"AT LEAST EQUAL TO" GUIDELINE FOR STATE MEAT AND POULTRY INSPECTION PROGRAMS

November 2016



United States Department of Agriculture

Food Safety and Inspection Service

State-Federal Cooperation



What if I still have questions after I read this guideline?

If the desired information cannot be found within the Guideline, FSIS recommends users search the publicly posted Questions & Answers (Q&As) in the <u>AskFSIS</u> database or submit questions through <u>AskFSIS</u>. Documenting these questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Compliance Guideline for State Meat and Poultry Inspection Programs.

Question Field: Enter question with as much detail as possible.

Product Field: Select General Inspection Policy from the drop-down menu.

Category Field: Select Cooperative State Inspection Programs from the drop-down menu.

Policy Arena: Select Domestic (U.S.) Only from the drop-down menu. When all fields are complete, press Continue and at the next screen press Finish Submitting Question.

NOTE: Refer to <u>FSIS Directive 5620.1</u>, *Using AskFSIS*, for additional information on submitting questions.

"AT LEAST EQUAL TO" GUIDELINE FOR STATE MEAT AND POULTRY INSPECTION PROGRAMS

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KEY DEFINITION AND STATE MPI PROGRAM REQUIREMENT

"At Least Equal To"

The "at least equal to" standard requires State MPI programs operate in a manner that is not less effective than those standards adopted for the Federal inspection program.

The standard does not require the States operate their MPI programs in a manner that is the same as or identical to FSIS's inspection program, nor does it prohibit the State MPI programs from establishing safeguards they believe to be more effective than those employed by FSIS.

SIGNIFICANT CHANGES

This guideline replaces the previous version, issued July 2008. FSIS updated the guideline to consolidate components, add new components and resource information, and to revise tables. The most notable changes are as follows:

The date for the States' annual self-assessment submission has changed from November 15th to November 1st of each year.

Component 1 - Statutory Authority and Food Safety Regulations has a new table titled "Statutory Side-by-Side Comparison Table"

Component 2 - Inspection includes:

- Former Component 6 Non-Food Safety Consumer
 Protection is added in its entirety;
- The Quarterly New Issuance Review process is a new section added to this component; and
- The guideline titled, "At least equal to data system requirements for State
 Cooperative Meat and Poultry Inspection (MPI) programs electing not to use FSIS's Public Health Information
 System (PHIS)" published in January 2015 is added at the end of Component 2.

Component 3 – Sampling Programs (formerly known as "Product Sampling") has been retitled.

I. PURPOSE

This guideline provides information to State Cooperative Inspection programs on the criteria that the Food Safety and Inspection Service (FSIS) uses to determine each year whether State Meat and Poultry Inspection (MPI) programs are operating verifiably in accordance with requirements that are "at least equal to" the Federal inspection requirements. The guideline contains information that State MPI programs need to establish and maintain such programs.

II. BACKGROUND

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 661) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 454) authorize FSIS to cooperate with State agencies in developing and administering their own Meat and Poultry Inspection (MPI) programs. Individual State MPI programs are required to operate under authorities that are "at least equal to" the provisions for ante-mortem and post-mortem inspection, reinspection, sanitation, recordkeeping, and enforcement in the FMIA and PPIA and implementing regulations. State MPI programs are also expected to ensure livestock are treated humanely by assuring the methods of handling livestock are "at least equal to" those outlined in the Humane Methods of Slaughter Act of 1978 (HMSA)(7 U.S.C. 1901-906).

The FMIA (21 U.S.C. 661(b)) and the PPIA (21 U.S.C. 454 (b)) authorize FSIS to cooperate with a single State agency and subordinate governmental unit primarily responsible for the coordination of a State MPI program. In matters concerning the State MPI program, FSIS will communicate and coordinate with designated State employees assigned to the single State agency identified by the State as responsible for ensuring that all applicable inspection and compliance activities outlined in these guidelines comply with specified laws, regulations and policies. The activities include those conducted by State or contract laboratories, public health departments, law enforcement agencies, State human resource departments, budget departments and other State regulatory agencies.

Component 6 – Compliance (formerly known as "Component 7 – Compliance") has been retitled and includes a new table titled "Summary of Statutory Authority per Business Type."

Component 7 – Laboratory Methods and Quality Assurance Program is a new component for laboratory methods and quality assurance criteria. This information was previously published in June 2014 as a separate guideline titled "At Least Equal To Compliance Guideline for State Meat and Poultry Inspection (MPI) Programs for Laboratory Methods" and has been updated and added as a component.

The following Tables have been updated to better reflect the information needed by FSIS in the evaluation of State MPI program operations:

Component 3 – State MPI Program Sampling Activity Table.

Component 4 – State MPI Program Establishment Count and the State MPI Program Employee Primary Roles.

Component 6 – Compliance Activity Report.

Additional Resources is a new section added at the end of the guideline to provide State MPI program Directors with reference material that may be needed to perform business processes related to budget submissions, training and Federal resource information, cooperation between State and Federal Compliance programs, and information on internal controls. The section also includes a Reference Table of Related FSIS Policy Documents, which is a reference guide to FSIS policy documents relevant to the implementation of the nine program components.

III. ANNUAL SELF-ASSESSMENT

FSIS expects the State MPI programs to submit their annual self-assessment documents to FSIS's Federal-State Audit Branch (FSAB) on or before November 1st of each year. Each State MPI program should start its annual self-assessment with a review of the prior-year selfassessment. Each component of the annual selfassessment should include a written narrative statement and documentation demonstrating the program continuously meets the criteria to be "at least equal to" the Federal program. The self-assessment should identify any program changes in the previous 12 months and include documentation which will support the State's ability to maintain its program for the next 12 months. State MPI programs should also submit sufficient documentation to demonstrate the State MPI program has stayed current with FSIS statutes, regulations, applicable FSIS Directives and Notices, and has implemented any changes necessary to maintain its "at least equal to" status.

The annual self-assessment submission should also include one or more narratives describing internal controls used by the State MPI program that:

- Provide assurances that internal controls can measure the effectiveness of the program under the "at least equal to" criteria:
- Demonstrate how nonconformances will be addressed by corrective actions; and
- Demonstrate how the State MPI program will be maintained throughout the next 12 months.

These internal controls should provide an objective assessment of the State MPI program's operations and processes to determine whether:

- Financial and operating information is accurate and reliable;
- Operational risks are appropriately identified and managed;
- Applicable regulations and internal policies and procedures are followed; and
 - The "at least equal to" standard is maintained.

Ultimately, State MPI programs need to operate in a manner that protects the health and welfare of consumers within their State by ensuring the meat and poultry products distributed by the program establishments are wholesome, not adulterated, and properly marked, labeled, and packaged.

More specifically, the annual self-assessment should also address each of the following nine program components so as to demonstrate the State's MPI program is administered in a manner that is "at least equal to" the Federal inspection requirements and describe how it will maintain this status for the following 12 months. FSIS Directive 5720.3, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs, provides the FSIS review methodology and criteria for each component.

The Nine Program Components

Component 1

Statutory Authority and Food Safety Regulations

Component 2

Inspection

Component 3

Sampling Programs

Component 4

Staffing, Training, and Supervision

Component 5

Humane Handling

Component 6

Compliance

Component 7

Laboratory
Methods and
Quality Assurance
Program

Component 8

Civil Rights

Component 9

Financial Accountability

For each of the first six (1-6) components, State MPI programs need to submit self-assessment documentation demonstrating the State MPI program is meeting the "at least equal to" Federal inspection requirements. Such documentation should include the attached *Annual Certification* – "At Least Equal To" Meat and Poultry Inspection Program (Attachment 1, page 10) and a narrative describing any changes made in the State MPI program during the previous 12 months.

For Component 2, State MPI programs that have elected not to use the FSIS Public Health Information System (PHIS), should refer to guidance information (Attachment 3,

page 38) titled, "At least equal to" data system guidance for State Cooperative Meat and Poultry Inspection (MPI) programs electing not to use Public Health Information System (PHIS) can be found at the end of Component 2. State MPI program Directors are to submit the requested data system information with the annual self-assessment submission to FSAB for review.

For Component 7, State MPI programs need to submit the following self-assessment documentation to FSIS, Office of Public Health Science (OPHS):

- A list of current State laboratory and/or contract laboratory test methods and copies of new or revised methods accompanied by a Laboratory Method Notification Form; and
- A completed <u>FSIS Form 5720-14</u>, <u>FSIS MPI Program Laboratory Quality</u>
 <u>Management System Checklist</u> or use another easy to read format for each
 State or contract laboratory performing MPI-related analyses or their current ISO
 17025 certificates of accreditation for each State and/or contract laboratory
 performing MPI-related analyses

For Component 8, the State MPI programs are to complete and submit <u>FSIS Form</u> <u>1520-1</u>, <u>Civil Rights Compliance of State-Inspection Programs</u>, or use another easy to read format to the FSIS Civil Rights Staff.

Relative to Component 9, the State MPI programs should submit specified financial reports as requested throughout the fiscal year. Although deadlines for submitting certain financial reports may coincide with FSIS's self-assessment submission deadline of November 1. Financial Reviews and Analysis Section (FRAS) does not require the inclusion of these financial reports as part of the annual self-assessment submission for Component 9. Component 9 includes a list of supporting documentation the State agencies should have readily available for FSIS reviewers, upon request, prior to or during the on-site financial review.

State MPI program Directors should submit the self-assessment for the various program components and any required or requested documents as follows:

Components 1-6

Email: StateMPIProgramSubmissions@fsis.usda.gov

USDA, FSIS, OIEA, MCAD, FSAB Chief Edward Zorinsky Federal Building 1616 Capital Avenue, Suite 260 Omaha, NE 68102-5908 Telephone: 402-344-5018

Fax: 402-344-5104

Component 7

Email: <u>Statelabinquiry@fsis.usda.gov</u>

Director, USDA, FSIS, OPHS, Laboratory Quality Assurance Staff

950 College Station Road

Athens, GA 30605

Telephone: 706-546-3559

Component 8

FSIS Civil Rights Staff 5601 Sunnyside Avenue, Mail Drop 5261 Beltsville, MD 20705-5261 Telephone: 800-269-6912

Fax: 301-504-2141

Component 9

Email: FRAS@fsis.usda.gov

Financial Reviews and Analysis Section USDA/FSIS/OA/OCFO/FMD/FASMB 5601 Sunnyside Avenue, Mail Drop 5264 Beltsville, MD 20705-5264

Telephone: 301-344-0479

Fax: 301-504-5914

Annual Certification "At Least Equal To" Meat and Poultry Inspection Program

I have reviewed the attached self-assessment submission of the [insert name of State] State-Federal Cooperative Inspection program. Based on current information, I certify that the State Meat and Poultry Inspection (MPI) program is "at least equal to" the requirements specified in the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Humane Methods of Slaughter Act (HMSA) and current FSIS regulations, directives, notices and policies. The State MPI program officials intend to maintain the program as "at least equal to" the applicable requirements specified in the FMIA, PPIA and HMSA, and certify that the program is able to stay current with applicable FSIS regulations, directives, notices and policies to ensure an "at least equal to" status. If conditions change that impact this certification, I will immediately notify the Chief of the Federal-State Audit Branch.

USDA, FSIS, OIEA, MCAD, FSAB Chief Edward Zorinsky Federal Building 1616 Capital Avenue, Suite 260 Omaha, NE 68102-5908 Telephone: 402-344-5018

Fax: 402-344-5104

Name of Responsible State Official		
Title of Responsible State Official		
Signature of Responsible State Official		
Date		
State		
Contact Telephone Number		
Contact E-Mail		
Contact Fax Number		

IV. ON-SITE REVIEW

In addition to the annual self-assessment submission, State MPI programs are subject to an on-site review at a minimum frequency of once every three years to verify the accuracy and implementation of the self-assessment submissions. In the year that a State MPI program is scheduled for an on-site review, FSIS's annual determination of

whether the program is "at least equal to" the Federal inspection program will be based on a review of the annual self-assessment submission and the on-site review. Please refer to FSIS <u>Directive 5720.3</u>, <u>Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs</u>, for the <u>FSIS Review Methodology</u>.

The purpose of the on-site review is for FSIS to verify the State MPI program implements and maintains its inspection system in

accordance with its annually submitted self-assessment, and to determine whether the State MPI program is "at least equal to" the Federal inspection program in its administration and enforcement of requirements. The FSIS review team will review the State MPI program's current annual self-assessment submission in advance so that they are able to begin the on-site review of the State MPI program with a thorough understanding of the State program's current self-assessment submission. FSIS will review a selected number of establishments within the State MPI program and examine and evaluate documentation at the central office to verify the State MPI program's implementation, oversight, and management controls.

In October of each year, FSIS will announce the State MPI programs scheduled for an on-site review in the upcoming federal fiscal year. FSIS will send a written notification to State MPI programs at least 30 days before the start of the on-site review process. The on-site review will begin with a teleconference serving as the entrance meeting between FSIS and State MPI program officials. To facilitate FSIS's selection of establishments to review, State MPI program officials are to supply information from the last 12 months (12 months prior to review) to FSIS within 10 business days after the conclusion of the entrance meeting. The information is to include the following:

- A current list of establishments and their operating schedules (please omit ID warehouses and establishments which slaughter or process only non-amenable species), supervisory boundaries, program updates, and HACCP process categories for all establishments with the 5 highest producers for each category identified.
- Positive Shiga toxin-producing E. coli (STEC) results
- Positive Listeria monocytogenes (Lm) or Salmonella results in RTE products
- Failures of Salmonella and Campylobacter Performance Standards for raw products
- Enforcement actions taken
- Recalls conducted and associated documentation.

