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

FSIS DIRECTIVE

5740.1

9/27/12

COOPERATIVE INTERSTATE SHIPMENT PROGRAM

CHAPTER I--GENERAL

I. PURPOSE

This directive describes the procedures that FSIS personnel are to follow in implementing, overseeing, and enforcing the Cooperative Interstate Shipment (CIS) program for the interstate shipment of certain State-inspected meat and poultry products.

KEY POINTS:

- Procedures to review and respond to a State's request to participate in the CIS program
- Procedures to enter into an agreement with a State for its participation in the CIS program
- Procedures to select establishments for the CIS program
- Procedures to oversee and to enforce the requirements of the CIS program
- Procedures to deselect establishments from the CIS program
- Procedures to terminate a State's agreement to participate in the CIS program
- Roles of the Office of Field Operations (OFO) and other FSIS program personnel in implementing the CIS program

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, et seq.)
Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et seq.)
Humane Methods of Slaughter Act 1978 (7 U.S.C. 1901–1906)
9 CFR part 300 to end
ESIS Directive 5720 2 State Cooperative Inspection Programs

FSIS Directive 5720.2 State Cooperative Inspection Programs

FSIS Directive 5720.3 Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs

DISTRIBUTION: Electronic OPI: OPPD

V. BACKGROUND

- A. Section 11015 of Title XI of The Food, Conservation, and Energy Act of 2008 ("The 2008 Farm Bill"), enacted on June 18, 2008, amended the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) to establish a cooperative inspection program under which certain small and very small State-inspected establishments will be eligible to ship meat and poultry products in interstate commerce (Pub.L-110-246, 112 Stat. 1651; 21 U.S.C. 683 and 472). The law provides that the Secretary of Agriculture (FSIS by delegation) "in coordination with the appropriate State agency of the State in which the establishment is located," may select State-inspected establishments with 25 or fewer employees to ship meat and poultry products in interstate commerce (21 U.S.C. 683 (b) and 472(b)). Thus, establishments selected for this program will be permitted to ship their products across State lines and export them to foreign countries.
- B. The program is limited to establishments located in States that have established and continue to maintain an "at least equal to" State meat or poultry inspection (MPI) program (21 U.S.C. 683(b)(2)(E) and 472(b)(2)(E)). To be eligible for selection into the CIS program, State-inspected establishments must employ, on average, 25 or fewer employees; be in compliance with all requirements under the State inspection program; and be in compliance with all Federal requirements under the FMIA, PPIA, and their implementing regulations (21 U.S.C. 683(a)(3), 683(b), 472(a)(3), and 472(b)). Inspection services for these establishments must be provided by State inspection personnel that have "undergone all necessary inspection training and certification to assist the Secretary with the administration and enforcement of [the Acts]" (21 U.S.C. 683(a) (2) and 472(a) (2)). Meat and poultry products inspected and passed by the State inspection personnel will bear a "Federal mark, stamp, tag, or label of inspection" and will be permitted to be shipped in interstate commerce (21 U.S.C. 683(b) (1) and 472(b) (1)).
- C. The law requires that FSIS designate an employee to "provide oversight and enforcement" of the program (21 U.S.C. 683(d) (1) and 472 (d) (1)). If the Federal employee finds that an establishment selected for the program is in violation of the Acts, he or she is authorized to "deselect the selected establishment or suspend inspection at the selected establishment" (21 U.S.C. 683(d)(3)(c) and 472(d)(3)(c)). The law requires that any selected establishment that FSIS "determines to be in violation of any requirement of the Act, be transitioned to be a Federal establishment" (21 U.S.C. 683(h) and 472(g)).
- D. The law requires that FSIS reimburse a State for costs related to the inspection of selected establishments in the State in an amount of not less than 60 percent of eligible State costs (21 U.S.C. 683(c) and 472(c)). The law also states that FSIS "may provide grants to appropriate State agencies to assist the appropriate State agencies in helping establishments covered by this Act to transition to selected establishments" (21 U.S.C. 683(g) and 472(f)).
- E. FSIS published a final rule to implement the CIS program on May 2, 2011, <u>Cooperative Inspection Programs Interstate Shipment of Meat and Poultry Products</u>. The regulations that implement the CIS program are in 9 CFR 321.3, part 332, 381.187, and part 381subpart Z.

CHAPTER II—EVALUATING A STATE'S REQUEST TO PARTICIPATE IN THE CIS PROGRAM AND ENTERING INTO AN AGREEMENT WITH THE STATE

I. RECEIPT OF A STATE REQUEST TO PARTICIPATE IN THE CIS PROGRAM: DISTRICT MANAGER (DM) AND CIS PROGRAM COORDINATOR RESPONSIBILITIES

- A. States that are interested in entering into an agreement with FSIS to participate in the CIS program are required to submit a written request for such a program through the FSIS District Office (DO) that covers that State (9 CFR 332.4 and 381.514).
- B. When a State submits a request, the DM is to:
 - 1. Send a written response to the State to acknowledge receipt of the request. The response is to be sent no later than three business days after the request is received.

- 2. Provide a copy of the response to the OFO Headquarters (HQ) CIS Program Coordinator and the OFO Executive Associate for Regulatory Operations (EARO) for the CIS program.
- 3. Designate an FSIS DO contact to work with FSIS HQ to evaluate the State's request.
- 4. Forward a copy of the request and all supporting materials to the CIS Program Coordinator and give the CIS Program Coordinator the name of the DO contact.

NOTE: The CIS Program Coordinator is the primary OFO HQ contact for the CIS program.

C. The CIS Program Coordinator is to coordinate with the DO and other FSIS programs to form a CIS Review Committee to evaluate the State's request and to determine whether the State qualifies to enter into an agreement with FSIS to participate in the CIS program.

II. VERIFYING THAT A STATE HAS AN "AT LEAST EQUAL TO" COOPERATIVE STATE MEAT OR POULTRY INSPECTION (MPI) PROGRAM

- A. Participation in the CIS program is limited to States that have implemented an "at least equal to" State MPI program (9 CFR 332.4(a) and 381.514(a)). FSIS expects State MPI programs to resolve any deficiencies in their "at least equal to" status before requesting participation in the CIS program.
- B. The FSIS Office of Program Evaluation, Enforcement, and Review (OPEER), Federal State Audit Branch (FSAB), performs ongoing annual reviews to determine whether each State MPI program meets the "at least equal to" standard (see <u>FSIS Directive 5720.3</u>). When a State submits a request to participate in the CIS program, the CIS Program Coordinator is to consult with the FSAB Branch Chief to verify the State MPI program's "at least equal to" status.
- C. If FSAB has determined that the State MPI program does not meet the "at least equal to" requirements or is aware of conditions or events that evidence program deficiencies (e.g., foodborne illness investigations or other credible, verifiable information), the DM or designee is to inform the State that FSIS will not consider the CIS program request until FSAB determines that the State MPI program has resolved the deficiencies and meets the "at least equal to" standard.

