collection, place the bagged tissue specimens in a secure freezer and keep frozen until the sample can be shipped overnight on the next available shipping day.

D. On the day of sample shipping, IIC are to

1. Retrieve the frozen gel coolant packs from the freezer and the pre-chilled shipping container.
2. Retrieve the tissue specimens from the refrigerator, if shipping overnight on the same day as sample collection, or from the freezer, if shipping one or more days after sample collection, on the next available shipping day.
3. Place the cardboard separator and absorbent pad on the bottom of the shipping container and place the frozen gel coolant pack on top of the corrugated cardboard pad.
4. Place all bagged tissue specimens into a large zipper lock bag, expel the excess air from the bag, and close the bag using the zipper lock closure. Apply the medium sized bar-coded FSIS Laboratory Sample Identification Label (FSIS Form 7355-2B) to the zipper lock bag. Place the sealed sample bag containing the frozen tissue samples in the shipping container on top of the frozen gel coolant pack. When needed, place a second frozen gel coolant pack on top of the frozen tissue sample, to ensure that the sample arrives at the laboratory at an acceptable temperature.
5. Review the information on the pre-printed carrier shipping airbill (i.e., FedEx airbill) provided with the sampling supplies and select the airbill with the laboratory name and address that corresponds

to the FSIS laboratory name and address printed on the FSIS sample form to ensure delivery of the sample to the correct FSIS laboratory. Enter the return address information on the airbill.

6. Place the completed, signed and dated sample form in the plastic sleeve provided. Place the completed sample form and any unused sample seals in the shipping container.
7. Insert the foam plug and press down to minimize the space between the sample and foam plug. If the shipping container does not have a foam plug, place the insulated lid on the container. Do not overfill the shipping container.

NOTE: Do not tape or wrap the samples or use any newspaper or similar material as packing material. Use of such materials may result in a sample discard by the laboratory.

8. Complete the information on the large bar-coded seal from the same FSIS Form 7355-2A/2B sample seal set, sign the seal, and affix the signed, large bar code seal across the seam of the closed sample box flap.
 - a. For shipping containers with self-sticking closures, apply the large bar-coded seal to the closed inner flap of the box parallel to the edge of the closed flap. Then, close the outer flap over the seal and engage the self-sticking closures to secure the top.
 - b. For shipping containers without self-sticking closures, apply the seal across the closed outer flaps. Then secure the outside flaps with clear packaging tape.
9. Affix the carrier shipping airbill on the shipping container and remove any old stamp receipts and carrier shipping bar codes from the container.
10. Ensure that the samples collected remain under FSIS control prior to pickup by the contract carrier.

E. Special instructions for packing and shipping residue samples for Florfenicol analysis.

F. IIC who are seeking to submit tissue samples for Florfenicol analysis are to contact the FSIS Eastern Laboratory for specific instruction on how to pack and ship the sample, using the following Outlook address: [FSIS - Laboratory Inquiry - Eastern Lab \(LaboratoryInquiryEasternLab@fsis.usda.gov\)](mailto:LaboratoryInquiryEasternLab@fsis.usda.gov).

VIII. ACCESSING LABORATORY RESIDUE TEST RESULTS

A. IIC are to periodically check PHIS for the status of residue test results. Test results are reported in PHIS upon completion of the sample analysis. IIC can access test results in PHIS through the Laboratory Sample data field on the Inspector Home page.

B. Sample discard: If the FSIS Laboratory discards a sample submitted for residue testing, the IIC are to take appropriate action, based on the reason for sample discard.

1. The IIC are to review the reason for sample discard as indicated in PHIS 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.
2. If the discarded sample was an inspector-generated residue sample, and there are any tissues from the original submission available, IIC are to send replacement tissue samples from the same carcass. IIC are to complete the task in PHIS as an inspector-generated sample, enter all necessary information in the data fields in the Sample Collection window using the instructions provided in Attachment [One](#), MSA PHIS Directive 13000.2 and the PHIS User Guide. The IIC is to

note in the "Remarks" field that the sample submitted is "REPLACEMENT TISSUES" and reference the sample form number from the original submission.