- Establishments that sustained structural damage in production areas due to natural disasters
- Establishments that the State MPI program reviewed, e.g., FSAs, supervisory reviews, internal reviews, management control audits

At least one week before the scheduled on-site review, FSIS will notify the State MPI program of the establishments chosen for the on-site review. Should the State MPI program officials ask FSIS to omit a chosen State establishment from its review, they will need to provide written justification for their request (e.g., the establishment is closed the day of the review, the establishment is a seasonal operator). FSIS travels to the chosen State establishment and follows the on-site review protocol. If a chosen State establishment decides not to operate after the on-site review process begins, FSIS selects an alternate State establishment to visit. An electronic draft report of individual establishment findings will be provided to the State MPI program officials by the next business day. At the end of each establishment review, after a short correlation with FSIS, the State MPI program personnel will lead an exit meeting with State establishment management.

Within 10 working days of completing the on-site review, FSAB will schedule a teleconference exit meeting with State MPI program officials. Before the teleconference exit meeting, FSAB will provide a summary report of all findings to the State MPI program officials.

The types of findings detailed in the aforementioned FSAB summary report that requires corrective actions will include:

- Processes that are not operating or functioning in the manner intended as detailed in the State's annual self-assessment or that are not included in the self-assessment submission;
- Processes that are ineffective; and
- Regulatory noncompliances.

The State MPI program has 10 working days after the teleconference to present an action plan designed to address all findings that require corrective actions. The State MPI program is to identify any underlying causes for findings that require corrective actions. Corrective actions may include the implementation of preventive measures e.g., targeted staff training, increased supervisory oversight, where applicable. If the State MPI program is unable to identify underlying causes for certain findings they are to share and explain the method they used in their attempts to identify the underlying causes and the results of the associated evaluation conducted to draw the conclusion. They are to also justify why they believe the corrective actions identified in the action plan for such findings are adequate. After receiving documentation demonstrating implementation of the action plan, FSAB will assess the plan and determine if actions taken are sufficient. If the action plan is adequate FSAB will issue a determination

memorandum and *Interim Annual Comprehensive Review and Determination Repor*t to the State MPI program Director.

FSIS may request clarification of specific items regarding the State MPI program's implementation of its action plan, and in certain cases, may perform a targeted on-site review before the issuance of a determination memorandum. A targeted on-site review conducted prior to the issuance of a determination memorandum is an in-depth evaluation of the State MPI program's implementation of its action plan. FSIS uses the targeted review to verify resolution of any public health concerns and compliance with the "at least equal to" criteria.

The Annual Comprehensive Review and Determination Report will summarize the results of the State's self-assessment submission and on-site review of the State MPI program (including the results of the targeted on-site review, if applicable). The report will include the FSIS review team's final "at least equal to" determination supported by individual component determinations.

V. DETERMINATION PROCESS

FSIS makes a determination after evaluating the State's annual self-assessment and the results of the on-site review, as applicable. The definitions for the three FSIS determinations on the status of the State MPI program are:

- "At Least Equal To"—The State MPI program has adopted laws, regulations, and programs, and implements them in a manner that is "at least equal to" FSIS's Federal inspection program for all review components.
- 2. "At Least Equal To," with Provisions—FSIS makes a provisional determination of the State MPI program's "at least equal to," status provided the program takes additional action to resolve review findings.
- 3. Not "At Least Equal To"—The State MPI program has not adopted laws, regulations, or programs, or does not implement them in a manner that is "at least equal to" FSIS's Federal inspection program for one or more of the review components.

At the conclusion of each annual self-assessment review, FSIS decides whether the State MPI program is or is not meeting the "at least equal to" requirements. If the State MPI program is not scheduled for an on-site review during the current fiscal year, FSIS makes an annual determination based only on the results of the self-assessment review. If the State MPI program is scheduled for an on-site review during the current fiscal year, FSIS bases the annual determination on the results of the self-assessment and the on-site review. If the determination of the self-assessment, or self-assessment and the on-site review, if applicable, is that the State program meets the "at least equal to" standard, FSIS promptly gives the State program officials written notification of that

fact. If additional clarification is needed for a determination, FSIS requests supplemental information from the State MPI program and issues an *Interim Annual Comprehensive Review and Determination Report*.

When an analysis of all findings, clarifications, and corrective actions from the self-assessment or on-site review indicates a State MPI program cannot support an "at least equal to" determination, FSIS recommends to the Secretary of Agriculture that the State be designated for Federal inspection. If a State cannot immediately implement an action plan but is committed to making the corrections and has the resources to support the changes, FSIS defers designation instead of making a final determination that the State program is not "at least equal to" FSIS's Federal inspection program.

Before the Secretary initiates the Federal designation process that results in State establishments being subject to the Federal inspection program, FSIS and the State agency confer on the State MPI program's deficiencies. If the State MPI program is unable to meet the "at least equal to" requirements or if its responsible officials are unwilling to do so, the Secretary of Agriculture notifies the Governor of the State that the State does not have an "at least equal to" MPI program and is not in compliance with the cooperative agreement between FSIS and the State, and is subject to the Federal designation of its MPI program.

If deficiencies are not resolved, the Secretary will designate the State MPI program for Federal meat and poultry inspection and publish a notice of the designation in the Federal Register. Upon the expiration of thirty days after the publication of the Federal Register notice the State-inspected establishments will become subject to Federal inspection.

VI. APPEAL PROCESS

State officials have the right to appeal any program status determination made by FSIS. The appeal process follows the Office of Investigation, Enforcement and Audit's (OIEA) chain of command. The chain of command ensures that Agency employees most familiar with the facts of the appeal will perform the initial evaluation of the appeal. The Appeal process gives State officials the right to appeal to the next highest level if not satisfied with the outcome. The OIEA chain of command is:

- 1) FSIS employee who made the finding (e.g., FSAB Program Auditor);
- 2) FSAB Team Lead;
- FSAB Chief;
- 4) Management Controls and Audit Division (MCAD) Director;
- 5) OIEA Deputy Assistant Administrator;

¹ Directive 5710.1, Designation of States for Federal Meat or Poultry Inspection, outlines the procedures for designation of States for Federal meat or poultry inspection.

- 6) OIEA Assistant Administrator; and
- 7) FSIS Administrator.

VII. FSIS REPORTS

The State MPI program officials are notified in writing when FSIS makes a determination after analysis of the self-assessment and on-site review, as applicable. An individual end-of-year report is sent to each State MPI program summarizing program findings. Additionally, each year FSIS publishes on its Web site an overall end-of-year summary report of the findings and final determinations for all State MPI programs at http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/state-inspection-programs/state-inspection-and-cooperative-agreements/reviews-of-state-programs

VIII. NINE PROGRAM COMPONENTS

Component 1: Statutory Authority and Food Safety Regulations

Criteria for "at least equal to" determination

State MPI programs need to have meat and poultry inspection laws and regulations that impose mandatory ante-mortem and post-mortem inspection, reinspection, sanitation requirements, recordkeeping requirements, and enforcement authorities "at least equal to" those prescribed by the FMIA² (21 U.S.C. 601, et seq.) and PPIA ³(21 U.S.C. 451, et seq.). State MPI programs need to also enforce requirements that are "at least equal to" those imposed under the Humane Methods of Slaughter Act of 1978 (HMSA)⁴ (7 U.S.C. 1901, et seq.).

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² The Federal Meat Inspection Act (21 U.S.C. 601, et seq.) governs the slaughter of livestock and the processing and distribution of meat products in the United States. Passed by Congress in March 1907, the FMIA authorizes the Secretary of Agriculture to set national standards for meat inspection. The FMIA was amended in the Wholesome Meat Act of 1967, granting the Secretary of Agriculture the authority to authorize each State to develop its own meat inspection program if their requirements are "at least equal to" Federal requirements. The amended FMIA assures uniformity in regulation of products shipped interstate, intrastate, and in foreign commerce.

³ The Poultry Products Inspection Act (21 U.S.C. 451, et seq.) governs the slaughtering, processing, and distribution of poultry products in the United States. Passed by Congress in August 1957, the PPIA authorizes the Secretary of Agriculture to make rules and regulations setting national standards for poultry inspection. The PPIA was amended in the Wholesome Poultry Products Act of 1968, granting the Secretary of Agriculture the authority to authorize each State to develop its own poultry inspection program if their requirements are "at least equal to" federal requirements. The amended PPIA assures uniformity in regulation of products shipped interstate, intrastate, and in foreign commerce.

⁴ The Humane Methods of Slaughter Act (7 U.S.C. 1901 et seq.) governs the humane treatment of animals at official establishments. Passed by Congress in 1978, the HMSA authorizes the Secretary of Agriculture to make rules and regulations setting national standards for livestock inspection. The HMSA prevents needless suffering of animals,

State MPI programs need to also be in compliance with Federal Civil Rights laws:

- Title VI of the Civil Rights Act of 1964 [42 U.S.C. 200 (d)];
- Section 504 of the Rehabilitation Act of 1973, as Amended (29 U.S.C. 794);
- Age Discrimination Act of 1990 (42 U.S.C. 12101, et seq.);
- Applicable USDA Civil Rights regulations;
- Financial Accountability requirements pursuant to the Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments (7 Code of Federal Regulations (CFR) Part 3016), (previously known as the Common Rule);
- The Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments (7CFR Part 3016), (previously known as the Common Rule); and
- FSIS Directive 3300.1, Rev. 2, Fiscal Guidelines for Cooperative Meat and Poultry Inspection Programs.

To ensure States are in compliance with the statutory and regulatory requirements detailed above, State MPI programs need to:

 Adopt by reference the FMIA, PPIA, and HMSA and implementing regulations; or impose State laws that meet the "at least equal to" requirements of the FMIA, PPIA, and HMSA, and explain in their submission to FSIS how those requirements provide a level of protection that is "at least equal to" that which is imposed by the FMIA, PPIA, HMSA and implementing regulations

FSIS allows time for the State's rulemaking process when necessary, because there are States that have legislatures that do not always meet on an annual basis. The State MPI program needs to ensure there are measures in place to verify compliance and take enforcement actions for non-compliance findings until the final rulemaking process has been completed. The State MPI program needs to have the authority to expedite the rulemaking process in a manner "at least equal to" that provided for in the Administrative Procedure Act, 5 U.S.C. §553.

If a State MPI program has enacted its own comparable State statutes and regulations that are "at least equal to" those governing the Federal inspection requirements, it needs to ensure that the statutes and regulations establish requirements that State

produces safer and better working conditions, brings about improvement of products and economies, and produces other benefits for producers, processors and consumers. Nothing in the HMSA shall be construed to prohibit, abridge, or in any other way hinder the religious freedom of any person or group.

establishments maintain sanitary conditions and operate in a manner that includes evaluating hazards, taking steps to control hazards, and routinely verifying that product is safe, wholesome, not adulterated, and properly marked and labeled.

States need to ensure that their statutes and regulations adequately address, in an "at least equal to" manner, mandatory ante-mortem and post-mortem inspection, reinspection, sanitation requirements, recordkeeping requirements, compliance provisions, and enforcement authorities to ensure that product is wholesome and not adulterated. In addition, State regulations need to address the humane treatment of animals at establishments under inspection.

Outcome

The expected outcome is a set of laws and regulations in place that, when objectively reviewed by FSIS, are determined to be "at least equal to" FSIS's Federal laws and regulations.

"At least equal to" Requirements

State MPI program officials need to stay current with applicable laws, administrative rules, FSIS regulations, FSIS directives and notices, and any other policies, and be able to explain how their State programs are "at least equal to" FSIS's Federal inspection program requirements. The State officials should include a narrative that describes any changes in the State laws and regulations over the past 12 months, and of any proposed changes that may affect their "at least equal to" status over the subsequent 12 months.

Objective

State MPI programs need to periodically review applicable State laws, regulations, FSIS Directives and Notices and other FSIS policies to ensure the State programs provide a level of protection that is "at least equal to" those imposed by FMIA, PPIA, HMSA and regulations in section 9 of the CFR.

Statutory Authority and Food Safety Regulations Methods and Procedures

State MPI programs need to have methods to periodically evaluate changes to Federal laws and regulations for applicability to State MPI programs, and need to revise State MPI laws and regulations as necessary.

The methods should, at a minimum, address the following critical aspects:

- Procedures for periodic evaluation of changes to applicable laws and regulations;
- State legislative procedures;
- State emergency legislative procedures;

- State rulemaking procedures; and
- State emergency rulemaking procedures.

Evidence of system application

State MPI programs should provide evidence which demonstrates implementation of methods and procedures that are "at least equal to" those of FSIS's Federal inspection program.

At a minimum, the State MPI program should submit:

- Documentation of periodic evaluations of current State laws, regulations and other policies;
- The State laws and regulations applicable when species other than those covered by the FMIA and PPIA are considered amenable under State laws;
- Current copies or Web links to State laws, regulations, and other policies with specific cross-references to 9 CFR;
- Current copies or Web links to State rulemaking and emergency rulemaking procedures;
- Documentation of laws and regulations currently undergoing State rulemaking and emergency rulemaking processes which affect the State MPI program;
- Documentation that verify State laws are "at least equal to" the provisions of the FMIA, PPIA, and HMSA as specified in Attachment 2; and

NOTE: The *Statutory Side-by-Side Comparison Table* (Attachment 2, page 19) has been provided as a tool for the State MPI programs to demonstrate comparable State statutes, laws, or regulations for each of the applicable FMIA, PPIA, and HMSA provisions.

• Legal documentation that State MPI programs have the authority to impose meat and poultry inspection laws and regulations with the same purposes as the Federal laws that govern FSIS's Federal inspection program.