III. VERIFYING THAT A STATE MEETS EACH CIS PROGRAM ELEMENT

- A. A State's request to participate in the CIS program must demonstrate that the State is able to provide the necessary inspection services to selected establishments in the State and to conduct any related activities required under the CIS program (9 CFR 332.4(b)(2) and 381.514(b)(2)). The 2008 amendments to the FMIA and PPIA make clear that the inspection services that the State provides to selected establishments must enforce all requirements of the FMIA or PPIA rather than requirements that are "at least equal to" those of the Federal program.
- B. After the State MPI program's "at least equal to" status is verified, the CIS Program Coordinator is to coordinate with the DO contact and other appropriate FSIS programs to review the State's request. The purpose of the review is to determine whether the request includes sufficient documentation to demonstrate that the inspection services that the State will provide to selected establishments in the State will be adequate to enforce all of the requirements of the FMIA or PPIA in the selected establishments.
- C. For this review, the CIS Program Coordinator is to coordinate with the DO contact to conduct the following activities for each element of the CIS program:
 - 1. <u>Legal Authority</u>: The CIS Program Coordinator and DO are to verify that the State's request for a CIS program includes the following documentation to demonstrate that designated State personnel have the necessary legal authority to administer and enforce Federal food safety standards in selected establishments in the State:

- a. A copy of a State law that incorporates the FMIA or PPIA and the implementing regulations explicitly or by reference;
- b. A copy of a law that gives State personnel the authority to enforce Federal food safety standards for purposes of the CIS program;
- c. A legal opinion from the State attorney general that confirms that State personnel have such authority; or
- d. Any other documents that demonstrate that the State MPI program is authorized to enforce Federal food safety standards in establishments selected for the CIS program.

The CIS Program Coordinator and DO are to verify that the State has the authority to take actions to enforce Federal food safety standards in the same manner that FSIS is authorized to act under the FSIS Rules of Practice in 9 CFR part 500. If the State has not incorporated the FSIS Rules of Practice explicitly or by reference, the CIS Program Coordinator and the DO are to verify that the State designated personnel are otherwise authorized to take actions that are the same as those provided for in the Rules of Practice.

- 2. <u>Staffing</u>: The CIS Program Coordinator and DO are to verify that the State's CIS program request includes the following documentation to demonstrate that the State MPI program has staffing sufficient to conduct the same inspection services in selected establishments as FSIS conducts in official Federal establishments:
 - a. The method that the States will use to assign inspectors, including veterinarians, to each selected establishment in the State;
 - b. The methods that the State will use to determine the inspectors' workloads and assignments;
 - c. The methods that the State will use to verify achievement of staffing, and
 - d. The method that the State will use to ensure relief inspection coverage in the selected establishments.

The CIS Program Coordinator and DO are to consult with OFO Resource Management and Planning Staff (RMPS) to review the State's staffing information. If selected establishments in the State will be conducting slaughter activities, these personnel are to verify that the State can staff livestock slaughter at the level provided for in 9 CFR 310.1 or poultry slaughter at the level provided for in 9 CFR 381.68 and 381.76. If selected establishments in the State will be conducting processing activities, the CIS Program Coordinator and the DO are to verify that the State will be able to assign a designated State inspector to all selected processing establishments on a per-shift basis whenever the mark of inspection is to be applied.

- 3. <u>Computer Systems and Forms</u>: The CIS Program Coordinator and DO are to verify that the State's request includes documentation to demonstrate that computer systems and forms that the State intends to use to administer the CIS program are the same as those used by FSIS to administer the Federal inspection program.
 - a. If the State intends to use State-sourced computers, the CIS Program Coordinator and DO are to consult with the FSIS Office of the Chief Information Officer (OCIO) to determine whether the State's request demonstrates that the FSIS software load can be run on the State computers, and whether the State adheres to the Federal informational security standards.

- b. If the State intends to purchase computers from FSIS, the CIS Program Coordinator and DO are to consult with the FSIS OCIO State Coordinator to verify that the State has made arrangements to purchase computers that can run the FSIS software load from FSIS.
- c. Transition to Public Health Information System (PHIS): States will need to implement a public health-based, data driven approach to inspection that is the same as the FSIS PHIS. States will be permitted to use the FSIS Performance Based Inspection System (PBIS) to schedule inspection activities in selected establishments while they transition to the system that is the same as PHIS. In its request for a CIS program, a State is expected to agree to develop a plan to supplement its inspection system to achieve a targeted public health-based, data driven approach to inspection that is the same as PHIS (see Attachment 1 for the "Critical Components for a CIS PHIS Program"). Therefore, when reviewing a State's CIS program request, until PHIS becomes available to the States, the CIS Program Coordinator and the DO are to:
 - i. Verify that the State uses PBIS to schedule inspection activities; and
 - ii. Give the State the information in Attachment 1 on "Critical Components for a CIS PHIS Program" and explain that the State is expected to develop a plan to implement a targeted public health-based, data driven approach to inspection that incorporates the major components of PHIS.
- 4. <u>Training</u>: The CIS Program Coordinator and DO are to verify that the designated State personnel have completed and passed the minimum FSIS-sponsored training requirements necessary for the State to begin to administer a CIS program. The basic training courses are listed in Attachment 2. The courses that designated State personnel will need to complete will depend on the operations conducted at the selected establishments to which they are assigned. Thus, designated State personnel may not need to complete all of the training courses listed in Attachment 2. The State is responsible for ensuring that assignments for designated State personnel are based on the training that the State personnel have completed. FSIS expects designated State personnel to complete training courses administered by FSIS.
- 5. <u>Laboratory Services</u>: The CIS Program Coordinator and DO are to verify that the State's request contains documentation to demonstrate that the laboratory services that the State intends to use to analyze regulatory chemistry, microbiological, and residues samples under the CIS program have or are actively seeking to be accredited by an internationally recognized organization that accredits food testing laboratories against the International Standards Organization (ISO) document 17025, "General requirements for the competence of testing and calibration laboratories," and against the International AOAC document "Guidelines for Laboratories Performing Food Microbiological and Chemical Analyses of Food and Pharmaceuticals Testing" written by the Analytical Laboratory Accreditation Criteria Committee (ALACC).
 - a. If the laboratory services that the State intends to use for the CIS program are ISO 17025 accredited, the CIS Program Coordinator and DO are to consult with the Office of Public Health Science (OPHS), Laboratory Quality Assurance Division (LQAD), to verify that the State's request includes an authentic copy of the ISO certificate and other documentation to demonstrate that the laboratory has the necessary accreditation.
 - b. If the laboratory services that the State intends to use for the CIS program are not ISO 17025 accredited, the CIS Program Coordinator and DO are to consult with OPHS/LQAD to verify that:
 - The laboratory is actively seeking, and has provided a timeline for obtaining, ISO 17025 accreditation within two years; and