3. If the discarded sample was an inspector-generated residue sample, and there is only muscle tissue available from the original submission, the IIC are to submit replacement muscle tissue samples from the same carcass and follow the instructions in Section VIII.B.2 of this chapter for completing the task in PHIS. FSIS will use the results from the laboratory testing on the muscle tissue to determine whether there is a residue violation and the disposition of the carcass.

C. IIC are to provide a printed copy of the test results from PHIS to establishment management. IIC are to inform the establishment that it can receive sample results by e-mail if it provides an e-mail address to the IIC, who will enter it into the establishment profile information in PHIS. IIC are to advise establishments to add LIMSDirect@fsis.usda.gov to its e-mail address book to ensure that the e-mails are not blocked. IIC are to provide a printed copy of sample results to the establishment regardless of whether it receives results via e-mail.

IX. IIC ACTIONS UPON REPORTING OF TEST RESULTS

A. IIC are to check PHIS and review the test results for any residue samples submitted (directed or inspector-generated). The CM is to make a final disposition on the carcass and parts and take any necessary regulatory enforcement actions based on the results.

1. For residue test results reported as "Not Detected" or "Detected - non-violative," the IIC is to:
 - a. Inform the establishment that the test result is "in compliance," and
 - b. Release the carcass and its parts.
2. For residue test results where the identified compound does not have an established tolerance for muscle, such as those test results reported as "Detected but not Quantified, Violation" or those having a quantified violation for some part (such as organ tissue or fat) without a quantified muscle result, the IIC is to:
 - a. Condemn the carcass and all parts, and
 - b. Notify the establishment of the results and the final disposition of the carcass and parts.
3. For a residue test result reported as "Detected –violative," the IIC is to ensure that appropriate disposition is made for the carcass and parts as follows:
 - a. Violation in muscle or in muscle and parts – condemn carcass and parts.
 - b. Violation in parts but no violation in muscle – condemn parts, pass carcass.
4. IIC are to notify the establishment of each new violation, any developing trends, and final disposition of any carcass and its parts at the weekly meeting and document the meeting in an MOI.

B. IIC are to seek guidance through their supervisory chain of command for any questions regarding residue test results or action to take based on test results.

CHAPTER FIVE – COMPLIANCE AND ENFORCEMENT ACTIONS

I. IIC Responsibilities

A. IIC are to verify that an establishment reassesses its HACCP plan whenever any changes occur that could affect the hazard analysis or HACCP plan (9 CFR 417.4(a)(3) for chemical hazards (i.e., residues) and as part of the corrective action when an unforeseen hazard has occurred (9 CFR 417.3(b)(4)) for a chemical hazard (i.e. residues) in its slaughter process. Changes that may affect the hazard analysis or alter the HACCP plan may include changes in livestock suppliers or any new source of livestock for slaughter, such as show animals, cull dairy cows, veal calves, and cattle imported from Mexico for immediate slaughter. Under HACCP, these types of animals represent a different source of livestock that potentially have a higher incidence of drug residue violations and the potential for use of expensive human-use medications or illegal or exotic compounds.

B. Veal Calves with Suspected Implants: CMs are to condemn any pre-ruminant calf presented for slaughter that has an implant or evidence of implant use.

NOTE: CMs do not need to collect or submit tissue samples when there is an implant present.

1. During antemortem inspection of pre-ruminant calves whose meat will be labeled as “veal,” CM are to determine whether the animal has an implant. Signs that an implant has been used include:
 - a. Palpable implant (linear, firm swelling under the skin of the ear);
 - b. Missing ears;
 - c. Ears with incisions, indicating recent surgery;
 - d. Mutilated ears;
 - e. Atrophied testicles; or
 - f. Unusually heavy muscle development.

When CM observe signs on antemortem inspection of a pre-ruminant calf that an implant exists, they are to retain the animal and tag it as “Texas Suspect.” IIC are to correlate with the CO to determine when the entire lot (i.e., all calves) from the same producer should be tagged “Texas Suspect.”

2. During post-mortem verification activities in pre-ruminant calves, IIC are to palpate the ears, brisket, and tail head of the “Texas Suspect” carcasses for implants. IIC are to consult with their supervisor to determine whether adjustments in the slaughter line speed may be necessary to complete the inspection procedure.