STATE MPI PROGRAM STATUTORY SIDE-BY-SIDE COMPARISON TABLE		
FEDERAL Acts	Comparable Specific State Statutes, Laws, Rules or Regulations	
Federal Meat Inspection Act		
Subchapter I - Inspection Requirements; Adulteration & Misbranding. §601. Definitions.		
§602. Congressional statement of findings.	Not applicable to "at least equal to" criteria	
Ante-Mortem And Post-Mor	tem Inspection Requirements	
§603. Inspection of meat and meat food products.		
Authority To Take Action Against Any Persons Foun	d To Be Engaging In Inhumane Methods Of Slaughter	
b) Humane methods of slaughter.		
In conjunction with: 7 U.S.C. § 1902 - Humane methods.		
§604. Post mortem examination of carcasses and marking or labeling; destruction of carcasses condemned; reinspection.		
	Requirements	
§605. Examination of carcasses brought into slaughtering or packing establishments, and meat food products issued from and returned thereto; conditions for entry.		
§606. Inspection and labeling of meat food products.		
§607. Labeling, marking, and container requirements.		
Sanitation Requirements		
§608. Sanitary inspection and regulation of slaughtering and packing establishments; rejection of adulterated meat or meat food products.		
§609. Examination of animals and food products thereof, slaughtered and prepared during nighttime.	Not applicable for "at least equal to" criteria	
Prohibited Acts		
§610. Prohibited acts.		
Devices, Marks, Labels, and Certificates; Simulations		

§611. Devices, marks, labels, and certificates; simulations.		
Notification Notification		
§612. Notification.		
	Reassessment	
§613. Plans and reassessments.		
§614. Repealed.	Not applicable for "at least equal to" criteria	
§615. Inspection of carcasses, meat intended for export.	Not applicable for "at least equal to" criteria	
§616. Inspectors of carcasses, etc., meat intended for export; certificates of condition.	Not applicable for "at least equal to" criteria	
§617. Clearance prohibited to vessel carrying meat for export without inspector's certificate.	Not applicable for "at least equal to" criteria	
§618. Delivery of inspectors' certificates, and of copies.	Not applicable for "at least equal to" criteria	
§619. Marking, labeling, or other identification of kinds of animals of articles' derivation; separate establishments for preparation and slaughtering activities.	Not applicable for "at least equal to" criteria	
<u>§620.</u> Imports.	Not applicable for "at least equal to" criteria	
§621. Inspectors make examinations provided for; appointment; duties; regulations.		
Bri	bery	
§622. Bribery of or gifts to inspectors or other officers and acceptance of gifts.		
§623. Exemptions from inspection requirements.		
§624. Storage and handling regulations; violations; exemption of establishments subject to non-Federal jurisdiction.	Not applicable for "at least equal to" criteria	
§625. Inapplicability of certain requirements to catfish.	Not applicable for "at least equal to" criteria	
Prohibition of articles not intended for use as human food; denaturation or other identification prior to distribution in commerce; inedible articles		
Subchapter II - Meat Processors & Related Industries §641. Prohibition of subchapter I inspection of articles not intended for use as human food; denaturation or other identification prior to distribution in commerce; inedible articles.		

Record-Keeping Requirements And Examination Of Records			
§642. Recordkeeping requirements.			
Registration Of Business, Name Of Person, And Trade Names.			
§643. Registration of business, name of person, and trade names.			
§644. Regulation of transactions, transportation, or importation of 4-D animals to prevent use as human food.			
§645. Federal provisions applicable to State or Territorial business transactions of a local nature and not subject to local authority.	Not applicable for "at least equal to" criteria		
Subchapter III - Federal & State Cooperation §661. Federal and State cooperation.	Not applicable for "at least equal to" criteria		
Provisions For Withdrawal Of Services Unaffected; Resp	usiness Unfitness Based Upon Certain Convictions; Other consible Connection With Business; Finality Of Secretary's I Review; Record.		
Subchapter IV - Auxiliary Provisions §671. Inspection services; refusal or withdrawal; hearing; business unfitness based upon certain convictions; other provisions for withdrawal of services unaffected; responsible connection with business; finality of Secretary's actions; judicial review; record.			
Dete	ention		
§672. Administrative detention; duration; pending judicial proceedings; notification of governmental authorities; release.			
Seizure and	Condemnation		
§673. Seizure and condemnation.			
§674. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations of section 607(e) of this title.	Not applicable for "at least equal to" criteria		
Assaults-I	ntimidation		
§675. Assaulting, resisting, or impeding certain persons; murder; protection of such persons.			
	ations		
§676. Violations.			
§677. Other Federal laws applicable for administration and enforcement of chapter; location of inquiries; jurisdiction of Federal courts.	Not applicable for "at least equal to" criteria		
§678. Non-Federal jurisdiction of federally regulated	Not applicable for "at least equal to" criteria		

matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters.		
§679. Application of Federal Food, Drug, and Cosmetic Act.	Not applicable for "at least equal to" criteria	
§679a. Safe Meat and Poultry Inspection Panel.	Not applicable for "at least equal to" criteria	
§679b. Pasteurization of meat and poultry.	Not applicable for "at least equal to" criteria	
§679c. Expansion of Food Safety Inspection Service activities.	Not applicable for "at least equal to" criteria	
§680. Authorization of appropriations.	Not applicable for "at least equal to" criteria	
Subchapter IV-A - Inspections By Federal and State Agencies §683. Interstate shipment of meat inspected by Federal and State agencies for certain small establishments.	Not applicable for "at least equal to" criteria	
Subchapter V - Inspections by Federal and State Agencies §691. Omitted.	Not applicable for "at least equal to" criteria	
§692. Inspection extended to reindeer.	Not applicable for "at least equal to" criteria	
§693. Inspection of dairy products for export.	Not applicable for "at least equal to" criteria	
§694. Authorization of appropriations.	Not applicable for "at least equal to" criteria	
§695. Payment of cost of meat-inspection service; exception for cost of overtime.	Not applicable for "at least equal to" criteria	
Doubtry Products Inspection Act	Comparable Specific State Statutes Laws or Bules	
Poultry Products Inspection Act	Comparable Specific State Statutes, Laws, or Rules	
§451. Congressional statement of findings.	Not applicable for "at least equal to" criteria	
§452. Congressional declaration of policy.	Not applicable for "at least equal to" criteria	
§453. Definitions.		
§454. Federal and State cooperation in development and administration of State poultry product inspection programs.	Not applicable for "at least equal to" criteria	
Ante-mortem and Post-mortem inspection and Reinspection requirements		

§455. Inspection in official establishments.			
Sanitation I	Requirements		
Sanitation Requirements §456. Operation of premises, facilities and equipment.			
§457. Labeling and container standards.			
	ited Acts		
§458. Prohibited acts.			
Devices, Marks, Labels, a	nd Certificates; Simulations		
(b) No brand manufacturer, printer, or person			
(c) No person shall forge			
Notif §459. Compliance by all establishments.	ication		
(b) Notification.			
(2)			
Plans and R	Reassessment		
(c) Plans and reassessments.			
Prohibition Of Articles Not Intended For Use As Hum	an Food; Denaturation Or Other Identification Prior To		
	nerce; Inedible Articles		
§460. Miscellaneous activities subject to regulation.			
Record-Keening And I	Examination Of Records		
(b) Recordkeeping requirements; persons liable; scope of	Administration of Records		
disclosure; access to places of business; examination of			
records, facilities, and inventories; copies; samples.			
(c) Registration of business, name of person, and trade			
names. (d) Regulation of transactions, transportation, or			
importation of dead, dying, disabled or diseased poultry			
or carcasses to prevent use as human food.			
(e) Federal provisions applicable to State or Territorial			
business transactions of a local nature and not subject to			
local authority.			
Accoulte and	d Intimidation		
§461. Offenses and punishment.	a intimudation		
2.52. Oncook and parisonnella			
§462. Reporting of violations; notice; opportunity to			
present views.			
5400 0 1 1 1 1 1			
§463. Rules and regulations.	Not applicable for "at least equal to" criteria		
§464. Exemptions.			
§465. Limitations upon entry of poultry products and			

other materials into official establishments.		
<u>§466</u> . Imports.	Not applicable for "at least equal to" criteria	
Inspection Services; Refusal Or Withdrawal; Hearing; Business Unfitness Based Upon Certain Convictions; Other Provisions For Withdrawal Of Services Unaffected; Responsible Connection With Business; Finality Of Secretary's Actions; Judicial Review; Record.		
§467. Inspection services.	neview, record.	
<u>§467a</u> . Administrative detention; duration; pending	ention	
judicial proceedings; notification of government authorities; release; removal of official marks.		
Seizure and	Condemnation	
§467b. Seizure and condemnation.		
§467c. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations; United States as plaintiff; subpoenas.	Not applicable for "at least equal to" criteria	
§467d. Administration and enforcement; applicability of penalty provisions; conduct of inquiries; power and jurisdiction of courts.	Not applicable for "at least equal to" criteria	
§467e. Non-Federal jurisdiction of federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters.	Not applicable for "at least equal to" criteria	
§467f. Federal Food, Drug, and Cosmetic Act applications. (a) Exemptions; authorities under food, drug, and cosmetic provisions unaffected. (b) Enforcement proceedings; detainer authority of representatives of Secretary of Health and Human Services.	Not applicable for "at least equal to" criteria	
§468. Cost of inspection; overtime.	Not applicable for "at least equal to" criteria	
§469. Authorization of appropriations.	Not applicable for "at least equal to" criteria	
<u>§470</u> . Omitted.	Not applicable for "at least equal to" criteria	
§471. Safe Meat and Poultry Inspection Panel.	Not applicable for "at least equal to" criteria	
§472. Interstate shipment of poultry inspected by	Not applicable for "at least equal to" criteria	

Federal and State agencies for certain small establishments.	
Humane Methods of Livestock Slaughter Act	Comparable Specific State Statutes, Laws, or Rules
§1901. Findings and declaration of policy.	Not applicable for "at least equal to" criteria
§1902. Humane methods.	
§1904. Methods research; designation of methods.	Not applicable for "at least equal to" criteria
§1906. Exemption of ritual slaughter.	
§1907. Practices involving nonambulatory livestock.	Not applicable for "at least equal to" criteria

Criteria for "at least equal to" Determination

Each State MPI program need to submit a current narrative describing the State inspection system used to enforce all applicable laws, regulations, and FSIS policies. The State system should have the capability to correct any deviations from regulatory requirements that may affect its program's being "at least equal to" FSIS's Federal inspection program.

State MPI programs need to submit any supporting documentation (preferably completed reports and documents) to demonstrate the State inspection system, as described in the narrative, has been implemented, is functioning as intended, and will ensure the State MPI program has the ability to remain "at least equal to" FSIS's Federal inspection program for the next 12 months.

Inspection methods and procedures followed under a State MPI program must be "at least equal to" the FMIA, PPIA, HMSA, the applicable regulations in 9 CFR 300 to end, and applicable policies issued for FSIS's Federal inspection program. At a minimum, the State inspection program should include the following criteria:

- Ante-mortem A State MPI program is to examine and inspect all livestock and poultry before slaughter to determine whether animals are fit for slaughter and can be used for human food. A State MPI program should verify that establishments present all animals for ante-mortem inspection in accordance with the FMIA, PPIA, and 9 CFR, ensuring animals with abnormalities and signs that could otherwise indicate disease are removed from human edible food channels.
- Post-mortem State Inspection Program Personnel (IPP) should examine and inspect carcasses in the slaughter process and post-mortem in State inspected establishments to determine whether carcasses and parts are wholesome and not adulterated and thus permitted to receive the State mark of inspection. Inspection of meat and poultry carcasses, including applicable parts, is conducted in a manner "at least equal to" FSIS's processes, as described in 9 CFR 311 and 381, Subpart K, respectively.
- <u>Sanitation</u> A State MPI program should verify that establishments have developed, implemented, and maintained Sanitation Standard Operating Procedures (Sanitation SOPs) consistent with requirements in 9 CFR 416.
- <u>Food Safety Requirements</u> A State MPI program should verify each State inspected establishment's food safety system, including Hazard Analysis and Critical Control Point (HACCP) plans are consistent with requirements in 9 CFR 417.
- Non-Food Safety Requirements A State MPI program should verify all products produced for distribution in intrastate commerce are wholesome, and properly labeled. State IPP need to perform the appropriate activities for verifying

compliance with applicable requirements to those in the FMIA, PPIA, and 9 CFR. These activities include verifying accuracy of State inspected establishment product formulation for labeling and product standard of identity requirements; observing preparation or processing procedures; reviewing establishment records; and performing a variety of in-plant measurements and calculations.

- Regulatory Enforcement A State MPI program should develop and apply administrative enforcement consistent with those in 9 CFR 500 (Rules of Practice) to ensure establishments are provided due process of law and bring noncompliant establishments back into compliance with the FMIA, PPIA, HMSA, and 9 CFR.
- <u>Exempt Facility Reviews</u> A State MPI program should verify that all products produced in State exempt facilities (either in official State inspected establishments or a separate facility) comply with regulatory and statutory requirements for sanitation, adulteration, and labeling.
- New Issuance Reviews A State MPI program should evaluate the applicability of new FSIS laws, regulations, FSIS Directives and Notices and any other policies, and ensure they are implemented, as appropriate.

<u>Outcome</u>

When objectively reviewed by FSIS, the State MPI program is determined to be "at least equal to" FSIS's Federal inspection program.

A State MPI program has:

- A series of standards and policies that define how State inspected establishments can operate to produce safe, wholesome, not adulterated and properly labeled and packaged products.
- A comprehensive State regulatory inspection system (e.g., Public Health Information System (PHIS)) that collects, consolidates, and analyzes data and enforces the meat and poultry regulations at State-inspected establishment.

NOTE: State MPI program Directors that have elected not to use FSIS's PHIS can find guidance information titled, "<u>At least equal to" data system guidance for State</u>

<u>Cooperative Meat and Poultry Inspection (MPI) Programs electing not to use Public Health Information System</u> (PHIS) (Attachment 3, page 38). State MPI program Directors are to submit the requested data system information with the annual self-assessment submission to the FSAB for review. By August 1st of each year, FSIS will provide State MPI programs with guidance on the PHIS inspection tasks.