- ii. The laboratory has demonstrated that it can meet the criteria in the FSIS laboratory quality assurance (QA) checklist while it seeks to obtain ISO 17025 accreditation.
- 6. Laboratory Methods: The CIS Program Coordinator and DO are to consult with OPHS/LQAD to verify that the State's request contains documentation to demonstrate that the laboratory that the State intends to use to analyze samples for the CIS program will follow the protocols described in the FSIS Chemistry, Microbiological, and Pathology Laboratory Guidebooks. If the laboratory cannot follow an FSIS method as written, the CIS Program Coordinator and DO are to consult with OPHS/LQAD to verify that the State has submitted a justification to modify an FSIS method and that the LQAD has reviewed any modifications made to the FSIS method, and determined that the methodology is consistent with the original FSIS protocol. The State's method must be capable of achieving results that are consistent with the corresponding FSIS method. If a State's laboratory is ISO 17025 accredited, but some of the analyses that it conducts are not under its scope of accreditation, the State may still qualify for a CIS Program if the laboratory can demonstrate proficiency in FSIS Laboratory Guidebook methods, and the laboratory agrees to actively seek and obtain scope of accreditation for the analyses during the next accreditation cycle. Inquiries on laboratory accreditation or methods should be submitted to OPHS/LQAD through the following Outlook e-mail address: FSIS InterstateShipmentProgramLabInquiries@fsis.usda.gov
- 7. <u>Sample Collection</u>: The CIS Program Coordinator and DO are to verify that the State's request includes documentation to demonstrate that designated State personnel will collect the same number and type of regulatory samples from selected establishments in the State that FSIS collects from official Federal establishments.
 - a. The CIS Program Coordinator and DO are to consult with the OPHS Microbiology Division (MD) to verify that the State developed its sampling plan using the same risk-based algorithm that FSIS uses to determine the number and type of microbiological samples to collect each year.
 - b. The CIS Program Coordinator and DO are to consult with the OPHS Risk Assessment Division (RAD) to verify that the State developed its sampling plan using the same risk-based algorithm that FSIS uses to determine the number and type of chemical samples to collect each year.
- D. If the State's request for a CIS program does not contain sufficient information to demonstrate that the designated State personnel will provide same inspection services to selected establishments as those that FSIS provides under the Federal inspection system, the CIS Program Coordinator is to prepare a letter to be signed by the DM for the State that describes in detail the information that FSIS needs to complete its review of the State's CIS program request. The DM is to sign the letter and send it to the appropriate State official.

IV. ENTERING INTO A COOPERATIVE AGREEMENT FOR STATE PARTICIPATION IN THE CIS PROGRAM

- A. When the CIS Review Committee has completed its review of all elements required for a State to participate in the CIS program, the FSIS Office of Outreach, Employee Education, and Training (OOEET), Outreach and Partnership Division is to prepare a draft written cooperative agreement for review by the FSIS Administrator or designee.
- B. If FSIS approves the State's request, the Administrator or designee and an appropriate State MPI official will sign the cooperative agreement.

CHAPTER III--SELECTING ESTABLISHMENTS FOR PARTICIPATION IN THE CIS PROGRAM

I. GENERAL

A. In their requests to participate in the CIS program, States are required to Identify establishments in the State that have requested to be selected for the program and that the State recommends for selection into the program, if any (9 CFR 332.4(b)(1) and 381.514(b)(1)). Before a State recommends an establishment for selection into the CIS program, the State is expected to have conducted its own evaluation of the establishment to determine whether the establishment is eligible to participate in the program (see 76 Federal Register 24730)

B. After FSIS has entered into an agreement with a State to participate in the CIS program, the FSIS DO that covers the State is to coordinate with the State to select establishments to participate in the program (9 CFR 332.4, 381.514).

II. DM ROLE IN SELECTING ESTABLISHMENTS TO PARTICIPATE IN THE CIS PROGRAM

The DM or designee is to conduct the following activities to determine whether a State-inspected establishment is eligible to be selected to participate in the CIS program:

- 1. Review the State's submission to verify that the State has conducted its own evaluation of each establishment it has recommended for selection into the CIS program;
- 2. Develop a District action plan to assess each State-inspected establishment that the State MPI program has recommended for selection into the CIS program to verify that the establishment meets all Federal regulatory requirements and is otherwise eligible to participate in the program. The District action plan is to provide for an initial on-sight survey to evaluate each recommended establishment and a follow-up visit to any establishment that did not meet Federal standards on the first survey;
- Appoint a selected establishment coordinator (SEC) to conduct surveys of the State-inspected establishments that the State MPI program has recommended for the CIS program. The SEC is the Federal employee assigned to provide oversight and enforcement of the CIS program in the particular State;

NOTE: The DM may designate qualified FSIS personnel, such as a Frontline Supervisor (FLS), to conduct surveys of the State-inspected establishments on behalf of the SEC.

- 4. Arrange a meeting or conference call with the SEC or designee and the MPI State Director to discuss the procedures for assessing the State-inspected establishments;
- 5. Arrange pre- and post- selection meetings with the establishment operators and the State MPI officials that will be administrating the CIS program to provide information on the selection process for the program;
- 6. Give establishment operators the electronic link to the FMIA, PPIA, and Humane Methods of Slaughter Act on the FSIS Website or order these documents for establishments that do not have electronic access to them;
- 7. Notify each of the State-inspected establishments of the approximate survey date at least two weeks in advance;
- 8. Compile all materials from the establishment survey, including the Plant Information FSIS Form 9020-2 the Survey Report FSIS Form 9020-3, and the survey checklist (Attachment 3):

- Coordinate the submission of labels from establishments selected for the CIS program to the Office
 of Policy and Employee Development (OPPD), Label and Program Delivery Division (LPDD), for
 evaluation; and
- 10. Give the FSIS OCIO State Coordinator a list of individuals and State-inspected establishments that the State MPI program will need to purchase computers, peripherals, software, phone lines and possible high speed connections for to be able to administer the CIS program.

III. SEC ROLE IN SELECTING ESTABLISHMENTS FOR THE CIS PROGRAM

The SEC or designee, in coordination with State MPI officials, is to conduct an initial and, if necessary, a follow-up survey of each State-inspected establishment that the State has recommended for selection into the CIS program. The purpose of the survey is to verify that each establishment is in compliance with all Federal laws and regulatory requirements and is otherwise eligible to participate in the CIS program. The SEC is to conduct the following activities to complete the survey:

- 1. Prepare to lead the survey teams that will visit and conduct the individual State-inspected establishment surveys as provided in the District action plan. The survey teams are to include the SEC and State MPI officials who will be administering the CIS program for the State;
- Coordinate with the State MPI officials to conduct entrance and exit meetings with establishment management. Encourage establishment management to accompany the team during the survey. If establishment management declines to be surveyed, discontinue the survey and notify the DM. Inform establishment management that if it does not agree to be surveyed, it cannot be selected to participate in the CIS program;
- 3. Prepare a Memorandum of Interview (MOI) to document that establishment management has received information on inspection requirements under the CIS program, and that the establishment agreed that it will not use Federal brands or labels until notified by the SEC or designee. Forward original copy of the MOI to the DM, one copy to the establishment file, and one copy to establishment management;
- 4. Complete "Plant Information" sheet, FSIS form 9020-2, and ensure that it includes the establishment name, address, and telephone number; establishment operator and title; and nature of operations, hours of operations, types of species slaughtered, types of processing operations, and distribution information. If the establishment intends to produce products under both the CIS program and the State MPI program, specify the information for hours of operations, types of species slaughtered, and processing operations for both programs;
- 5. Review establishment employment documentation to verify that the establishment employs on average fewer than 25 employees as determined by the standards for counting employees in 9 CFR 332.3(b) and 381.513(b). To verify that an establishment employs 25 or fewer employees on average, the SEC is to:
 - a. Request that the establishment provide a list of the employees whose duties involve the handling of the meat or poultry products for each pay period over the past 12 months, as well as a list of volunteers whose duties involved the handling of the meat or poultry products each pay period over the past 12 months. These volunteers are considered to be employees for the purposes of the CIS program. If the establishment has not been in business for 12 months, request that the establishment provide a list of employees and volunteers whose duties involved handling the meat or poultry products for each of the pay periods in which the establishment has been in business.
 - b. Verify that the establishment's list includes all full-time, temporary, and part-time employees as well as full time, part-time, and temporary volunteers whose duties involve handling the meat or poultry products produced by the establishment.