NOTE: If an implant is present, IIC will feel a linear, firm swelling under the skin when palpating the ear, brisket, and tail head. The implant may feel like “beads on a string.” The individual pellets that make up the implant are approximately 3 mm in size and about 2 mm apart.

- a. If necessary, establishment personnel may remove ears before hide removal, place them in a plastic bag, and attach the bag to the carcass. The establishment may also remove the ears when skinning the head and present them for inspection in a manner acceptable to the IIC.
- b. IIC are to retain the carcasses of “Texas Suspect” pre-ruminant calves exhibiting signs of an implant for post-mortem inspection by the CM to determine compliance.

c. The CM is to examine the rumen of the retained carcass to determine its functionality.

3. Following completion of the examination, the CM is to:

a. Pass the carcass for human food if the animal has a functioning rumen, and the carcass is not subject to condemnation under 9 CFR 311 because of the presence of an implant, or

b. Condemn the carcass if the rumen was not functioning (pre-ruminant), and the animal had an implant, missing ears, ears with incisions that indicate recent surgery, or ears mutilated to the extent that the CM is unable to determine whether an implant was present.

NOTE: If the carcass is missing an ear, the CM is unable to determine whether an implant was present and, therefore, cannot pass the carcass because there is no basis to find that the carcass is not adulterated.

4. If the CM determines that a calf had an implant and a non-functioning rumen, he or she is to verify that the establishment takes the appropriate corrective actions under 9 CFR 417.3(a) or 417.3(b).

5. If the establishment fails to take appropriate corrective action, the CM is to document a noncompliance record (NR) and take the appropriate enforcement action as set out in [FSIS PHIS Directive 5000.1](#).

C. IIC are to verify that the establishment collects and maintains animal ID until the completion of post-mortem inspection, in accordance with 9 CFR 310.2. IIC are to document noncompliance when an establishment fails to comply with MSA regulations for identifying, holding, and sampling of carcasses and parts for drug residues:

1. Livestock: 9 CFR 309.16 (suspected of having biological residues), 310.2 (identification of carcass), 310.23 (identification of swine), and 320.1(records required to be kept); and

2. Poultry: 9 CFR 381.74 (suspected of having biological residues), 381.78(b) (separation of poultry suspected of containing biological residues), 381.80(b) (biological residues), and 381.175 (records required to be kept).

D. IIC are to take appropriate action based on test results reported through the FSIS laboratory, as described in Chapter Four, Section IX. If IIC determine that the establishment failed to hold or maintain control of a livestock carcass selected for directed residue testing, they are to immediately contact the CO. The CO may instruct the IIC to write an NR because the establishment shipped product before MSA 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 set out in 9 CFR 417.5(c).

E. When the FSIS laboratory reports a violative residue result, IIC are to review the establishment's residue control program.

1. If an establishment includes a chemical residue control program in its food safety system but fails to follow its program as written, and FSIS detects a chemical residue at a violative level, IIC are to document an NR using:

a. 9 CFR 417.5(a)(1), if the establishment has a prerequisite program that it failed to follow because the establishment's decisions are not supported;

b. 9 CFR 416.15, if the establishment addresses residue control in its Sanitation Standard Operating Procedures (SOP) but has failed to take corrective actions, or the corrective actions are ineffective;

- c. 9 CFR 417.3(a), if the establishment addresses residue control in its HACCP plan and fails to take corrective actions or corrective actions were ineffective; and
 - d. 9 CFR 318.20, to document the establishment's failure to prevent livestock with violative residue levels from entering slaughter when the violation is associated with a Residue Repeat Violator.
2. If the establishment has not incorporated chemical residue control in its HACCP plan or Sanitation SOP, or in another prerequisite program, IIC are to issue an NR citing 9 CFR 417.3(b).
 3. If an establishment has determined in its hazard analysis that chemical residues are not reasonably likely to occur because they have implemented a prerequisite program to reduce or prevent the hazard, and MSA detects a violative residue through Agency testing, IIC are to verify that the establishment's corrective actions. IIC are to verify that the corrective actions meet all the applicable requirements of 9 CFR 417.3(b) for an unforeseen hazard, including reassessment (9 CFR 417.3(b)(4)) and documentation of its reassessment, even if the establishment made no changes to its HACCP plan as a result of its reassessment.