 Assurances that State-inspected establishments can maintain food safety systems to reduce, eliminate, or prevent food hazards (i.e., any biological, chemical, or physical property that may cause a food to be unsafe for human consumption)

- A system to carry out administrative actions when State inspected establishments are not meeting the provisions of "at least equal to" the FMIA, PPIA, HMSA, applicable State laws, and 9 CFR
- A system to review exempt facilities to determine their compliance under the sanitation, adulteration, labeling, and other statutory and regulatory requirements
- A system to evaluate the applicability of new FSIS policies and determine how to implement the policies in the State MPI program

"At least equal to" Requirements

The State MPI program is required to maintain:

- A Slaughter Inspection System;
- A Food Safety Verification System;
- A Non-Food Safety Verification System;
- An Exempt Facility Review System; and
- A New Issuance Review System.

NOTE: State MPI program Directors need to submit the data integrity information for the data collected and maintained in their system in place of the PHIS. The data integrity information should include:

- The type of data maintained outside of PHIS (e.g., FSAs, custom exempt reviews, NOIEs);
- How the data integrity is maintained (e.g., safeguards to restrict access, security tools); and
- The State law or administrative rule that governs the security and integrity preservation of meat and poultry inspection program records.

Slaughter Inspection System

State MPI programs should maintain a slaughter inspection system that is able to verify whether State inspected establishments comply with requirements consistent with the FMIA, PPIA, and HMSA. The slaughter inspection system should have a method for assigning tasks and documenting task results for slaughter inspection requirements at State inspected establishments. The slaughter inspection system needs to be able to capture the results of ante-mortem and post-mortem inspection activities (e.g., suspected animals, condemned carcasses and parts) including the capability to capture any regulatory noncompliance and regulatory control actions taken. State MPI program officials should create or adopt slaughter inspection policies and procedures for conducting ante-mortem and post-mortem inspection activities that ensure compliance with Federal and State laws and regulations.

Objective

To implement state inspection activities which ensure animals are suitable for slaughter; products are not adulterated, wholesome, properly labeled, marked, and packaged, and carcasses and parts are eligible for human consumption.

<u>Inspection Methods and Procedures</u>

State MPI programs should implement slaughter inspection methods and procedures "at least equal to" those of FSIS's Federal inspection program. The methods and procedures at a minimum should include:

- Methods and procedures to inspect livestock and poultry before slaughter (antemortem inspection) and verify that animals offered for slaughter have received ante-mortem inspection
 - Procedures to follow when State IPP observe animals showing symptoms
 of disease or abnormalities and signs that could indicate disease or other
 health conditions that would prohibit the animal from entering the food
 supply
 - Procedures to mark and document dispositions of livestock following antemortem inspections
- Methods and procedures to inspect livestock and poultry after slaughter (postmortem inspection) to make and document dispositions of carcasses following post-mortem inspections
 - Procedures to verify State inspected establishments that slaughter cattle and establishments that process the carcasses or parts of cattle are complying with 9 CFR 310.22, requiring the removal, segregation, and disposition of specified risk materials (SRMs)
- Methods and procedures used to document and maintain case files supporting administrative enforcement and other actions taken under the authority of FMIA, PPIA, and applicable State laws
- Methods and procedures to assess whether slaughter inspection activities successfully meet the State MPI program management's expectations for:
 - In-Plant Level Slaughter Inspections
 - Ante-mortem
 - Post-mortem
 - Noncompliance regulatory documentation
 - Enforcement actions
 - Product recalls (e.g., uninspected animals and carcasses)
 - Central Office Level Assessments
 - Administrative case development

Program personnel competency

Evidence of system application

A State MPI program should provide evidence that demonstrates the implementation of a State slaughter inspection system that is "at least equal to" that of the FSIS's Federal inspection program. At a minimum, the State MPI program should submit:

- Representative State Animal Disposition Summary/PHIS analogous reports that list animal and carcass dispositions performed within the last 12 months
- Documentation of regulatory control, withholding, suspension, enforcement, or administrative actions taken when noncompliance is identified (e.g., Noncompliance Records (NRs), 30 day letters, Notice of Intended Enforcement (NOIE) letters, Suspension letters, or notification to withhold the marks of inspection)
- Management's evaluation and results of State slaughter inspection system performance

Food Safety Verification System

The sanitation criteria incorporate the regulations that address SPS, Sanitation SOPs, and HACCP, which are identified as essential parts of a food safety system. The regulations require that State inspected establishments maintain Sanitation SOPs and meet the SPS requirements. Sanitation SOPs are a prerequisite to an establishment's HACCP plan, and establishments may use Sanitation SOPs to support decisions in the hazard analysis that certain hazards are not reasonably likely to occur. State inspected establishments may also maintain other prerequisite programs to support decisions in their hazard analyses.

The State MPI programs are required to maintain a food safety verification system capable of identifying noncompliances in an establishment's food safety systems. The State MPI system should have the ability to identify deleterious trends that occur in State inspected establishments' food safety system (e.g., increased number of NRs, increased positive sample results), and should also be able to document the results of food safety verification activities, including regulatory noncompliance and regulatory actions taken. Additionally, State MPI program managers are required to adopt or create policies for conducting food safety verification activities to ensure compliance with Federal and State laws and regulations.

Objective

To implement food safety verification activities that ensure all State inspected meat and poultry products found in intrastate commerce are safe, wholesome, not adulterated and properly marked, labeled and packaged, and can verify State inspected establishments comply with applicable State laws, regulations and policies.

Food Safety Verification System Methods and Procedures

State MPI programs need to implement food safety verification system methods and procedures "at least equal to" those of FSIS's Federal inspection system. The methods and procedures at a minimum should include:

- Methods to schedule tasks, record food safety verification tasks, and document noncompliance with regulatory requirements
 - Procedures to protect the public health by properly verifying State inspected establishments' compliance with the pathogen reduction, sanitation, and the HACCP regulations
 - Procedures to verify that State inspected establishments that slaughter cattle and establishments that process the carcasses or parts of cattle are complying with 9 CFR 310.22 and prescribe to requirements for the removal, segregation, and disposition of SRMs
 - Procedures to verify State inspected slaughter operations are implementing sanitary dressing and process control procedures that prevent contamination of carcasses
 - Procedures to verify that State inspected establishments implement other prerequisite programs as described and in accordance with 9 CFR 417
 - Procedures for protecting public health by verifying, documenting, and enforcing the requirements for no visible fecal material, milk, or ingesta on livestock carcasses at or immediately after the final rail, and by verifying feces, ingesta, and milk are not present on head meat, cheek meat, and weasand meat
 - Procedures for verifying visible fecal material are not present on State inspected poultry carcasses entering the chill tank
 - Procedures to protect the public health by properly verifying State inspected establishments' compliance with the pathogen reduction, sanitation, and the HACCP regulations
 - Procedures for holding weekly meetings with State inspected establishment management to discuss topics pertaining to the establishments' food safety system and other issues which could affect public health
- Methods to investigate and analyze all food safety aspects (e.g., FSA) that relate
 to State inspected establishments and their individual products, the design and
 validity of the establishments' hazard analyses, HACCP plans, Sanitation SOP,
 pre-requisite programs, testing programs, and any other programs that constitute
 the establishments' HACCP systems
- Methods to categorize State inspected processing and slaughter establishments into a priority level for FSA scheduling, using public health decision criteria, in addition to traditional event-based scheduling

- Methods used to document and maintain case files that support administrative enforcement and other actions taken under the authority of the FMIA, PPIA, and applicable State laws
- Methods to assess whether food safety verification activities successfully meet the State MPI program management's expectation for:
 - In-Plant Level Food Safety Verifications
 - SPS
 - SSOP
 - Prerequisite programs
 - HACCP
 - Noncompliance regulatory documentation
 - Enforcement actions
 - Product recalls
 - Central Office Level Assessments
 - FSA
 - Administrative case development
 - Program personnel competency

Evidence of system application

A State MPI program should provide evidence that demonstrates implementation of a food safety verification system "at least equal to" that of the Federal inspection system. At a minimum, the State MPI program should submit:

- Representative HACCP Summary/PHIS analogous reports by State inspected establishments/circuits/districts that list all food safety verification tasks performed within the last 12 months
- Documentation of enforcement and administrative actions taken when regulatory noncompliance was identified (e.g., Noncompliance Records (NRs), 30 day letters, Notice of Intended Enforcement (NOIEs) letters, Suspension letters, withhold the marks of inspection letters)
- In-depth establishment food-safety reviews (e.g., FSAs, and supervisory establishment reviews)
- State issuances and policies that are different than those issued by FSIS
- Completed grant-of-inspection approval process, and withdrawal documents
- Evidence and verification methods that State MPI programs use as an assurance that their program is effectively implemented

 Documentation of actions taken (e.g., rejection of the knock box, suspension) in response to identified SPS, Sanitation SOP, or HACCP noncompliance

State MPI programs should submit completed supporting documentation to demonstrate that these programs, as described in the narrative, have been implemented. The State MPI programs need to ensure controls exist and are functioning as intended to maintain their operations over the next 12 months.

Non-Food Safety Verification System⁵

The State MPI program should maintain a non-food-safety verification system that includes methods and procedures for verifying that State inspected meat and poultry products are wholesome, not economically adulterated, truthfully labeled, and meet the non-food-safety regulatory requirements. The system should also document identified noncompliances and regulatory actions taken. State MPI program managers should adopt policies for conducting non-food-safety verification to ensure compliance with Federal and State laws and regulations.

Objective

To implement State inspection activities that ensure all State inspected meat and poultry products found in intrastate commerce are safe, wholesome, not adulterated and properly marked, labeled and packaged to verify State-inspected establishments comply with applicable State laws, regulations and policies.

Non-food Safety Verification System Methods and Procedures

State MPI programs need to implement methods and procedures "at least equal to" those of FSIS's Federal inspection program. The methods and procedures at a minimum should include:

- Methods to schedule and record non-food safety verification tasks, and document noncompliance with regulatory requirements
- Methods to verify State inspected establishments comply with non-food safety regulatory requirements
 - Procedures for:

Observing establishment product formulation

- Verifying the accuracy of labeling
- Observing preparation or processing procedures

⁵ "Non-food safety consumer protection" refers to consumer protection activities other than those focused directly on food safety and public health. Under the FMIA and the PPIA, FSIS is responsible for ensuring that products are wholesome; are properly marked, labeled, and packaged; and are not economically adulterated or do not contain components that, while not actually unsafe, are undesirable.

- Reviewing establishment records
- Examining product
- Checking product identification, condition and temperature
- Performing a variety of other in-plant measurements, testing, and calculations
- Procedures to verify and determine whether product labels are not false or misleading and meet applicable requirements of 9 CFR 412 (formerly 9 CFR 317.4, 317.5, 381.132, and 381.133).
- Methods to review and approve sketch labels and supporting documentation
- Methods used to document and maintain case files supporting administrative enforcement and other actions taken under the authority of the FMIA, PPIA, and applicable State laws
- Methods to assess whether State non-food safety requirements and label approval verification activities successfully meet the State MPI program management's expectation for:
 - In-Plant Level Non-Food Safety Verifications
 - Net weights
 - Standards of identity
 - Generic label requirements
 - Noncompliance regulatory documentation
 - Enforcement actions
 - Product recalls for non-food safety situations
 - Central Office Level Assessments
 - Label approval process
 - Administrative case development
 - Program personnel competency

Evidence of System Application

A State MPI program needs to provide evidence that its non-food-safety verification system is "at least equal to"" FSIS's Federal inspection program. At a minimum, the State MPI program should submit:

- Representative Summary or PHIS-analogous reports by establishments/circuits/districts that list all non-food-safety requirement verification tasks performed within the last 12 months
- Final labels including supporting documentation (e.g., sketch labels, label applications, ingredient formulation worksheets)

- Approved label tracking logs
- In-depth establishment reviews (e.g., supervisory establishment reviews)
- Evidence and verification methods State MPI programs use to assure their program is effectively implemented (e.g., label approvals, label reviews)
- Documentation of actions taken in response to non-food safety requirements verification noncompliance

Exempt Facility Review System

The State MPI program needs to maintain a system to conduct reviews of exempt facilities (either within official State inspected establishments or separate facilities) to determine their compliance with the FMIA, PPIA, applicable State laws, regulations and policies. State MPI program managers should adopt or create policies for conducting reviews of exempt and poultry exempt facilities.

Objective

To ensure State exempt facilities comply with applicable State laws, regulations and policies.

Exempt Facility Review Methods and Procedures

State MPI programs need to implement review methods "at least equal to" those of FSIS's Federal inspection program. The methods, at a minimum, should include:

- A review of the State exempt operation to verify livestock and poultry carcasses and products are:
 - Not adulterated or misbranded
 - Handled humanely (livestock)
 - Prepared under sanitary conditions
 - Properly marked and packaged
 - Stored separately from State inspected products
 - Documented according to regulatory requirements
- A method to assess whether the State exempt facility activities successfully meet the State MPI program management's expectations

Evidence of system application

A State MPI program needs to provide evidence that demonstrates implementation of an exempt facility review system that is "at least equal to" that of FSIS's Federal inspection system. At a minimum, the State MPI program should submit:

- Documentation and tracking logs for State exempt facility reviews
- Management's evaluation and results of the State exempt facility review system performance

New Issuance Review System

Objective

The new issuances list is updated quarterly and is used to verify that State MPI programs are staying current with new FSIS policies. FSIS routinely issues regulations and notices in the Federal Register to communicate new policies and requirements to the public. FSIS also routinely issues Directives and Notices to Federal IPP to provide direction and guidance regarding inspection and enforcement activities.

Each quarter, FSIS provides State MPI programs with an updated list of all applicable issuances published since the previous quarter. FSIS continues to provide this information in an effort to better communicate the "at least equal to" criteria for State MPI programs. State MPI programs are to review all issuances and incorporate any necessary modifications in their programs. State MPI programs are to submit a response to the Quarterly List of Applicable FSIS Issuances within 30 days after receipt of the list.

New Issuances Methods and Procedures

While State MPI programs are not required to follow FSIS issuances verbatim or to issue similar documents to their inspection program personnel, they need to consider the implications of each issuance and are expected to be able to explain their "at least equal to" actions (even if their decision is to do nothing) related to the activity or issue covered by the FSIS issuances.