- c. Verify that the number of employees listed for any given pay period does not exceed 35.
- d. Examine time and attendance, payroll, or other employee records to verify that the establishment has appropriately identified the average number of employees for purposes of the CIS program.
- e. Verify that the average number of employees is 25 or fewer by adding the number of employees listed for each pay period and dividing by the total number of pay periods.

Example: For each two week pay period, an establishment that operates three months out of the year had the following number of employees for each pay period based on the standards for counting employees in 9 CFR 332.3(b) and 381.513(b).

Pay Period 1: 23 Employees Pay Period 2: 30 Employees Pay Period 3: 31 Employees Pay Period 4: 24 Employees Pay Period 5: 20 Employees Pay Period 6: 10 Employees

139 Employees Total

To verify that the establishment had the appropriate number of employees, add the number of employees for each pay period and divide the number by the number of pay periods:

139 employees÷ 6 pay periods = 23.2 Average number of employees.

If this number is 25 or less, the establishment has the appropriate number of employees to participate in the cooperative shipment program because the average number of employees is fewer than 25, and the number of employees for any given period never exceeds 35.

NOTE: An establishment that employed more than 25 employees but fewer than 35 employees as of June 18, 2008, is eligible for selection into a CIS program. However, if selected, the establishment must employ on average no more than 25 employees as of July 1, 2014, or it must transition to become an official Federal establishment (9 CFR 332.3(a)(2) and 381.513(a)(2)).

- 6. Conduct an in-depth survey of the establishment in coordination with State personnel using the checklist provided in Attachment 3. During the survey, the SEC or designee, in coordination with the State personnel, is to:
 - a. Review the establishment grounds, facilities, and equipment and determine whether the establishment complies with 9 CFR 416.1 through 416.5;
 - b. If the establishment conducts slaughter activities, assess whether the establishment is capable of handling and slaughtering livestock humanely as set out in 9 CFR Part 313, or whether it is capable of following humane methods of handling and slaughter for that are consistent with good commercial practices for poultry slaughter;
 - c. If the establishment only conducts processing operations, verify that the source materials used to produce products under the CIS program are from an official Federal establishment or from another selected establishment in good standing under the CIS program.
 - d. Verify that the establishment has developed a written Sanitation Standard Operating Procedures (SOPs) as set out in 9 CFR 416.11 through 416.16;

- e. Verify that the establishment conducted, or had conducted for it, a hazard analysis and has developed HACCP plans applicable to its products in accordance with 9 CFR Part 417;
- f. If applicable, evaluate the establishment control programs for *Listeria monocytogenes*. Have the establishment provide the same information on post-lethality exposed ready-to-eat products that FSIS collects from federally-inspected establishments through PHIS. Until PHIS becomes available to the CIS program, establishments may provide the same information that FSIS used to collect using FSIS form 10,240-1, "Information on Post-Lethality Exposed Ready-to-Eat Products." Ensure that the State officials also receive this information. Although FSIS discontinued the use of this form in September 2011, it may be used as a reference to ensure that establishments that produce RTE products under the CIS program provide the relevant information on post-lethality exposed ready-to-eat products.
- g. If the establishment intends to conduct operations under both the CIS program and the State MPI program, verify that the establishment has written procedures for complete physical separation of product and process for each operation by time or space as required under 9 CFR 332.13 and 381.523
 - i. <u>Separation by space</u>: If the establishment chooses to separate operations by space, it may either conduct each operation in separate physical areas, or it may conduct each operation in the same area, provided that the separation in space is sufficient to ensure that potential food safety hazards, if present, are not likely to spread from one area to the other. For example, an establishment may designate certain employees on a given day to work on the State MPI operations and have these employees wear white clothing, and it may designate other employees to work exclusively on the CIS program operations and have these employees wear yellow clothing. The establishment could also color-code knives, food contact surfaces, and other equipment associated with each operation.
 - ii. <u>Separation by time</u>: If an establishment chooses to conduct the State MPI operations and CIS program operations at separate times, the establishment's procedures for separation will need to address clean-up between operations. Establishments that conduct both operations in the same facility and on the same equipment will need to fully clean and sanitize the facility and equipment between operations.
 - iii. <u>Separation of product</u>: Establishments that choose to conduct operations under both the State MPI program and the CIS program will need to establish written procedures to ensure that product produced under the State MPI program will not become co-mingled with product produced under the CIS program. The procedures need to ensure that products produced under each program are appropriately identified as State MPI products or CIS program products, and that each product bears the appropriate mark of inspection.
- 7. Document the establishment's level of compliance with each of the regulatory requirements described above on the "Survey Report", FSIS Form 9020-3. If on the initial survey the plant does not meet all of the Federal standards described above, identify on that same form the actions that the establishment will need to take to comply with the necessary Federal standards to qualify for selection into the CIS program. Send a copy of the completed "Survey Report" to the DO, provide a copy to the establishment management, provide a copy to the State MPI program officials, and retain the original and one copy. Discuss the initial survey results with establishment management and the State MPI program officials.

NOTE: Until PHIS becomes available to States participating in the CIS program, results of the establishment surveys and other information associated with the program are to be documented as provided in this directive. When PHIS is made available to the CIS program, the Agency intends to update

this directive to provide additional guidance as to how to document the results of the on-site establishment surveys and other information related to the CIS program.

8. If an establishment does not meet all Federal standards on the initial survey, instruct the State MPI program officials to contact the FSIS DO when the State MPI program has verified that the establishment has completed the necessary actions to comply with Federal standards.

NOTE: FSIS expects that an establishment that did not meet Federal standards on the initial survey will inform the State MPI program when the establishment has completed the actions needed to meet Federal standards. FSIS expects that the State MPI program will contact the SEC or designee after State officials verify that the establishment has completed the necessary actions to become eligible for a CIS program.