F. In addition, when the FSIS laboratory reports a violative residue result, IIC are to verify that the establishment has provided information about the violator at the time of sample collection and for the carcass that was reported as violative. If the information was not provided at the time of sample collection, IIC are to request it. IIC are to document a NR when an establishment fails to provide information about the violator upon reporting of a violative residue on FSIS testing. IIC are to cite the noncompliance under 9 CFR 417.2(c), if the establishment addresses residues in its HACCP plan; 417.5(a), if they address residues in a pre-requisite program; or 416.16, if they address residues in their Sanitation SOP.

NOTE: An establishment may demonstrate that it is informing itself of the source of the animals it slaughters by maintaining information identifying the violator, including but not limited to the producer's name and physical address. However, providing the identification of the producer is not a regulatory requirement. In lieu of producer information, an establishment may obtain a letter or other type of credible certification from the seller or livestock market. The establishment may use this type of documentation to demonstrate that the animals received for slaughter are not from a producer known to have more than one (1) residue violation in the last 12 months on the most recently posted Residue Repeat Violator List. In addition, this documentation may also identify those animals from a producer known to be on the Residue Repeat Violator List.

G. The CM is to review information on livestock and poultry suppliers used by the establishment and discuss any concerns regarding their suppliers and violative residue findings with the establishment at the weekly meeting. When necessary, the CM is to raise concerns, through supervisory channels, to the CO. IIC are to document the information discussed in an MOI, as set out in MSA PHIS Directive 5000.1.

H. The IIC is to discuss with the establishment at the weekly meeting, and document in an MOI, any concerns that the establishment may lack an effective residue control program, or any information that the establishment receives animals for slaughter from a:

1. Producer that has more than one (1) FSIS laboratory-confirmed chemical residue violation in the previous 12 months; or
2. Producer that is under an injunction or issued warning letters by FDA.

The IIC is also to provide the following link to the [Residue Repeat Violator List](#) to the establishment:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry>

NOTE: A firm or person listed on the Residue Repeat Violator List remains eligible to market its livestock for slaughter provided the livestock do not bear or contain violative levels of chemical residues. An official

establishment would need to be aware when it receives livestock from a person or firm on the Residue Repeat Violator List in order to be able to design and implement its food safety program to effectively address the potential chemical hazard.

I. When a CM or IIC is notified that the establishment has had more than one (1) FSIS laboratory-confirmed residue violation from animals purchased from a single producer, he or she is to discuss this finding with the establishment and document the discussion in an MOI.

J. The CM or IIC is to discuss all new noncompliance with the establishment at the weekly meeting and inform the establishment that its failure to prevent this hazard from recurring raises questions about the adequacy of the establishment's HACCP system.

1. If the Agency finds additional residue violations between an establishment and a firm or person listed on the Residue Repeat Violator List, IIC are to issue an NR for each occurrence, as described in Section I.D, of this chapter. IIC are to link the NRs in accordance with MSA PHIS Directive 5000.1, Chapter IV, to document that there is a trend occurring.
2. The IIC are to include in the NR a description of any developing trend of noncompliance, the number of the previous NRs with the same cause, and a description of how the noncompliance derived from the same cause.
3. With multiple or recurring noncompliances, the IIC are to assess whether the establishment's HACCP system is inadequate under 9 CFR 417.6. The IIC are to keep their supervisor apprised of the situation.

K. If the IIC determine that the HACCP system is inadequate, and that enforcement action is warranted, the IIC are to contact the CO to discuss whether to issue a Notice of Intended Enforcement (NOIE), citing 9 CFR 417.6 and whether to schedule the establishment for a Food Safety Assessment (FSA).

II. DOCUMENTING VERIFICATION RESULTS IN PHIS

A. IIC are to document the results of their verification procedures in PHIS, including findings of regulatory compliance and noncompliance. IIC are to refer to MSA PHIS Directive 5000.1, Chapter V, MSA PHIS Directive 13,000.1, and the PHIS User Guide for instructions on how to use PHIS to document inspection results.

B. If a noncompliance exists, IIC are to document these findings in an NR using the instructions provided in MSA PHIS Directive 5000.1, Chapter V., Section II..

III. QUESTIONS

Questions regarding this Directive shall be directed to the MSA Central Office through the supervisory chain-of-command.