When a policy is issued by FSIS, State MPI programs need to have methods in place to determine the applicability of the policy to their State program, and decide how to communicate instructions for its implementation within their State inspection programs. The State's results will be documented as a response to each new issuance on the Quarterly List of Applicable FSIS Issuances. For each new issuance, using one of the alternatives listed below, the State MPI program should document that the State:

 Determined that the issuance has no application for its State MPI program maintaining its "at least equal to" status; the State should fully explain why;

- Adopted essentially the same approach in its State MPI program; and submitted documentation demonstrating implementation; or
- Adopted measures in the State MPI program that the State considers to be "at least equal to" FSIS's Federal inspection program; provided the reason and justification for doing so, explained why and how they became convinced that they are "at least equal to" FSIS's Federal inspection program, and provided documentation demonstrating implementation.

Evidence of system application

State officials need to be able to provide a justification for their "at least equal to" determination for each new Federal issuance. State MPI programs are to respond to the Quarterly List of Applicable FSIS Issuances sent on or before the first day of each quarter of the Federal fiscal year (e.g., October, January, April, and July) within 30 calendar days of receipt. The response should include a description of the methods used to distribute the issuances and evidence of delivery, and a summary of how the new issuance or policy change is being implemented. States should submit any documentation that demonstrates how each issuance was implemented.

Examples of the manner in which issuances are implemented are included in the Quarterly List of Applicable FSIS Issuances. However, other documents may be used to demonstrate the implementation.

States should enter information into the designated column on the Quarterly List of Applicable FSIS Issuances, and attach the responses to an email to the Federal State Audit Branch (FSAB) at: StateMPIProgramSubmissions@fsis.usda.gov, or by USPS, FedEx, UPS, or FAX (402-344-5104).

Attachment 3

"At Least Equal To" Data System Guidance for State Cooperative Meat and Poultry Inspection (MPI) Programs Electing Not to Use Public Health Information System (PHIS)

I. PURPOSE

To provide guidance to State Cooperative Meat and Poultry Inspection (MPI) programs electing to use a data system other than FSIS's PHIS for meeting the "at least equal to" data system essentials.

II. BACKGROUND

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 661) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 454) authorize FSIS to cooperate with State agencies in developing and administering their own Meat and Poultry Inspection programs. Individual State MPI programs are required to operate in a manner and with authorities that are "at least equal to" the ante-mortem and post-mortem inspection, reinspection, sanitation, recordkeeping, and enforcement provisions as provided for in the FMIA and PPIA. Therefore, State MPI programs are required to develop a data system with characteristics that can produce inspection and recordkeeping outcomes "at least equal to" FSIS's procedures. FSIS maintains PHIS as its data system.

FSIS developed PHIS to maintain detailed records of regulatory compliance verification activities. The activities are conducted by FSIS's Federal inspectors and the information is entered into PHIS by FSIS personnel at official establishments, official import establishments, and registered facilities. The PHIS database maintains establishment and facility data, and the results of inspection verifications. FSIS uses this information to identify issues that require Agency attention.

PHIS supports documentation of appeals to inspection decisions, scheduling, and documentation of Food Safety Assessments (FSA) and the ability to identify and notify suppliers of beef products that have tested positive for E. coli O157:H7. FSIS uses PHIS to manage FSIS's inspection assignments and FSIS's employee assignments to roles and establishments.

The PHIS sample scheduler distributes product sample requests to Establishment Task Lists. FSIS uses PHIS to apply business rules and risk-based algorithms for sample selection and output reports of scheduled samples. These scheduled sample requests tasks are performed by FSIS's Federal IPP. FSIS uses PHIS to process information about imported products. FSIS's Federal IPP input reinspection results for imported products in to PHIS. PHIS's functionality includes a means for FSIS's Office of Policy and Program Development (OPPD), International Equivalence Staff (IES) and the Office of Investigation, Enforcement and Audit (OIEA) Management Control and Audit Staff (MCAD) to schedule and track foreign country audit activities.

The information held in PHIS is shared with the Microbial (M2K) transactional database and the FSIS data warehouse. Information is written to the data warehouse from the PHIS transactional database to be used by other systems including the Enterprise Reporting System (ERS). The FSIS data warehouse provides a source of legacy system data which is used to support the analysis of inspection, audit, and assessment outcomes, and it maintains data from VetNet and PulseNet.

FSIS analyses the data collected in PHIS through its regulatory verification, compliance and enforcement, and sampling activities to assess the appropriateness of policy design and policy implementation. The analysis informs further policy development. Additionally, FSIS uses the information gathered from data analysis to ensure that policy and program components are effective in meeting the FSIS's public health goals and objectives.

FSIS recognizes that an integrated infrastructure with high-quality data and feedback interaction is essential to a data-driven approach to inspection. A data-driven approach to inspection requires quality data collection methods, ongoing data analysis to refine analytical decision-making tools, and performance measures to assess the impact of policies and programs.

The Task Library in PHIS supports the assignment of tasks to Establishment Task Lists. Each task is distributed to the Establishment Task List with a due date for completing the task. FSIS's Federal IPP have the ability to schedule the assigned tasks by moving the tasks from the Establishment task List to the Establishment Task Calendar. FSIS designed PHIS to allow IPP the flexibility to decide on which days they will perform the tasks.

Alerts are issued when specific events requiring immediate attention occur. Alerts are also used to remind FSIS's Federal IPP to take a particular action, such as, acquiring a product sample for laboratory analysis. An alert consists of a "trigger" and a "notification" function. The trigger is a feature that automatically scans the data for a specific event, and upon finding it, issues the notification. The notification can take the form of an email sent by PHIS, a message on the user's PHIS Alerts Dashboard, or both.

PHIS issues Public Health Regulation (PHR) alerts when there is a pattern of noncompliance at the establishment. Each month the Office of Data Integration and Food Protection (ODIFP) uses the results of inspection tasks to calculate the PHR noncompliance rate for each meat and poultry establishment as well as egg products plants. A PHR alert is issued to FSIS's Federal IPP when an establishment has a noncompliance rate that is elevated.

Examples of other events that trigger alerts are: a large number of inspection tasks not completed at an establishment, high rates of noncompliance in an establishment, and a positive adulterant pathogen test result at an establishment (e.g., *Escherichia coli (E. coli)* O157:H7 in raw ground beef, Shiga toxin-producing *Escherichia coli* (STEC) in beef manufacturing trimmings, or *Listeria monocytogenes (Lm)/Salmonella* in ready-to-

eat (RTE) products). The alert text gives directions to FSIS's Federal IPP by pointing them to the appropriate regulations and directives needed for the response.

PHIS Dashboard Alerts and e-mail notifications are issued to Headquarters and FSIS's Federal IPP as events occur. The alerts and notifications provide FSIS's Federal IPP and FSIS's Headquarters personnel with information that is important to the execution of their work assignments.

The PHIS includes a set of standard reports available to all FSIS administrative levels. FSIS produces a wide range of PHIS reports. The reports are run by FSIS personnel on an as needed basis. The reports are run for specific time frames identified by the user. The reports are available to FSIS personnel based on their assigned PHIS role. So, District management teams see aggregated reports for a District while FSIS's Federal IPP assigned to an establishment see reports for the assigned establishment. An example of a standard report is the monthly report of noncompliances by FSIS District Offices.

Reports are used at all levels of FSIS to monitor operations, to identify areas needing corrective actions, and to communicate progress towards goals. Users can review the reports and identify results that require investigation and establishment response. PHIS reports provide FSIS's Federal IPP and FSIS's Headquarters personnel with information that is important to the execution of their work assignments.

III. ELEMENTS OF AN "AT LEAST EQUAL TO" DATA SYSTEM

To be "at least equal to" the FSIS's system, the State MPI data system needs to:

- Collect, analyze and respond to State inspected establishment and State MPI program data;
- Monitor data streams to determine State inspected establishment performance;
 and
- Respond, near real-time, to State inspected establishments that may pose a risk to public health

To be "at least equal to" the State MPI data system needs to collect data from the following four activities:

- Daily inspection verification activities at operating State inspected establishments
- State MPI program HACCP verification testing
- State MPI program in-depth food safety reviews
- State MPI program administrative enforcement actions

Set out below are guidance and recommendations for State MPI programs to use in developing their data systems if they choose not to participate in PHIS. State MPI programs should monitor data collected from the four activities listed above. The data collected should be compared to different data sets (e.g., data of multiple circuits, data

of multiple establishments, and data from previous months) and analyzed to determine whether the State MPI program is meeting program goals and objectives. State MPI programs should take appropriate actions, based on the analysis, when goals and objectives are not being met.

1. <u>Daily inspection verification activities at operating State inspected</u> establishments

Data Collection

State MPI programs need to collect State inspected establishment demographics (profiles). These profiles should include critical up-to-date information about the establishment's size, products produced, production volume, recall history, non-compliance history, and food defense plans. HACCP information for the establishment should be available in the profile and include summary information, processing categories, food safety hazards, critical control points, and prerequisite programs. A State MPI program should ensure State IPP are able to verify that State inspected establishments' profile information is accurate and current at set intervals (e.g., at least every thirty days or whenever the HACCP plan changes).

NOTE: By August 1st of each year, FSIS provides State MPI programs with guidance on the PHIS inspection tasks. The *FSIS PHIS Inspection Task Catalog* will be updated annually to reflect current PHIS task information and then distributed separately as an addendum to the State MPI programs.

Data Analysis

The State MPI program's data system should contain public health-based decision criteria to identify State inspected establishments requiring more frequent inspection activities (e.g., increased directed food safety verification tasks).

The State MPI program's data system should also include a mechanism to react to State inspection results. Examples of events or trends that would trigger the State MPI program to react to State inspection results include:

- A large number of inspection activities not completed in State inspected establishments;
- High rates of non-compliance in State inspected establishments;
- A positive pathogen test result in State inspected establishments (e.g., E. coli O157:H7 in raw ground beef or Lm in RTE products)
- Infrequent State inspected establishment profile updates (e.g., HACCP plan changes failed to be identified or documented)
- Tasks are not being performed at frequencies sufficient to ensure the safety of public health

The State MPI programs should ensure data quality and accuracy so that the integrity of the information is not compromised (i.e., system identifying outdated establishment profile information or unperformed tasks).

2. State MPI program HACCP verification testing

Data Collection

The State MPI programs should maintain a system for tracking pathogen and residue testing results.

Data Analysis

The State MPI program's verification testing system should contain public health-based decision criteria to identify establishments requiring more frequent inspection activities (e.g., increased directed sampling due to positive sampling results or concerns with establishment's production process).

The system should include a mechanism to react to sampling results. Examples of events that would trigger the State MPI program to react to sampling results may include but are not limited to:

- A large number of sampling activities not completed at State inspected establishments
- A large number of laboratory discards
- Positive sampling results in State inspected establishments for adulterant pathogens (e.g., E. coli O157:H7 in raw ground beef, STEC in beef manufacturing trimmings, or Lm/Salmonella in RTE products)
- Violative residues
- Identifying long-term processes that may have exceeded their schedule (e.g., a Salmonella sample set that has not been finished)

3. State MPI program in-depth food safety reviews

State MPI programs should have procedures (e.g., Food Safety Assessments (FSA)) to verify that an establishment's food-safety systems are effective and yielding products that are wholesome and not adulterated, properly marked, labeled and packaged.

Data Collection

A State MPI program system should track routine and "for cause" in-depth foodsafety reviews.

Data Analysis

The State MPI program's data system includes a mechanism to react to sampling and inspection results that could lead to a "for cause" in-depth food safety system review. Examples of events that may trigger the State MPI program to conduct a "for cause" in-depth food safety system review may include, but are not limited to:

- State inspected establishments not in compliance with specific laws and regulations
- A positive for STECs in raw ground beef or raw ground beef components
- A positive Lm or Salmonella in RTE products or a positive Lm food contact surface sample
- A Class I recall or a food-safety-related enforcement action (e.g., Notice of Intended Enforcement) that is not the result of an in-depth food safety system review
- State inspected establishments that fail *Salmonella* or *Campylobacter* performance standards
- A State inspected establishment that is the supplier of a product that tested positive for STECs in raw beef products
- Human illness linked to a product from a State inspected establishment
- A State inspected establishment that has a high level of public health-related Non-compliance Records (NR)

4. State MPI program administrative enforcement action

State MPI programs should have procedures in place to initiate enforcement actions, as needed, to ensure food safety compliance.

Data Collection

The State MPI programs should maintain a system to collect data and facts to support administrative enforcement actions, and to track the results of actions taken (e.g., NRs, in-depth food-safety system reviews, intensified verification testing (IVT), suspensions, and recall information).

Data Analysis

The State MPI program's data system should include a mechanism to react to the data collected in support of administrative enforcement actions. Examples of events that may trigger the State MPI program to take administrative enforcement actions may include:

• Positive STECs in raw ground beef or raw ground beef components

- Positive *Lm*, *Salmonella*, or *E. coli* O157:H7 in RTE products or a positive *Lm* food-contact-surface sample
- A State inspected establishment that is the supplier of a product that tested positive for STECs in raw beef products
- Human illness linked to State inspected product from an establishment (possible recall)
- State inspected establishments not in compliance with specific State laws and regulations

An explanation of the data system and supporting documents should be included in the annual State Self-Assessment that is submitted to the Federal State Audit Branch by November 1 of each year.

IV. REFERENCES

FSIS Public Health Information System (PHIS) Reference Information:

FSIS Strategic Data Analysis Plan for Domestic Inspection

http://www.fsis.usda.gov/wps/wcm/connect/84fa563e-0f5c-4df5-8e04-99a04e9ce102/2010_Strategic_Data_Analysis_Plan.pdf?MOD=AJPERES

Data-Driven Inspection for Processing and Slaughter Establishments

http://www.fsis.usda.gov/wps/wcm/connect/fcaeabab-b89e-4bd4-b990-c697f34a797f/2010 Public Health Decsion Criteria Report.pdf?MOD=AJPERES

Public Health Regulation List, Fiscal Year 2017

http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/fsis-data-analysis-and-reporting/data-reporting/public-health-regulations

Component 3: Sampling Programs

Criteria for "at least equal to" Determination

Each State MPI Program needs to submit a current narrative describing the complete verification sampling program used to evaluate the effectiveness of each State inspected establishment's food safety system. The narrative should identify the various chemical and microbiological sampling projects that are a part of the State MPI program's verification sampling program. The State MPI program should ensure that the product and the production environment are tested for microbiological contaminants or chemical residues, in a manner that is "at least equal to" FSIS's Federal sampling programs.