- 9. After being contacted by the State officials, schedule and conduct follow-up surveys for establishments that were found to not have met all Federal regulatory requirements on the initial survey. Verify that these establishments have completed the actions needed to meet all Federal standards. Record whether the establishment was able to meet all Federal standards on the follow-up visit on the retained original and remaining copy of the FSIS Form 9020-3.
- 10. During the survey, collect copies of labels that the establishment intends to use on products produced under the CIS program.
 - a. Provide label applications and request that the establishment management complete the label application for products they intend to produce for the CIS program that are not permitted to be generically approved as provided in 9 CFR 317.5 and 381.133.
 - b. Upon determination that labels meet Federal labeling requirements, and that they do not have false nor misleading information, submit the label application and one copy of the label through the DO to OPPD, Labeling and Program Delivery Division. Instruct the establishment to retain one copy for its label file.
 - c. Evaluate all shipping containers labels to ensure they do not have false or misleading labeling.
- 11. After completing the initial or follow-up survey, identify the State-inspected establishments that have met the necessary Federal standards and all other requirements to qualify for selection into the CIS program.
 - a. On the FSIS Form 9020-3, write "Recommend State-inspected establishment be selected for the CIS program." Forward the original copy to the DM, give a copy to establishment management, give a copy to the State MPI program, and retain a copy for your records.
 - b. Issue FSIS 5200-7, "Authorization Certificate," to order Federal metal carcass brands for State-inspected slaughter establishments that FSIS will select to participate in the CIS program.
 - c. Verify that Federal and State brands are inventoried and kept under security by the designated State personnel at the State-inspected establishment
- 12. Identify State-inspected establishments that did not meet all Federal standards or that were otherwise ineligible to be selected for a CIS program, e.g., the establishment employs more than 25 employees on average, based on the initial survey or on the follow-up survey. On the FSIS Form 9020-3, write "Do not recommend selection of State-inspected establishment for the CIS program," and document the reason for not recommending the establishment. Forward original copy to the DM, give a copy to establishment management, and give a copy to the State MPI program.

- 13. Verify that the State has assigned an official selected establishment number to each establishment that has been selected to participate in the CIS program. The official number assigned to a selected establishment must contain a suffix, e.g., "SE," that identifies the establishment as a selected establishment, and that identifies the State, e.g., "SETX," for "selected establishment Texas" (9 CFR 332.5(c)). The number for a poultry establishment must also include the letter "P" in the suffix that identifies the establishment as a poultry establishment, e.g., "SEPND," for "selected establishment poultry North Dakota" (9 CFR 381.515(c)).
- 14. During the initial survey or any of the follow-up surveys, if a State-inspected establishment is found to be producing adulterated products for distribution within the State that would clearly endanger the public health, immediately inform the State MPI program officials of the need to control the adulterated products. Verify that the State officials have taken appropriate product control actions to protect public health and contact the DM.

CHAPTER IV—FEDERAL OVERSIGHT OF THE CIS PROGRAM, ESTABLISHMENT DESELECTION, AND TERMINATION OF A STATE'S PARTICIPATION IN THE CIS PROGRAM

I. FEDERAL OVERSIGHT OF THE CIS PROGRAM: SEC RESPONSIBILTITES

A. The SEC for a State that has entered into an agreement to participate in the CIS program is responsible for providing oversight of the State's participation. To provide the required oversight, the SEC is to visit each selected establishment in the State on a regular basis to verify that the establishment is operating in a manner that is consistent with the FMIA or PPIA and the implementing regulations in 9 CFR Part 300 to end (9 CFR 332.7(a) and 381.517(a)). To determine the frequency with which the SEC will visit each selected establishment in the District, the SEC, in consultation with the DM, is to consider the complexity of the establishment's operations, the establishment's schedule of operations, and the establishment's performance under the CIS program(9 CFR 332.7(a) and 381.517(a)).

NOTE: The SEC, in consultation with the DM for the State in which a selected establishment is located, may designate qualified FSIS personnel to visit the selected establishment on the behalf of the SEC.

- B. The SEC, in coordination with the State, is to conduct the following activities to verify that each selected establishment in the State is receiving the necessary inspection services from the designated State personnel, and that each establishment is eligible, and remains eligible, to participate in a CIS program (9 CFR 332.7(b) and 381.517(b)). The SEC is to:
 - 1. Verify that each selected establishment employs, and continues to employ, 25 or fewer employees, on average;
 - 2. Verify that the designated State personnel are providing inspection services to selected establishments in a manner that complies with the FMIA or PPIA and the regulations in 9 CFR part 300 to end. Verify that the designate State personnel:
 - a. Apply appropriate Federal inspection methodology;
 - b. Use effective decision making to determine whether there is non-compliance with Federal requirements;
 - c. Appropriately document his/her findings and, when necessary, initiate appropriate enforcement actions authorized under the FSIS Rules of Practice in 9 CFR part 500.

The SEC is to compare the designated State personnel's NRs, MOIs, weekly meeting notes, and enforcement records with the selected establishment's food safety systems and associated records. The SEC is to also compare documentation related to the establishment's performance with the conditions of the establishment's ground, facilities and equipment.

- 3. Verify that the State staffing levels for each of the selected establishments are appropriate to carry out the required inspection activities in the same manner as Federal inspection. The SEC is to compare the establishment's hours of operation to the inspection records to determine whether an establishment received the necessary inspection services whenever the Federal mark of inspection was applied under the CIS program. The SEC is to review the inspection tasks performed by the designated State personnel and the results of those tasks.
- 4. Assess each selected establishment's compliance with the FMIA or PPIA and the implementing regulations in 9 CFR part 300 to end.
 - a. Review the written sanitation SOP and a sample of daily records documenting the implementation of the sanitation SOP and any corrective actions taken.
 - b. Observe the condition of the selected establishment's grounds and facilities, equipment and utensils, employee hygiene, and sanitary operations to determine whether the establishment complies with sanitation performance standards in 9 CFR 416.1 through 416.6.
 - c. Observe the establishment employees perform their duties.
 - d. Review the establishment's HACCP system and associated records (e.g., hazard analyses, HACCP plans, prerequisite programs, critical control points (CCP), critical limits, monitoring and verification procedures and frequencies, corrective actions, and supporting documentation).
 - e. Review "other consumer protection" (OCP) processes that require regulatory oversight (e.g., labels, product formulations, use and control of restricted ingredients) and review the OCP-related NRs.
 - f. Review the establishment's compliance with all applicable Federal regulatory requirements (e.g., condemned product handling, humane handling, removal, segregation, and disposition of specified risk materials) and any NRs in regards to these requirements.
 - g. Submit product samples for analysis, if needed, to verify that the product produced by the selected establishment meets Federal food safety standards.
- 5. Initiate appropriate enforcement action if the SEC determines that an establishment is not operating in compliance with the FMIA or PPIA and the implementing regulations in 9 CFR part 300 to end. The SEC is authorized to initiate any appropriate enforcement action provided for in the FSIS Rules of Practice under 9 CFR part 500 if the SEC determines that a selected establishment is operating in a manner that is inconsistent with the Acts (9 CFR 332.9(b) and 381.519(b)).
- 6. Consult with the DM to determine the need to request that an FSIS Enforcement, Investigation, and Analysis Officer (EIAO) conduct an FSA or the need to request that an FSIS District Veterinary Medical Specialist (DVMS) assess humane handling and slaughter at the selected establishment.
- 7. Review the State MPI program's product sampling records to verify that the State is collecting and analyzing product samples in the same manner that FSIS does in its regulatory sampling programs. States are to collect product samples as specified in their regulatory sampling plans based on guidance provided by MD/OPHS and RAD/OPHS.
- 8. Verify that the State MPI program is scheduling and conducting FSAs in selected establishments in the same manner that FSIS schedules and conducts FSAs in official Federal establishments.