A handwritten signature in black ink, appearing to read "Dr. Johnson". The signature is written in a cursive, flowing style with a large initial "D" and "J".

Dr. Howard C. "Butch" Johnson, DVM, MS, DACVPM
Director, Texas State Meat and Poultry Inspection Program
Department of State Health Services

ATTACHMENT ONE: COMPLETING RESIDUE SAMPLING TASKS IN PHIS

A. This attachment to FSIS Directive 10,800.1 provides instructions to inspection program personnel (IIC) on how to:

1. Properly submit directed residue lab samples,
2. Enter KIS™ test results, and
3. Submit an inspector-generated tissue sample for confirmatory residue testing in PHIS.

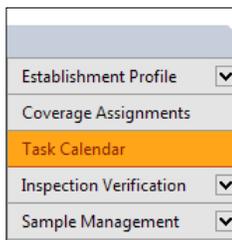
NOTE: These instructions are consistent with, and are a supplement to, the sample submission sections found in [FSIS PHIS Directive 13,000.2](#). Detailed instructions on scheduling and submitting lab samples are also available at [InsideFSIS](#) on the “Find PHIS Information” page.

B. KEY POINTS

1. IIC are to use the task list and task calendar when scheduling or collecting a directed sample and not the **Sample Management** navigation menu tab.
2. After collecting the directed sample, IIC are to click on the **Submit to Lab** button prior to printing the form.
3. IIC are to use the **Animal Disposition** navigation menu tab for entry of KIS™ test results (both negative and positive) and for sample submission in response to positive KIS™ test results.

C. To schedule and submit a directed lab sample for residue testing, IIC are to:

1. Go to **Task Calendar** on the left navigation menu.



2. Go to Establishment Task List.
3. Select the correct assignment from the Assignments dropdown list.
4. Select the correct establishment from the Select Establishment dropdown list.
5. Select **Lab Sampling** from the Filter tasks by dropdown list.
6. Click **Add** to schedule a sample on the task calendar as soon as possible.
7. After the **Collection and Parcel Pickup** dates default to the current date, change the collection date and Parcel Pickup date, if needed. Make certain the window shows available lab capacity (number <100 and a green box). Click the **Save** button.

USDA FSIS PHIS

Project Code: MT43 Analysis Requested: E. coli O157:H7
 Task Start Date: 5/2/2012 Task End Date: 6/1/2012

Collection Date*: 5/30/2012
 Parcel Pickup Date*: 5/30/2012
 Arrive at Lab Date: 5/31/2012

Arrive at Lab Date	Percent Capacity	
5/31/2012	31	■
6/1/2012	17	■

If sampling supplies are needed follow the instructions in FSIS Notice [02-11](#)

Save Cancel

8. After scheduling the sample, collect the sample.
9. After collecting the sample, right click on the task on the calendar and select **Document**. The Sample Collection popup window will open.
10. Enter all information on the **Sample Collection Data** tab. The Remarks box can be left blank. Click **Save and Continue**. The **Additional Info** tab is now displayed for completion of the questionnaire.

Sample Collection Data Additional Info

MT43 Questions

Click a question to view the answer options. Click Save after each answer.

[2] Was plant management notified of this sample collection? 2 Was plant management notified of this sample collection?
 Yes
 No
 Save

[3] Check one:
 [4] Is the submitted sample beef or veal?
 [5] How many pounds or product are represented by this sample (as determined from pre-shipment review records)? Enter numbers only.
 [6] Pounds of ground beef this

Submit to Lab Go Back

Tip: To adjust the question pane on the left, hover over the vertical bar until you see a double-pointed arrow (<->), and then click. To collapse or expand the question pane, hover over the top inch of the vertical bar until you see a hand icon, and then click.