NOTE: State MPI programs should not include any sampling activities (e.g., generic *E. coli*) conducted by establishments in the narratives.

State MPI programs need to submit documentation that the verification sampling programs, as described in the narrative, have been implemented and have been functioning as intended over the last 12 months. Documentation should include factual information on the State's ability to maintain its program for the next 12 months. State MPI program officials report laboratory sample results per sample project in an easy-to-read format of the *State MPI Program Sampling Activity Table* (Attachment 4, page 50-51).

To be considered "at least equal to" FSIS's Federal inspection program in its verification sampling program, at a minimum, the State MPI sampling program needs to include the following criteria:

- Sampling Project Eligibility State MPI programs consider product risk, product class, the product's intended use, and production volume when determining the eligibility for each sampling project. State programs are to include the criteria for determining the scope of sampling, including the frequency of scheduled samples on an average basis per year across all applicable State inspected establishments.
- Sample Result Analysis State MPI programs analyze sample results for trends (e.g., samples collected but not analyzed, increased positive test results, and product non-availability for sample collection) that may influence program inspection activities.
- Response Plan for Positive Test Results State MPI programs have action plans for responding to positive results, including actions taken by the State MPI program to recall product (See Component 6) and prevent adulterated product from entering commerce.
- Sampling Project Adaptability The State MPI program's sampling verification projects should be adaptable to keep pace with changes, such as emerging

pathogens, new products and processes, new or revised policies, and new laboratory analytical methods.

By August 1st of each year, FSIS provides State MPI programs with guidance on minimum testing frequencies for small and very small establishments.

State MPI programs need to maintain a verification testing program, with laboratory capacity, to address food safety (e.g., adulterants) and other regulatory requirements (e.g., standards of identity, species identification).

The verification program needs to include more specific criteria for routine analysis for the following product classes:

Raw Product

- Adulterant
 - Shiga toxin-producing Eschericia coli (STEC) in non-intact beef or intact product used to produce non-intact beef
 - Violative chemical compound residues (e.g., antibiotic drugs, pesticides, etc.)
- Measure of food-safety system process control
 - Pathogen reduction performance standards for Salmonella in certain raw meat and poultry products.
 - Pathogen reduction performance standards for *Campylobacter* in certain raw poultry products.

Ready-to-eat (RTE) product

- Adulterant
 - Salmonella in meat and poultry products
 - Listeria monocytogenes in meat and poultry products

NOTE: *Listeria monocytogenes* is also a food-contact-surface and environmental contaminant associated with meat and poultry products. Thus, the sampling project (e.g., routine *Listeria monocytogenes* (R*Lm*) sampling project) needs to address the post-lethality environment in which RTE products are produced.

State MPI programs need to have the capability to conduct the following analyses as needed:

Raw and ready-to-eat (RTE) product

Adulterant

- Unexpected biological, chemical, or physical hazards sufficient to cause illness (e.g., allergens)
- Misbranding
 - Significant nutrition labeling deviations
 - Central nervous system tissue in boneless meat derived from advanced meat recovery systems
 - Species not identified on the label

NOTE: It is not expected that the State MPI programs have a special laboratory for atypical analyses (e.g., bovine tuberculosis), but rather, that the State MPI program be able to procure atypical analyses when needed.

Outcome

When objectively reviewed by FSIS, the State MPI Program is determined to be "at least equal to" the Federal inspection system.

The State MPI program has a system for preventing products adulterated with pathogenic bacteria or violative residues from reaching the public through reliable and timely laboratory analyses of samples.

"At least equal to" requirements

State MPI programs should maintain a system for periodic verification of each State inspected establishment's food-safety system.

NOTE: State MPI program Directors are to submit the data integrity information for the data collected and maintained in a system elected in place of PHIS. The data collected may include State laboratory or contract laboratory sample test results. The data integrity information should include:

- The type of data maintained in the State MPI program system elected in place of PHIS (e.g., FSAs, custom exempt reviews, NOIEs).
- How the State MPI program's data integrity is maintained (e.g., restriction to access the data, ability to track data changes).
- The State law or administrative rule governing the security and integrity preservation of meat and poultry inspection program records.

Objective

To verify the effectiveness of each State inspected meat and poultry establishment's food-safety system to ensure that only safe, wholesome, not adulterated, properly marked, labeled and packaged meat and poultry products enter commerce.

Verification Sampling Methods and Procedures

State MPI programs need to apply verification sampling methods that are "at least equal to" those of FSIS's Federal inspection program. At a minimum, to "be at least equal" verification sampling program methods need to:

- Create sampling frequencies based on product risk, product type, production volume, time of year, product availability, etc.
- Ensure current sampling projects include all State inspected establishments producing eligible products (e.g., raw beef non-intact, RTE post-lethality exposed (see 9 CFR 430))
- Ensure current sampling projects include all State inspected establishments slaughtering eligible livestock and poultry classes and use the Kidney Inhibition Swab (KIS™) test to screen for violative drug residues in applicable livestock

NOTE: The KIS[™] test can detect residues for Tilmicosin, Tulathromycin, Bacitracin, Penicillin G, Neomycin, and Sulfonamide.

- Respond to public health concerns associated with products that test positive for adulterants (e.g., increase inspection activity, perform "for cause" FSA, conduct Intensified Verification Testing (IVT), initiate product recalls)
- Respond to performance standard failures (e.g., based on Salmonella Performance Standards, Campylobacter Performance Standards)
- Analyze sample results for trends (e.g., samples collected but not analyzed, increased positives results, product not available for sample collection)
- Respond to adverse trends (e.g., adapting sample frequency, evaluate State inspection program personnel (IPP) understanding of sample collection)
- Obtain serotype and Pulse-Field Gel Electrophoresis (PFGE) patterns of positive pathogens (partner with FSIS)
- Assess whether sampling activities successfully meet the State MPI program management's expectation for:
 - Creating sampling frequencies
 - Sampling eligibility
 - · Responding to positive sampling results
 - Managing positive pathogen results
 - State IPP competency

Evidence of System Application

A State MPI program needs to provide evidence that demonstrates implementation of a verification sampling program that is "at least equal to" FSIS's Federal inspection program. At a minimum, State MPI programs should submit:

- A list of applicable sampling projects that identify the target agent (microbial or chemical), eligible establishments, projected sampling frequency, actual samples analyzed, and the number of positive or violative samples
- Completed tracking log showing the scheduling and collection of samples per project (both microbiological and chemical)
- Laboratory results (e.g., completed lab forms)
- Documentation verifying how sample integrity is maintained (e.g., use of sample seals)
- Directed and inspector generated residue sampling and results
- Follow-up actions to positive results (e.g., recall actions, "for cause" FSA, IVT, administrative enforcement)

The information can be submitted using the table below or in another format.

State MPI Program Sampling Activity Table (Suggested Format)

Name of State Agency:	Sampling Dates Covered:				
Microbial and Residue Sampling	Number of ESTs Eligible for Sampling	Number Samples Targeted per EST (Intended Frequency)*	Number of Samples Actually Requested Program wide	Number of Viable Samples Analyzed per Program wide	Number of Confirmed Positives Program wide
E. coli O157:H7 in raw ground beef and Salmonella (MT43)					
E. coli O157:H7 and Non-O157 STEC (O26, O45, O103, O111, O121, O145) in raw beef trimmings (MT60) E. coli O157:H7 in components other than trim (MT64)					
E. coli O157:H7 in raw beef bench trim (MT65)					
MT 44 - Follow-up Testing for E. coli O157:H7 in Response to Ground Beef Positive Results (MT43)					
MT 52 - Testing of Beef Manufacturing Trimmings or Other Components from Originating Slaughter Suppliers(Based on a Positive Result (MT43))					
MT 53** – Follow-up Testing in Response to Positive Beef Manufacturing Trimmings Results (MT52 or MT60)					
Listeria monocytogenes and Salmonella in RTE products not due to risk (RTEPROD- random)					
Listeria monocytogenes and Salmonella in RTE products – risk based post-lethality exposed RTE products (RTEPROD- risk)					
Listeria monocytogenes in RTE products – risk based per 9 CFR 430 (RLm)					
Listeria monocytogenes in RTE products – risk based per 9 CFR 430 (IVT**)					

Salmonella in RTE products – risk based per 9 CFR 430 (IVT**)					
Microbial and Residue Sampling	# ESTs Eligible for Sampling	# Samples Targeted per EST (Intended Frequency)	# Samples Actually Requested Program wide	# Viable Samples Analyzed per Program wide	# Confirmed Positives Program wide
Salmonella in Young Chicken					
Salmonella in Young Turkey					
Salmonella in comminuted Chicken					
Salmonella in comminuted Turkey					
Campylobacter in Young Chicken					
Campylobacter in Young Turkey					
Campylobacter in Ground Chicken					
Campylobacter in Ground Turkey					
Salmonella in raw Ground Beef (HC01)					
Residue Directed					
Residue inspector Generated					
Food Chemistry					
			<u>, </u>	<u> </u>	
Other					

Names and addresses of all laboratories used: (attach additional sheets if needed) Name:

Address:

Phone number:

^{*}By August 1st of each year, FSIS will provide the *Guidance to States on Frequency of Microbiological Testing* to identify the minimum testing frequencies for small and very small establishments.

**Complete for State MPI program follow-up testing as a result of a positive sample.

Component 4: Staffing, Training, and Supervision

Criteria for "at least equal to" Determination

Each State MPI program needs to submit a current narrative describing the personnel management system used to staff State-inspected establishments, the training of State inspection program personnel, and the supervision of inspection and compliance enforcement activities.

State MPI programs need to submit any supporting documentation (preferably completed reports and documents) to show the system, as described in the narrative, has been implemented, is functioning as intended, and that the State MPI program remains "at least equal to" FSIS's Federal inspection program requirements for the next 12 months. State MPI program officials report the number of State-inspected establishments and number of State personnel performing duties, States can use the format of the *State MPI Program Establishment Count* (Attachment 5, page 59) and *State MPI Program Employee Primary Roles* (Attachment 6, page 60).

State MPI programs are required to be "at least equal to" FSIS's Federal inspection program. The Staffing, Training, and Supervision system at a minimum need to include the following criteria:

- Daily Inspection Coverage State MPI programs provide and maintain inspection coverage at State inspected meat and poultry establishments every day the State inspection marks are applied to products; at least once per shift at processing establishments and inspection on the line during all slaughter operations.
- Employee Training State MPI programs provide MPI employees with sufficient knowledge, skills, and training that provide them with the ability to carry out State meat and poultry inspection and compliance enforcement duties in a manner that is "at least equal to" FSIS's Federal inspection program.
- Supervision State MPI programs provide direction to daily State inspection and compliance enforcement activities performed by State MPI program personnel.

Outcome

When objectively reviewed by FSIS, the State MPI program is determined to be "at least equal to" FSIS's Federal inspection program in its staffing, training, and supervision systems.

The State MPI program needs to have:

 State inspectors that perform inspection activities at State inspected meat and poultry establishments, as required by State laws to ensure only safe, wholesome, not adulterated, properly marked, labeled and packaged meat and poultry products receive the State mark of inspection.

- Trained State inspection program personnel capable of applying State MPI program methods and procedures in accordance with applicable State laws, regulations and directives, and are capable of making sound decisions based upon facts and evidence.
- State MPI program managers and supervisors who can objectively evaluate the effectiveness of implemented program systems and competency MPI of State MPI program personnel

"At least equal to" Requirements

The State MPI program needs to maintain:

- A Staffing System,
- A Training Program, and
- A Supervisory System.

NOTE: State MPI program Directors need to submit the data integrity information for the data collected and maintained in a system used in place of PHIS. The data integrity information should include:

- The type of data maintained in the system used in place of PHIS (e.g., FSAs, custom exempt reviews, NOIEs).
- How the data integrity is maintained (e.g., restriction to access the data, ability to track data changes).
- The State law or administrative rules governing the security and integrity preservation of meat and poultry inspection program records.

Staffing System

The State MPI program needs to maintain a staffing system which periodically assesses the State's personnel needs required to meet the organizational objectives and public health goals. As priorities and needs shift, the State MPI program should be capable of considering changing factors when creating inspection assignments. State MPI programs also should be able to modify staffing policies to accommodate inspection demands of State inspected meat and poultry facilities without compromising the State MPI program's staffing objectives.

Objective

To provide daily inspection coverage at State meat and poultry establishments to ensure that only safe, wholesome, not adulterated, properly marked, labeled and packaged meat and poultry products receive the State mark of inspection.

Staffing System methods and procedures

State MPI programs need to implement staffing methods "at least equal to" those of FSIS's Federal inspection program. Staffing methods and procedures at a minimum should include:

- Methods to determine the workload (e.g., complexity of State inspected establishment operations, distances between establishments, availability of inspection personnel) of inspection assignments (i.e., single establishment, multiestablishment assignments) and ensure daily inspection coverage is provided at all establishments producing products under the marks of inspection
- Methods to verify inspectors perform required inspection activities on the scheduled inspection days:
 - Procedure to analyze staffing data for trends in missed inspections
 - Procedure to verify regulatory compliance at an establishment that applies marks of inspection to products on a day when State MPI program personnel miss a scheduled inspection
 - Procedure for providing inspection services (i.e., relief coverage) at an establishment when the assigned inspector is absent from duties
- Methods to assess whether staffing successfully meets the State MPI program management's expectation for:
 - Creating State inspection assignments
 - Verifying performance of scheduled and missed State inspection activities
 - Scheduling relief coverage for State inspection assignments

Evidence of System Application

A State MPI program needs to provide evidence to demonstrate the implementation of a State staffing system that is "at least equal to" that of FSIS's Federal inspection program. At a minimum, the State MPI program should submit:

State staffing documentation (e.g., calendars, inspection activity logs, daily
inspection assignments) to support they maintain inspection coverage on each
shift at each State inspected establishment on days when the marks of
inspection are being applied to products. The documentation should identify any
changes made to inspection assignments to accommodate for annual and
emergency leave taken.