<u>C. Quarterly Reports</u>: The SEC is to prepare a report on a quarterly basis that describes the status of each selected establishment under the SEC's jurisdiction (9 CFR 332.8(a) and 381.518(a)). The SEC is to submit the quarterly report to the FSIS Administrator through the DM and Assistant Administrator (AA), OFO (9 CFR 332.8(c) and 381.518(c)). The SEC quarterly report is to include:

- An assessment of the performance of the designated State inspectors in conducting inspections
 activities. The report is to identify whether the activities of designated State inspectors accurately
 depict each selected establishment's level of compliance with the FMIA or PPIA and 9 CFR 300 to
 end:
- 2. A list of selected establishments that SEC has verified are in compliance with all Federal requirements; and
- 3. A list of selected establishments that have been deselected and those that are transitioning to become official Federal establishments.

<u>D. Oversight of Recalls under a CIS Program</u>: If a meat or poultry product produced by a selected establishment is the subject of a recall, the SEC that covers the State where the recalling establishment is located will serve as the District Recall Officer (DRO). The DRO is the official responsible for coordinating field recall activities and providing direction to inspection program personnel when there is a recall. If a selected establishment decides to recall a meat or poultry product produced under the CIS program, the SEC is to:

- 1. Coordinate with State officials to ensure that the appropriate designated State personnel for the selected establishment recalling the product are available to participate on the recall committee;
- 2. Provide recall worksheets, and if needed, guidance materials to the recalling establishment.
- 3. Direct the activities of FSIS personnel, such as the EIAO, to verify the information provided by the recalling firm;
- Coordinate with the Office of Public Affairs and Consumer Education(OPACE) to ensure that the recalling selected establishment has an opportunity to review the Recall Release or Recall Notification Report prior to issuance;
- 5. Coordinate with the DO and the State MPI officials to collect production distribution information and prepare the plan for conducting effectiveness checks and identify the personnel to conduct effectiveness checks;
- 6. Coordinate with the State MPI officials to conduct effectiveness checks within the State; and
- 7. Coordinate with DDMs and other FSIS personnel to conduct recall effectiveness checks in the other States where the recalled product was distributed.

E. Oversight of Exports under a CIS Program: If a selected establishment exports meat or poultry products to foreign countries, the SEC is to verify that designated State personnel are following the procedures for export certification that are set out in FSIS Directive 9000.1.

II. DESELECTION OF ESTABLISHMENTS FROM THE CIS PROGRAM: SEC AND DM RESPONSIBILITIES

A. Selected establishments that become ineligible to participate in the CIS program for any reason, e.g., they are no longer in compliance with the Federal acts, they employ more than 25 employees on average, or they employed more than 25 but fewer than 35 employees on average as of June 18, 2008, but failed to reduce their average number of employees to 25 by July 1, 2014, will be deselected from the CIS program

(9 CFR 332.10(a) and 381.520(a)). An establishment that has been deselected from a CIS program must transition to become an official Federal establishment (9 CFR 332.10(b) and 381.520(b)).

B. Deselection for Violating the Acts

- 1. If inspection at a selected establishment is suspended for any of the reasons specified in 9 CFR 500.3 or 500.4, the SEC, in consultation with the DM is to provide an opportunity for the establishment to implement corrective actions and remain in the CIS program or move to deselect the establishment (9 CFR 332.9(c) and 318.519(c)). In making this determination, the SEC and DM are to consider:
 - a. The noncompliance that led to the suspension;
 - b. The selected establishment's compliance history;
 - c. Whether the establishment's proposed corrective actions will adequately address all the deficiencies and will resolve the deficiencies if properly implemented; and
 - d. Whether the selected establishment's proposed corrective actions will ensure the safety of all affected meat and poultry products.
- 2. If an establishment is deselected for violating the Acts, the SEC, in consultation with the DM, is to notify orally both the establishment and the State MPI program officials. The SEC is to follow-up the oral notification with a written notification. The written notification is to clearly state the violations that led to the deselection and explain that the establishment will need to develop and implement a corrective action plan to address all violations to transition to become an official Federal establishment.
- 3. The SEC, in consultation with the DM, is to develop and implement a plan to coordinate with the State to transition the deselected establishment to become an official Federal establishment.
- C. Deselection for employing more than 25 employees on average
 - 1. If the SEC determines that a selected establishment employs more than 25 employees on average, based on the standards in 9 CFR 332.3 or 381.513, the SEC is to notify the DM.
 - 2. The SEC, in consultation with the DM, is to provide written notification to the establishment and State MPI program officials that the establishment is being deselected from the CIS program because it has employed more than 25 employees on average.
 - 3. The SEC in consultation with the DM is to develop and implement a plan to coordinate with the State MPI program to transition the deselected establishment to become an official Federal establishment.

III. TERMINATION OF A STATE'S AGREEMENT TO PARTICIPATE IN THE CIS PROGRAM- SEC AND DM RESPONSIBILITIES

A. FSIS will terminate a State's CIS program agreement if the State fails to conduct inspection services at selected establishments in a manner that complies with the FMIA or PPIA and the implementing regulations (9 CFR 321.3(d) and 381.187(d)).

B. SEC Role in Termination of a CIS program

1. If the SEC, in consultation with the DM, determines that State personnel are not providing inspection services in the same manner that Federal inspection personnel do, the SEC is to orally notify the State MPI program officials and follow-up the oral notification with a written notification.

The written notification is to clearly specify the deficiencies and specify a date by which the State MPI program is to submit a corrective action plan.

- 2. The SEC, in consultation with the DM, is to review the State MPI program's corrective action plan to determine whether it:
 - a. Includes corrective actions that will adequately address all the deficiencies identified by the SEC if properly implemented;
 - b. Ensures that meat and poultry products being produced by selected establishments in the State are safe, wholesome, and not adulterated or misbranded;
 - c. Includes a timeline for implementation; and
 - d. Includes a plan to verify effective resolution of all identified deficiencies.
- 3. The SEC is to verify that the State has effectively implemented the corrective action plan within the timeframe identified in the plan.
- 4. If the State MPI program's written corrective action plan is inadequate, or if the State MPI program fails to develop or effectively implement the corrective action plan, the SEC and the DM are to notify the OFO EARO for the CIS program and recommend that the State's CIS program be terminated. If the OFO EARO and OFO AA agree with the recommendation, they are to inform the Administrator.
- 5. If FSIS decides to terminate a State MPI program's agreement for the CIS program, the SEC is to identify which selected establishments in the State plan to transition to become official Federal establishments and which selected establishments plan to operate under the State's "at least equal to" intrastate MPI program. The SEC is to inform the DM.