11. After answering each question, scroll to the bottom and click **Save** before advancing to the next question. A green check indicates that the answer was saved. Answer all questions.
IMPORTANT: Review all information on the form for accuracy. Changes **cannot** be made after submission.
12. Click **Submit to Lab** button to transmit the information. A message stating that the sample collection data has been submitted to the lab will appear. If the **Submit to Lab** button is not clicked, the sample will be discarded.
13. Click **Print Form** at the top right of the window. Affix the sample seal label in the designated space at the top center of the printed form. **Sign and date** the printed form. Then, place this form in the shipping container with the sample.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE		Form ID:100176868
SAMPLE ANALYSIS REQUEST FORM		
-- For Lab Use Only--	Place Sample Seal Label Here	 100176868
COLLECTION INFORMATION		
1. SAMPLE FORM ID:	100176868	7. ESTABLISHMENT ID:
2. PROJECT CODE:	MT60	8. ESTABLISHMENT NAME:

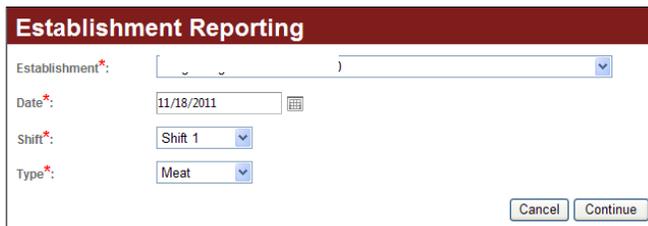
SIGNATURE: _____	TITLE: _____	DATE: _____		
FOR LABORATORY USE ONLY				
Date Received	Analyst Code	Receipt Temperature	Not-Analyzed Code	Not-Analyzed Explain

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14. Close the PHIS sample collection window by clicking on “X” in the upper right corner. After the task has been scheduled and submitted, the # **scheduled** and **Done** columns of the **Establishment Task List** will both increase by one (1).

D. To enter negative KIS™ screening test results in PHIS, IIC are to:

1. Go to **Animal Disposition** on the left navigation menu.
2. Go to **Establishment Reporting** to open the Establishment Reporting page.



3. Enter the Establishment, correct date, shift, and type of product in the dropdowns. Either add a new disposition by clicking **Add Disposition Record** or edit a disposition already in the system. Click on **Edit** pencil icon for the disposition that will be edited. The **Daily Disposition Record Detail** page will open. Click on the **Add Lab Sample Collection** link. The **Sample Management-ADR Sample Collection** page will open.

Sample Management -ADR Sample Collection	
Establishment Profile	Generate a Sample
Coverage Assignments	Establishment*:
Task Calendar	Project Code*:
Inspection Verification	KIS
Sample Management	KIS Test
Animal Disposition	Test Date*:
Establishment Reporting	07/25/2012
Weight Reporting	Slaughter Sub-Class*:
Frequency	Steer
No Kill Period	Tag #:
View Report	MPD12345678

4. Select **KIS** from the Project Code dropdown, and then wait for the KIS™ Test box to open.
5. The day's date and tag number of the selected record will be displayed by default.
6. Enter the residue case number, if there is a case number.
7. In the Reason Code dropdown, select the correct reason for sampling.
8. In the Result dropdown, select **Negative**.

Reason Code*:	Arthritis
N5 Zone*:	20 to 26 mm
Result*:	Select One
Comments:	Select One
	Positive
	Negative
	Indeterminate

9. Enter any other requested information.
10. Do not complete the **Analyses and Select Sample** dropdown for a negative test.

Generate a Sample	
Establishment*:y
Project Code*:	KIS
KIS Test	
Test Date*:	07/23/2012
Slaughter Sub-Class*:	Steer
Tag #:	MPD12345678
Case Number:	
Reason Code*:	Pneumonia
Result*:	Negative
Comments:	
Analyses:	<input type="checkbox"/> Antibiotics (Kidney, Liver, Muscle) <input type="checkbox"/> Sulfonamides (Liver, Muscle) <input type="checkbox"/> Flunixin (Liver, Muscle)
Select Sample:	Select One

11. Click the **Save** button. The **Sample Management-ADR Sample Collection** page will open. The top of the page will show, "Your negative sample result has been recorded for reporting purposes. The results will not be sent to a lab." Exit the window to enter results for another sub-class.

E. To enter positive KIS™ screening residue test results and submit an inspector-generated residue sample in PHIS, IIC are to:

1. Go to the **Animal Disposition** navigation menu tab.
2. Go to **Establishment Reporting** and start at the **Class Summary List**. Click on the **Edit** pencil to open the **Class Summary Information** page.