- Follow-up documents confirming food safety requirements are met at State inspected establishments on days when products receiving the marks of inspection are produced and the State MPI program is unable to provide inspection services
- Information regarding the number and types of State inspected establishments currently operating under the State MPI program in a plain language format (see the suggested table, *State Establishment Count*, at the end of this section)
- Information identifying, by job description, the number of State employees who currently perform duties for the State MPI program in a plain language format (see the suggested table, *State MPI Employee Primary Roles*, at the end of this section)
- A current organization chart identifying all State personnel who carry out aspects of the State meat and poultry inspection at all program levels. The State organization chart should include any personnel who are employed by other State programs outside of the State MPI program to assist in accomplishing their mission. In addition, the organizational chart should show supervisory boundaries and reporting lines of all State personnel involved. The submission of an organizational chart can provide the FSIS audit team with a clear understanding of how each State MPI program carries out its daily operational and administrative functions.

Training Program

Training and development of employees are key elements to the success of any organization. FSIS invests a considerable amount of time and resources in improving the skills of their workforce. State MPI programs need to have a State program in place to meet the training and development needs of their employees in a manner that is comparable to FSIS's Federal inspection program.

Objective

To provide the necessary knowledge, skills, and abilities, through formal and informal training, to ensure personnel can successfully complete inspection and other critical job duties.

Training System

The training system should include methods that provide State MPI program employees with both formal and informal learning experiences that contribute to individual growth and improved performance in their assigned positions. Formal training courses should be developed to provide employees with sufficient knowledge, skills, and the ability to carry out State meat and poultry inspection or enforcement duties in a manner that is "at least equal to" FSIS's Federal inspection program. The training methods and procedures at a minimum should address:

- Inexperienced and newly hired employees in performing the specific job positions of the State MPI program
- Ongoing professional and skill development for current employees (e.g., AgLearn courses, field workshops, professional conferences, on-the-job training)
- Core inspection activities (e.g., ante-mortem inspection, humane handling, postmortem inspection, pathogen reduction/HACCP, Sanitation SOPs, Sanitation Performance Standards, Inspection Methods)
- Core compliance enforcement activities (e.g., surveillance, follow-up surveillance, investigation, evidence collection, case development, compliance sample collection)
- Training needs of all State employees who perform MPI program related duties
- Testing criteria used to determine if employees have mastered the objectives and concepts of training courses
- Standards for evaluating the competency of State MPI program trainers
- Techniques for determining whether training activities meet the State MPI program management's expectations for:
 - Newly hired and inexperienced employees
 - Experienced employees
 - Core inspection activities
 - Core compliance enforcement activities
 - Assessment of training needs for all State MPI program employees

Evidence of system application

A State MPI program needs to provide evidence that demonstrates implementation of a training system "at least equal to" FSIS's Federal inspection program. At a minimum, the State MPI program should submit:

- A list of training courses offered to State MPI program personnel
- Training certificates for employees' training completed within the last 12 months
- Tracking logs (e.g., personnel, training class, circuit)
- Management's evaluation and results of State training system performance

Supervisory System

A State MPI program needs to maintain a State supervisory system that aligns individual work with its public health and regulatory goals, and ensures recognition of strong performance and correction of unsatisfactory performance. State MPI program managers should adopt or create policies that encourage employee development and strengthen workforce competency.

Objective

To implement an effective State MPI inspection program, the program managers should establish and effectively communicate clear and measurable employee performance standards, analyze performance results and trends, provide unbiased feedback to assess individual performance, and manage resources.

<u>Supervisory Methods and Procedures</u>

State MPI programs need to implement supervisory methods "at least equal to" those of FSIS's Federal inspection program to ensure effective implementation of the program's public health and regulatory obligations. The supervisory methods and procedures at a minimum should include:

- Methods and procedures used in developing policies for the State MPI program's critical inspection and compliance activities:
 - Methods and procedures to draft and distribute policies in a timely manner to all State MPI program personnel
 - Methods and procedures to assess FSIS issuances (i.e., FSIS Directives, Notices, and Compliance Guidelines) for applicability to the State MPI program
- Methods and procedures to evaluate job performance and competency of State MPI program personnel during their probationary periods (if applicable)
- Methods and procedures to evaluate job performance and competency of all State MPI program personnel to verify all State MPI program policies are implemented (e.g., IPPS, OPPS, annual performance appraisals)
- Methods and procedures to measure and analyze implementation of new and existing State MPI program policies and instructional documents for inspection and compliance activities
- Techniques for determining whether State supervisory activities meet the State MPI program management's expectation for:
 - Distribution and implementation of State MPI program policies
 - Employee performance feedback

Evidence of System Application

A State MPI program needs to provide evidence that demonstrates the implementation of supervisory methods and procedures "at least equal to" FSIS's Federal inspection program requirements. At a minimum, the State MPI program needs to submit:

 Letters, instructions, memoranda of interview or data tracking logs documenting the distribution and implementation of State MPI program policies regarding critical inspection and compliance enforcement activities • Completed evaluations of performance standards and results of trend analyses (i.e., reasons why policies are not effectively implemented by State IPP)

Completed performance and competency evaluation documents (redacted if necessary) for program employees (e.g., annual performance appraisals, IPPS reviews) States may use the tables below to submit this information.

State MPI Program Establishment Count Suggested Format

Name of State Agency:			As of Date:				
Instruction	In the section below, list each establishment only once. If the establishment performs multiple processes, identify the best category that encompasses all the establishment processes.						
	Establishment Type	Slaughter Only	Processing Only	Combination Slaughter and Processing	TOTAL		
Number of State Inspected Establishments	Meat Only						
<u> </u>	Poultry Only						
	Combination Meat and Poultry						
	TOTAL						
Number of Exempt Establishments	Meat Only						
	Poultry Only						
	Combination Meat and Poultry						
	TOTAL						
Number of CIS, TA, or CU Establishments	Meat Only						
Establishinents	Poultry Only						
	Combination Meat and Poultry						
	TOTAL						
Damanha							
Remarks:							

State MPI Employee Primary Roles Suggested Format

Name of State Agency:		As of Date:			
# State MPI employees		Total:			
Instruction	In the section below, lis	t each em	plovee onl	y once. If the employee has multiple	
	roles, identify the emplo	oyee unde	r their primary role only and provide details of		
	additional roles in the a				
	Employee Roles	Full	Part	Comments	
		time	time		
Headquarters/	Managers				
Central Office	Administrative				
	EIAOs				
	VMO/PHVs				
	Other				
Circuit/Area/	Field Supervisors				
District/Etc.	VMO/PHVs				
	Other				
In-Plant State	VMO/PHVs				
Inspection	Inspectors				
	Relief				
	Other				
010 011 TA	\/N 4 G / D \/	l			
CIS, CU, or TA	VMO/PHVs				
Inspection	Inspectors				
	Relief				
	Other				
Compliance Program	Managers				
Compliance i rogiam	Compliance Officers				
	Other				
	Oulei				
Remarks:		<u> </u>	<u> </u>		

Component 5: Humane Handling

Criteria for "at least equal to" Determination

Each State MPI program needs to submit a current narrative describing the State verification system used to enforce all applicable laws, regulations, and FSIS policies. The system should have the capability to correct any deviations from regulatory requirements that may affect its program being "at least equal to" FSIS's Federal inspection program in its humane treatment of animals.

State MPI programs should submit supporting documentation (e.g. completed reports and documents) to show the State verification system (as described in the narrative, has been implemented) is functioning as intended, and ensures that the State MPI program remains "at least equal to" FSIS's Federal inspection program over the next 12 months.

State verification methods and procedures provided under a State MPI program are "at least equal to" the FMIA, PPIA, HMSA, FSIS Directives and Notices, Federal Register publications, regulations, and other applicable policies provided under FSIS's Federal inspection program in its humane treatment of animals and good commercial practices with poultry. At a minimum, the humane handling system should include the following criteria:

- Humane Slaughter A State MPI program verifies all livestock are slaughtered in accordance with one of two humane methods specified in the HMSA or applicable State laws.
 - The first humane method requires that livestock be rendered insensible to pain on the first application of the stunning device before being shackled, hoisted, cast, or cut.
 - The second humane method is in accordance with the ritual requirements of any religious faith that prescribes a method of slaughter where the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument.
- In addition, State IPP are to verify State inspected establishments that slaughter poultry follow good commercial practices described in 9 CFR 381.

Outcome

When objectively reviewed by FSIS, the State MPI program is determined to be "at least equal to" FSIS's Federal inspection program in its humane treatment of animals.

A State MPI program has capabilities to ensure State inspected establishments humanely handle all livestock presented for slaughter and follow good commercial practices when poultry are slaughtered and processed on premises.

"At least equal to" Requirements

The State MPI program is required to maintain

A Humane Handling Verification System.

NOTE: State MPI program Directors need to submit data integrity information for the data collected and maintained in a system elected in place of PHIS. The data integrity information should include:

- The type of data maintained in the elected data system in place of PHIS (e.g., FSAs, custom exempt reviews, NOIEs
- How the data integrity is maintained (e.g., restriction to access the data, ability to track data changes)
- The State law or administrative rule governing the security and integrity preservation of State meat and poultry inspection program records

Objective

To implement State verification activities that ensure State inspected establishments are humanely handing all livestock when presented for slaughter, follow good commercial practices when poultry are slaughtered, and comply with applicable State laws, rules, and policies.

Humane Handling Verification System methods and procedures

State MPI programs need to implement State slaughter verification methods and procedures "at least equal to" those of FSIS's Federal inspection program in the humane treatment and handling of animals and good commercial practices with poultry. The methods and procedures at a minimum should include:

- Methods to schedule and record humane handling tasks, and document noncompliance with the requirements consistent with 9 CFR 313
- Procedures to verify whether State inspected establishment personnel humanely handle all livestock presented for slaughter throughout the time they are on establishment premises
- Methods to conduct and document humane handling verification reviews (e.g., District Veterinary Medical Specialist (DVMS) reviews) at livestock establishments and conduct poultry good commercial practices reviews at poultry establishments
- Methods to assess whether slaughter verification activities successfully meet the State MPI program management's expectation for:
 - In-Plant Level Slaughter Verifications
 - Humane handling

- Good commercial practices
- Noncompliance regulatory documentation
- Enforcement actions
- Central Office Level Assessments
- Humane handling oversight
- Administrative case development
- Program personnel competency

Evidence of System Application

A State MPI program needs to provide evidence that demonstrates the implementation of a slaughter verification system "at least equal to" FSIS's Federal inspection program in the humane treatment and handling of animals and good commercial practices with poultry. At a minimum, the State MPI program should submit:

- Documentation of regulatory control, withholding, suspension, enforcement, or administrative actions taken when humane handling noncompliance is identified (e.g., NRs, 30 day letters, NOIE Letters, Suspension letters, notification to withhold the marks of inspection)
- Humane handling verification reviews (e.g., DVMS analogous reports, in-depth supervisory establishment reviews)
- Management's evaluation and results of humane handling verification system performance

Component 6: Compliance

Criteria for "at least equal to" Determination

Each State MPI program needs to submit a narrative describing the State's compliance system used to enforce all applicable laws, regulations, and FSIS policies, and takes appropriate enforcement action in the event that misbranded or adulterated product is identified in commerce.

The US Code Title 21, Sections 643, 644, 645 and 460 require businesses to register with the Secretary of Agriculture. FSIS compliance conducts surveillance reviews at these registered firms which may lead to investigations and enforcement actions. Under 21 U.S.C. 661 and 454, FSIS expects the States to impose "at least equal to" FSIS's Federal inspection program assurances that affected individuals, firms, and corporations are complying with applicable State statutes when producing, transporting, storing, and distributing meat and poultry products in intrastate commerce. The State MPI program's narrative should address and cite the State MPI program's statutory authority for performing surveillance reviews, investigations, and taking enforcement actions at the following business types:

Distributors 3D/4D operators Institutions

Warehouses Salvages Restaurants

Food banks Animal food Retailers

Brokers Renderers

Transporters Exempt poultry

If the State MPI program is not granted statutory authority under State law to review, investigate, or take enforcement actions for any of the business types above, the narrative should identify the State agency with the State's statutory authority and cite the applicable statute. The narrative should also describe how the State MPI program cooperates with the authorized State agency when meat and poultry products are involved in the surveillance reviews, investigations, and enforcement actions. State MPI program officials may provide the narrative information in the plain language format of the *Summary of Statutory Authority per Business Type*, (Attachment 7, page 69) or another format. FSIS identifies the State MPI program as the State Agency responsible for coordinating with other State agencies to ensure all applicable compliance activities outlined in the guidelines comply with specified laws, regulations, and policies. This includes State or contract laboratories, health departments, law enforcement, State human resources division, and other State regulatory agencies.

State MPI programs need to submit supporting documentation to demonstrate the compliance system, as described in the narrative, has been implemented and is functioning as intended, to ensure that the State MPI program remains "at least equal to" FSIS's Federal inspection program in its compliance activities over the next 12 months. State MPI program officials may provide a report on compliance activities in a

plain language format of the *Compliance Activity Report* (Attachment 8, page 70) or in another format.