C. DM Role in Termination of a CIS program

- 1. If FSIS decides to terminate a State's agreement for a CIS program, the DM is to orally notify the State MPI program officials and follow-up with a written Notice of Program Termination. The Notice of Termination is to:
 - a. Describe the reasons for terminating the State's cooperative agreement for a CIS program;
 - b. Identify the effective date of the termination;
 - c. Identify the selected establishments that will transition to become official Federal establishments and those that will revert back to the State MPI program; and
 - d. Inform State MPI program officials that they may appeal the decision to the OFO EARO for the CIS program and inform them that if they do not appeal within 30 days from the date of the Notice of Termination, the decision will be final.
- 2. When a State's agreement for a CIS program is terminated, the DM, in consultation with the SEC, is to develop a plan to transition selected establishments that choose to continue to ship products interstate to become official Federal establishments and to transition establishments that choose to revert back to the State MPI program, and become eligible to ship products intrastate only, to that program.
- 3. The DM is to notify the FSIS programs listed in Chapter V of the State's Notice of Termination from the CIS program.

CHAPTER V--ESTABLISHING THE CIS PROGRAM AND THE ROLES OF OTHER FSIS PROGRAMS

I. Office of Policy and Program Development (OPPD), Labeling and Program Delivery Division (LPDD)

A. LPDD is to evaluate the labels of meat and poultry products that will be produced in selected establishments participating in the CIS program if such labels are not generically approved. LPDD is to verify that the labels of these products meet all Federal standards.

NOTE: Labels may be generically approved in accordance with 9 CFR 317.5 and 381.133. Such labels do not need to be submitted to LPDD for approval but will need to be included in the establishment's labeling records as provided in 9 CFR 320.1(b)(11) and 381.175(b)(6). The link below provides instructions on establishments' responsibilities with respect to generic labeling records.

Establishment Responsibilities Regarding Generic Labeling

- B. LPDD will provide clarification and assistance in answering questions concerning the Federal requirements for labels.
- C. If LPDD determines that the labels from a selected establishment comply with all Federal requirements and are truthful and not misleading, it will approve the labels and inform the DO that covers the State where the establishment is located. After LPDD approves the labels, the establishment may apply the labels to products produced under the CIS program. LPDD is to retain a copy for a label file for each selected establishment.
- D. LPDD is to inform the DO that covers the State where a selected establishment is located if LPPD cannot approve a label from the establishment because the label does not comply with Federal standards.

II. Office of Chief Information Officer (OCIO), OCIO State Coordinator

- A. The OCIO State Coordinator is to establish an annual supplemental cooperative agreement between the State MPI program and FSIS OCIO for the CIS program for the purchase of computers and for the use of FSIS software.
- B. The OCIO State Coordinator for the CIS program agreement is also to:
 - 1. Coordinate the purchase of desktop/notebook computers, peripherals, and software for the selected establishments in CIS program.
 - 2. Provide technical support and CD/DVD training on the FSIS provided software for State MPI inspection personnel and maintenance services for the computer hardware and peripherals.
 - 3. Provide long-distance telecommunication services for the purpose of accessing the FSIS provided electronic mail system.
 - 4. Provide technical assistance in connecting to FSIS Website, online access to the FSIS Directives, Notices and forms, askFSIS, and the foreign country export library requirements.

III. Office of Outreach, Employee Education and Training (OOEET)

OOEET is to:

1. Establish and, as appropriate, renew the cooperative agreement between the State MPI program and FSIS for the operation of the CIS program.

- 2. Provide for the timely announcement of FSIS inspection program training sessions and the enrollment of designated State MPI inspectors into those sessions.
- 3. Provide outreach and updates to State CIS program officials on how to obtain student training materials on the FSIS Website.
- 4. Provide assistance to CIS program personnel on how to complete and document trainings through the USDA AgLearn system.
- 5. Provide outreach and assistance directly to select establishments in complying with Federal rules and regulations as appropriate.
- 6. Provide liaison and coordination as needed between CIS programs and other FSIS and USDA offices.

IV. Office of Public Health Science (OPHS)

- A. OPHS/Laboratory Quality Assurance Division: The OPHS/LQAD is to:
 - 1. Provide guidance and answer questions from State or State-contracted laboratories that are actively seeking ISO 17025 accreditation.

NOTE: States or laboratories should use the following e-mail address to submit questions or requests for guidance to LQAD: FSIS_InterstateShipmentProgramLabInquiries@fsis.usda.gov

- Work with the CIS Program Coordinator to verify that State or State-contracted laboratories that do not have, but that are actively seeking, the required ISO 17025 accreditation can demonstrate that they meet the criteria in the FSIS laboratory QA checklist until they obtain the ISO 17025 accreditation.
- Review justifications submitted by laboratories that are unable to follow an FSIS method as written
 to determine whether the modified method is capable of achieving results that are consistent with
 the corresponding FSIS method.
- 4. Conduct initial and periodic laboratory audits or record reviews of performance of methods and critical QA/QC activities in accordance with the LQAD SOPs.
- B. <u>OPHS/Microbiology Division (MD)</u>: When contacted by a State, the OPHS/MD is to assist the States in developing a microbiological sampling plan for the establishments that the State will be inspecting under the CIS program. The OPHS/MD is to work with the CIS Program Coordinator to verify that the State's sampling plan provides for the State to collect and analyze the same number and type of samples that FSIS collects under the Federal regulatory sampling program.
- C. <u>OPHS/Risk Assessment Division (RAD)</u>: When contacted by a State, the OPHS/ RAD is to assist the States in developing a residue sampling plan for the establishments that the State will be inspecting under the CIS program. The OPHS/RAD is to work with the CIS Program Coordinator to verify that the State's sampling plan provides for the State to collect and analyze the same number and type of samples that FSIS collects under the Federal regulatory sampling program

V. Office of International Affairs(OIA), Export Programs Staff (EPS)

The OIA/EPS is to:

1. Provide technical guidance concerning foreign country export requirements posted in the Export Library, export certificates, and other required export documentation;

- 2. Coordinate the resolution of export policy issues with OPPD, International Policy Division; and
- 3. Provide liaison and coordination among FSIS, State MPI program officials, and foreign officials during onsite audits.

VI. DATA ANALYSIS

The Office of Policy and Program Development (OPPD) and the Office of Field Operations (OFO), with support from the Data Analysis and Integration Group (DAIG) within the Office of Data Integration and Food Protection (ODIFP), will review the SEC's quarterly reports and any other available data collected under the CIS program as they become available. OPPD and OFO will analyze these data to identify any potential issues and trends associated with selected and deselected establishments. If necessary, OPPD and OFO will make adjustments to the CIS program based on results of the analyses.

Acting Assistant Administrator

Office of Policy and Program Development

Critical Components for a CIS PHIS Program

Summary: States that participate in the CIS program need to implement a targeted public health-based, data-driven approach to inspection of selected establishments in the State. The goal is to have an integrated infrastructure to support a comprehensive and reliable data-driven inspection system that is able to identify and respond to events of public health concern in a manner that is timely enough to reduce the associated risks and to recognize and prevent recurrence of non-compliance. The State system needs to generate data that will be integrated into the FSIS data system. The data need to be in a format that FSIS can use to inform the Federal inspection system and to present a more comprehensive picture of national food safety protection efforts. States that use computerized systems need to obtain the necessary IT security certification.