3. Click on the type of Sub-Class. The **Sub-Class Summary** page will open.

4. Either add a new disposition or edit a disposition already in the system. Click on the **Edit** pencil icon for the disposition that will be edited. The **Daily Disposition Detail Record** page will open.

5. Click on the **Add Lab Sample Collection** link. The **Sample Management-ADR Sample Collection** page will open.

The screenshot shows a web-based form titled "Generate a Sample". On the left is a navigation menu with items like "Verification", "Management", "Position", "Sample Reporting", "Reporting", and "Diod". The main form area contains the following fields:

- Establishment***: A dropdown menu.
- Project Code***: A dropdown menu with "KIS" selected.
- KIS Test** section:
 - Test Date***: A date field showing "07/19/2012" with a calendar icon.
 - Slaughter Sub-Class***: A dropdown menu with "Steer" selected.
 - Tag #**: A text field containing "MPD50854667".
 - Case Number**: An empty text field.
 - Reason Code***: A dropdown menu with "Pyemia/Septicemia" selected.
 - Result***: A dropdown menu with "Positive" selected.
 - Comments**: A large empty text area.
- Analyses***: Three checked checkboxes:
 - Antibiotics (Kidney, Liver, Muscle)
 - Sulfonamides (Liver, Muscle)
 - Flunixin (Liver, Muscle)
- Select Sample***: A dropdown menu with "Animal-Cattle-Steer" selected.

6. Select **KIS**. The day's date and tag number of the selected record will be displayed by default.
7. Enter the requested information and select "positive" from the Result dropdown.
8. When the additional fields **Analyses** and **Select Sample** are presented, check the boxes for the appropriate analyses and sample.
9. Click the **Save and Continue** button. The **Sample Management-Sample Collection** page will appear. Because the sample was positive, schedule sample collection.
10. Click on the **Schedule Sample** link and the **Schedule Lab Sample Task** (yellow box in previous section) pop-up window opens.
11. After the **Collection and Parcel Pickup** dates default to the current date, change the collection date and Parcel Pickup date, if needed. Make certain the window shows available lab capacity (number <100 and a green box). Click the **Save** button.
12. Complete the required Collection Information and be certain the Seal # is entered correctly.

The screenshot shows a form for "Collection Information" with the following fields:

- Herd/Flock Owner***: Text field containing "Joe Farmer".
- Address***: Text field containing "1313 Mockingbird Ln".
- City***: Text field containing "Cheeseville".
- State***: Dropdown menu with "WI" selected.
- ZIP***: Text field containing "53233".

13. Complete Animal Information fields with red asterisks. The address defaults to the establishment address. Update the address to the herd/owner's address. However, if the owner's address is not known at the time of sample collection, submit with the establishment's address because residues in tissues degrade over time.

NOTE: If producer information on violative results is determined later, it should be sent to Residue@fsis.usda.gov, faxed to 402-344-5008, or provided by phone to 800-233-3935.

14. Click **Submit to Lab** button. A message will display to open the **Additional Info** tab and complete the questionnaire.
15. Click on each individual question in the questionnaire, provide an answer, and then click **Save** before proceeding to the next question. When a green check icon is displayed, the answer was successfully saved.
16. Answer all questions. If there is no tag number, enter "no tag."
17. Review all information on the form for accuracy. Changes **cannot** be made after submission.
18. Click the **Submit to Lab** button when all questions are answered.

-- For Lab Use Only --	Place Sample Seal Label Here	 100207895	
COLLECTION INFORMATION			
1. SAMPLE FORM ID:	100207895	7. ESTABLISHMENT ID:	M21488
2. PROJECT CODE:	KIS	8. ESTABLISHMENT NAME:	National Beef Packing
3. SAMPLE SOURCE:	Animal-Cattle-Steer	9. COLLECTION DATE:	07/23/2012
4. ANALYSIS:	Antibiotics (Kidney, Liver, Muscle), Flunixin (Liver, Muscle), Sulfonamides (Liver, Muscle)	10. SHIPMENT DATE:	07/23/2012
		11. COLLECTOR NAME:	Carlos Gomez

19. Print a copy of the lab form, place the sample seal label in the designated area, **sign and date** the form, and submit with the sample tissues to the lab. Exit the system.