Major Components of PHIS

1) <u>Establishment profile</u>: The State's system needs to maintain critical up-to-date information about each selected establishment's size, products produced, production volume, recall history, food defense practices, and plant demographic and geographic data. It also needs to include HACCP information for the establishment, including summary information, processing categories, food safety hazards, critical control points, and prerequisite programs. States need to conduct ongoing review of establishment profile information to ensure that the data remains current.

2) Scheduling and Recording Inspection Procedures and Outcomes

Scheduling: The State's system needs to use public health decision criteria to focus inspection resources on products and establishments that pose the greatest risk to public health, while maintaining a minimum standard of one visit per shift at all establishments to ensure safety and wholesomeness of all meat and poultry products. ¹ The basis for selection of decision criteria is that they identify establishments that 1) have produced product that tested positive for pathogens known to cause human illness and 2) are not in compliance with specific Federal laws and regulations.

Recording: The State's recordkeeping system needs to capture the results of inspection activities, including data on specific regulatory requirements verified, findings communicated to establishment management through memoranda of interview, and detailed findings of noncompliance. Data from NRs need to be captured in a format that uses standardized fields to capture the noncompliance finding to allow more effective data analysis. Inspectors need to have the ability to record what point within food safety system they inspected, what regulations they verified and whether they found the establishment to be compliant or non-compliant.

3) Scheduling and Recording Outcomes of Food Safety Assessments

Scheduling: The State's system needs to use public health decision criteria to determine when to schedule for cause and routine FSAs and Hazard Analysis Verifications (HAVs).

Recording: Data from FSAs need to be captured in a format that uses standardized fields to facilitate analysis and decision making.

4) <u>Scheduling and Recording Information on Laboratory Samples</u>

Scheduling: The State's system needs to use up-to-date information available from the establishment profile to determine the appropriate sampling frames. The system needs to provide for sample

¹ FSIS Directive 13,000, "Scheduling In-Plant Inspection Tasks in the Public Health Information system (PHIS)" sets out the frequencies and priorities of inspection tasks.

tracking and flexible sampling. The system needs to be designed to give inspectors the flexibility to schedule samples on the days when the product is being produced, and when the laboratory has the capacity to analyze the samples.

Recording: The State's system needs to capture reasons that a sample was not collected. The system also needs to ensure that the results of the laboratory analyses are reported in a manner that allows the State to respond to positive pathogen findings in an appropriate and timely manner.

5) Tracking Suppliers of Source Materials for Products that Test Positive for adulterants (e.g., *E. coli* O157:H7): The State's system needs to identify slaughter establishments that have supplied raw beef components to an establishment with a positive laboratory test for adulterants in beef. The system needs to ensure that information on suppliers is reported in a manner that allows the State to identify repeat offenders and take appropriate actions in a timely manner. ²

NOTE: PHIS will eventually be used for export certification. FSIS will develop criteria for export certification in the CIS program if there are selected establishments interested in exporting products.

21

^{2.} Until this feature is fully functional in PHIS, FSIS will continue to use the STEPS system for this purpose. The function in both of these systems is reflected in this paragraph.

Cooperative Interstate Shipment Program Basic Training Courses Requirements by Occupation

Food Inspectors

- Food Inspector course (Livestock or Poultry, depending on their assignment)
- Humane Handling, if assigned to and performing duties at an establishment that slaughters livestock

Consumer Safety Inspectors

- Food Safety Regulatory Essentials (FSRE) for raw products if assigned to establishment producing raw products (03J, 03B, 03C, 03H)
 - FSRE for raw products Sanitation
 - o FSRE for raw products HACCP
- FSRE for Ready To Eat/Not Shelf Stable products if assigned to an establishment producing ready-to-eat products (03G, 03I)
- FSIS Industry Practices for Producing Shelf Stable Products Offered in Aglearn
- Humane Handling, if assigned to and performing duties at an establishment that slaughters livestock
- FSIS-6005 Export Verification if assigned to an establishment eligible to export products to foreign countries. (Offered through Aglearn)
- Basic Supervisor Training for Frontline Supervisors

Public Health Veterinarians

- Public Health Veterinarian Training Program
- FSRE for raw products
 - FSRE for raw products Sanitation
 - FSRE for raw products HACCP
- FSRE for Ready To Eat/Not Shelf Stable products if assigned to an establishment producing ready-to-eat products (03G,03I)
- FSIS Industry Practices for Producing Shelf Stable Products Offered in Aglearn
- Humane Handling, if assigned to and performing duties at an establishment that slaughters livestock
- FSIS-6005 Export Verification if assigned to an establishment eligible to export products to foreign countries. (Offered through Aglearn)
- Basic Supervisor Training

Enforcement, Investigations, and Analysis Officer

- 4 week Enforcement, Investigations, and Analysis Officer (EIAO) Methodology Training
- FSRE for Raw and Ready To Eat/Not Shelf Stable products is a prerequisite to the four week EIAO course

Compliance Investigator

Surveillance, Investigations, and Enforcement Methods (SIEM) Training

In addition to these minimum requirements, the State is responsible for working in consultation with FSIS to develop a prioritized list of training courses for State inspectors to complete on an ongoing basis. The FSIS, Office of Outreach Employee Education and Training (OOEET) will coordinate with the States to provide the necessary training for designated State personnel.

1. District/Circuit Code		2. Est	2. Establishment Number 3.		Date of Survey	
4. Establishment Name			5. Establishment Address			
6. Establishment Telephone Num	ber					
Categories	Comply	Does not comply	Categories	Comply	Does not comply	
I. Required Documents			IV. Safety			
Written Sanitation SOP			Lock-out/Tag-out			
Written HACCP plan			Adequate exits			
Water potability certification			Hazards			
Sewage certification						
Other certification (e.g., inedible)			V. Facilities & Equipment			
BSE-SRM 310.22 (if applicable)			Welfare facilities			
II. Marks of Inspection			Outside premises (includes pest and rodent control)			
Labels			Ante-mortem			
Brands			Facilities & lighting			
Security for accountable items			Suspect pan facilities/lighting			
			Animal humane facilities & DVM verification	S		
III. Building Construction			Post-mortem			
Buildings, structures, & rooms			Facilities & equipment			
Walls			Lighting			
Floors			Retained product facilities			
Ceilings			Condemned/Inedible facilities			
Doors			Processing			
Ventilation in production areas			Facilities & equipment			
Ventilation in welfare facilities			Retained product facilities			
Separation of official selected establishment operations and non-official selected establishment operations			Condemned/Inedible facilities			
Facilities for Program Employees				Yes	No	
Plumbing			Establishment employs fewer than a employees on average under 9 CFR 332.3(b) or 381.513(b)			
Water supply & distribution			Dual Operations Establishment (produces product under CIS progra and State MPI program)	m		
Drains			Conditional Grant for CIS program	3		

⁻

 $^{^{\}rm 3}$ In accordance with 9 CFR 304.3(b) and 9 CFR 381.22(b)