State MPI programs are "at least equal to" the Federal inspection program in its compliance system activities. Compliance system activities need to include the following criteria:

- Surveillance State MPI compliance investigators conduct surveillance of persons, firms, and corporations operating in intrastate commerce who are subject to the provisions of the FMIA, PPIA, HMSA, 9 CFR, or State laws as applicable.
- Investigation State MPI compliance investigators conduct investigations of apparent violations, food safety incidents, or other allegations or incidents using the FMIA, PPIA, HMSA, 9 CFR, or State laws as applicable.
- Product Control Action State MPI compliance investigators take appropriate control of product found in intrastate commerce that may be adulterated, misbranded, or has not received the mark of inspection, and ensure proper disposition of such product (e.g., detention, seizure, condemnation, destruction).
- Case Development and Referral The State MPI compliance program is to include case development and referral mechanisms to take criminal, civil, and administrative enforcement actions, including sanctions, when firms and individuals violate Federal and State statutes. The State MPI compliance program recommends cases of criminal and civil violations for prosecution by the State legal system, or refers them to USDA, FSIS, OIEA, and CID for action.

Outcome

When objectively reviewed by FSIS, the State MPI program is determined to be "at least equal to" FSIS's Federal inspection program in its compliance activities.

The State MPI program has:

- Assurances that affected individuals, firms, and corporations are complying with applicable State statutes or the Federal Acts when producing, transporting, storing, and distributing meat and poultry products in intrastate commerce
- Documentation of surveillance activities, investigations, and enforcement actions (i.e., including sample collection that supports administrative, civil or criminal actions imposed against individuals or firms that have violated the State's laws)

"At least equal to" Requirements

The State MPI program is expected to maintain:

A Compliance System

NOTE: State MPI program Directors need to submit the data integrity information for the data collected and maintained in a system elected in place of PHIS. The data integrity information should include:

- The type of data maintained in a State compliance system elected in place of PHIS (e.g., Review and Compliance Records, LOW, ROIs, physical evidence).
- Where the State compliance data is stored (e.g., server name, name of SharePoint or share drive, hard copy file cabinet).
- How the State compliance data integrity is maintained (e.g., restriction to access the data, ability to track data changes).
- The State law or administrative rule governing the security and integrity preservation of meat and poultry inspection program records.

Compliance System

The State MPI program needs to maintain a compliance system to investigate violations of food safety, food defense, and other consumer protection statutory requirements, and controls unsafe or violative products through detentions, seizures, and voluntary recalls. State MPI program managers should create or adopt State compliance policies for conducting surveillance and investigation activities, and the development of cases to ensure the imposition of criminal, administrative, and civil enforcement actions are in accordance with State laws.

<u>Objective</u>

To ensure State MPI program's compliance activities are carried out in accordance with applicable State laws, rules and policies, ensuring all State inspected meat and poultry products found in intrastate commerce are safe, wholesome, not adulterated, properly marked, labeled and packaged and all enforcement actions imposed are legally supported.

Compliance Methods and Procedures

State MPI programs need to implement compliance methods "at least equal to" those of FSIS's Federal inspection program's compliance activities. The compliance methods and procedures should include:

- Methods for conducting State surveillance and follow-up surveillance of individuals, firms and corporations operating in intrastate commerce subject to State laws, regulations and policies pertaining to meat and poultry inspection program
 - Procedures to prioritize State surveillance resources on intrastate commerce businesses with the highest public health risk

- Procedures to determine the collection of raw ground beef samples for E. coli O157:H7 testing as part of the intrastate commerce surveillance activities at retail stores
- Methods for conducting investigations of apparent violations, food safety incidents, other allegations or incidents subject to State laws, rules, and policies pertaining to the State meat and poultry inspection program
 - Procedures for State MPI program compliance investigators to collect, safeguard, and dispose of evidence in the performance of surveillance, investigations and other activities subject to the State laws, rules, and policies pertaining to the State MPI program
 - Procedures for State MPI program compliance investigators to follow when detaining or in preparation for seizing meat and poultry products found in intrastate commerce, when there is reason to believe that the products are adulterated or misbranded
- Methods for preparing a report (e.g., Report of Investigation (ROI)) to support findings of apparent violations, food safety incidents, or other allegations subject to the applicable State laws
 - Procedures for the evaluation of case documents to support appropriate criminal, civil, or administrative enforcement actions (e.g., letters of warning, consent orders, fines, penalties, hearings)
- Methods for the State MPI program to determine whether to recommend a product recall
- Methods for documenting, prioritizing, and investigating consumer complaints directly related to State inspected meat and poultry products
- Methods to assess whether compliance activities successfully meet the State MPI program management's expectation for:
 - Surveillance
 - Investigation
 - Documentation and reports
 - Product recall
 - Consumer complaints
 - Compliance personnel competency

Evidence of System Application

A State MPI program needs to provide evidence demonstrating the implementation of a compliance system that is "at least equal to" FSIS's Federal inspection program in its compliance activities. The State MPI program should submit:

 Documentation and tracking logs for surveillance and follow-up surveillance activities of State MPI program compliance officers

- Retail and investigative product sample results
- Complete case files that include reports of investigation, evidence collected, notices of detention, notices of seizure, letters of warning, fines, consent orders, and documentation from legal proceedings.
- Evidence preservation and chain of custody verification documents
- Recall effectiveness checks, public notification of recalls, and other related documentation
- Documentation and tracking logs for consumer complaints
- Documentation and communications for surveillance reviews, investigations, and enforcement actions for the business types where the State MPI program is not granted statutory authority
- Management's evaluation and results of compliance system performance

States can use the tables below to provide this information.

State MPI Program Summary of Statutory Authority per Business Type Suggested Format

Name of State Agency:		Time Period Covered:			
Name of State Agency.		Time I chou dovered.			
Instruction:	List the State agency or program that is granted statutory authority to review, investigate or take enforcement actions for the business types listed. Cite the applicable statute that grants that authority, and describe how the State MPI Program cooperates with the authorized agency. (E.G., a State MPI program may not have authority at retail stores in the State because another State agency has the authority). The State MPI program should provide in this chart the applicable laws State laws and the name of the State agency that has the authority to enforce the laws.				
Business Type	State Agency Granted Authority and Statutory Citation		PI Program Cooperation with the zed Agency (if applicable)		
Distributors					
Warehouses					
Transporters					
3D/4D operators					
Salvages					
Renderers					
Food banks					
Exempt poultry					
Restaurants					
Retailers					
Institutions					
Animal food					
Brokers					
Remarks:					

Compliance Activity Report Suggested Format

Name of State Agency:		Time Period Covered:			
Compli	TOTAL NUMBER				
Surveillance per FSIS Directive 8010	.1				
Distributors, Warehouses, and T	ransporters				
3D/4D Operators, Salvages, Ren	derers, Food B	anks, and Exempt Poultry			
Restaurants, Retailers, Institution					
Processor, Port-of-Entry, Bonded	d Area, Broker,	and Miscellaneous			
Surveillance Follow-ups					
Violation Cases or Investigations					
Referrals to FSIS					
Letters of Warning					
Administrative Hearings					
Consent Orders					
Court Actions or Prosecutions					
Consumer Complaints					
State Recalls					
Effectiveness Checks					
Registrations of Meat and Poultry Ha	ndlers				
Miscellaneous Actions / Special Proje	ects / Personal	Contacts (Please itemize)			
Detentions	TOTAL NUMBER	Laboratory		TOTAL NUMBER	
Number of Detentions		Retail Ground Beef samples p Directive 8010.1	er FSIS		
Pounds of Product Detained		Investigative Samples (other the retail ground beef)	nan		
Pounds of Product Released					
Pounds of Product Donated					
Pounds of Product Condemned					
Pounds of Product Voluntarily					
Destroyed					
Remarks:					

Component 7: Laboratory Methods and Quality Assurance Program

Criteria for "at least equal to" Determination

State MPI programs need to have product sampling and laboratory methods with capabilities and safeguards that are "at least equal to" FSIS's Federal inspection program's product sampling and laboratory methods. State MPI programs should update and maintain their laboratory microbiological and chemical detection methods so they are "at least equal to" FSIS's Federal inspection program methods as detailed in the FSIS Microbiology Laboratory Guidebook.

To achieve and maintain "at least equal to" laboratory methods, each State MPI program should meet the criteria in the following areas:

- Laboratory Quality Assurance programs
- Laboratory Testing Methods

Outcome

When objectively reviewed by FSIS, the State MPI program is determined to be "at least equal to" FSIS's Federal inspection program in Laboratory methods.

FSIS integrates ongoing documents and on-site reviews of the applicable analytical methods in its annual comprehensive review of State MPI programs. FSIS determines if a participating State MPI testing program is "at least equal to" the corresponding FSIS Laboratory testing program.

"At least equal to" Requirements

Sampling methods need to provide analytical results "at least equal to" corresponding FSIS testing programs. Each State MPI program should provide documentation through self-assessment and on-site review to demonstrate that its program includes the following:

1. Laboratory Quality Assurance (QA) Programs

State MPI program laboratories, or contract laboratories, should have an appropriate QA program "at least equal to" the methods of FSIS's laboratories to ensure the reliability and integrity of analytical results. State MPI program laboratories, or contract laboratories, should ensure that each laboratory meets the criteria outlined in the FSIS MPI Program Laboratory Quality Management System Checklist.

A laboratory QA program assessment consists of the following:

 Assurances for sample integrity and identity. Laboratories that analyze samples for State MPI programs maintain procedures to ensure that samples are not compromised within the laboratory. These procedures include a documented

- chain of custody as well as traceability to the sample, equipment, and critical supplies used to analyze the sample.
- Demonstrated confidence in test results and an assurance that it does not resample or re-test pathogen-positive and non-compliant products
- Documented program of quality control procedures and an assurance that these procedures are followed
- Properly trained personnel; suitable facilities and equipment; and verified, calibrated, and maintained equipment in a manner consistent with international norms (e.g., European co-operation for Accreditation (EA) 04/10 or Analytical Laboratory Accreditation Criteria Committee (ALACC) guidance)
- Appropriate proficiency testing schemes for food analysis
- Use of validated method protocols
- Reporting and recordkeeping capabilities that track and link a test result to the correct establishment

2. Laboratory Testing Methods

Methods used in support of the State MPI program should be validated for the product type sampled and are to be "at least equal to" FSIS's laboratory requirements. State MPI programs should provide documentation necessary to explain the methods used and the scientific basis for their selection. Such documentation should include detailed testing method protocols, supplemental testing procedures, and evidence of method validation and sustained proficiency testing for microbiology methods and sustained proficiency testing for chemistry methods. Evidence of analyst training in each subject method should be provided. Method assessment by FSIS considers the following:

Microbiology

- Methods of analysis are designed to detect the lowest possible level of stressed pathogens from State inspected meat, poultry, and environmental samples in accordance with current FSIS testing programs for each pathogen (e.g., the method includes an enrichment step, adequate enrichment time, immunobead capture step for *E. coli*)
- Methods of analysis are validated through an experimental study. When methods are modified, it may be necessary to conduct a supplemental validation against a reference method (e.g., USDA FSIS Microbiology Laboratory Guidebook (MLG), FDA Bacteriological Analytical Manual, or International Organization for Standardization (ISO) Standards). For validation studies conducted outside Association of Analytical Communities (AOAC), Association Française de Normalisation (AFNOR), the French national organization for standardization, or similar organizations, refer to FSIS Guidance for Test Kit Manufacturers, Laboratories: Evaluating the Performance of Pathogen Test Kit Methods at:

http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e-4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJPERES

- Methods of analysis detect the same pathogens as the corresponding FSIS MLG method. Alternative methods are inclusive for strains defined as positive by the biochemical, genetic, and serological confirmation tests described in the FSIS MLG.
- Methods of analysis use appropriately-sized test portions or sampling methodology and frequency for samples offering enhanced opportunity for detecting foodborne pathogen contaminations. Information on the test portions used for FSIS testing programs is available at the USDA FSIS Microbiology Laboratory Guidebook website at the following link:
 - http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook/microbiology-laboratory-guidebook
- Each method includes culture confirmation testing using a validated method. If additional non-validated confirmatory tests are performed by the laboratory, those tests are not be relied upon to invalidate the previous results.
- Shipping enrichments to a second confirmatory laboratory is avoided.

FSIS guidance for evaluating microbiological testing methods are found in the Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory at the following link at:

http://www.fsis.usda.gov/wps/wcm/connect/464a4827-0c9a-4268-8651b417bb6bba51/Guidance-Selection-Commercial-Private-Microbiological-Testing-lab-062013.pdf?MOD=AJPERES

Food Chemistry

- Methods of analysis are capable of measuring food chemistry components as a
 percentage of sample weight. Moisture, protein, fat, and salt are included. FSIS
 conducts limited food chemistry analysis of products at official establishments
 when in-plant inspection personnel believe the product is misbranded.
- Acceptable methods of analysis are available on the USDA FSIS Chemistry Laboratory Guidebook website at:
 - http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/chemistry-laboratory-guidebook/chemistry-laboratory-guidebook
- AOAC Official Methods of Analysis for food chemistry are also acceptable.
- Alternative methods for food chemistry analysis are acceptable if they measure the same components with sufficient accuracy. Evidence to support the use of

an alternative method includes proficiency-testing data generated by the State MPI program laboratories or contract laboratories completing the analysis.

The FSIS Accredited Laboratory Program (ALP) provides proficiency-testing services for food chemistry. For further information, visit the following link:

http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/accredited-laboratories/accredited-laboratories

Residue

 Information on in-plant screening of residues in meat and poultry products is available at:

<u>FSIS Directive 10,800.1, Residue Sampling, Testing and Other Verification</u>

<u>Procedures Under the National Residue Program For Meat and Poultry Products</u>

NOTE: The results of laboratory analyses are reported simultaneously to the State MPI program and the establishment.

Submission of Laboratory Methods and Quality Assurance Records

State MPI programs need to submit a list of current State laboratory and contract laboratory test methods along with copies of new or revised methods of Standard Operating Procedures (SOPs) on or before November 1 as part of the annual self-assessment submission process and whenever their methods are changed throughout the year. Submission of revised test method SOPs should be submitted on the *Laboratory Method Notification Form* available at:

FSIS Form 5720-15, Laboratory Method Notification Form

State MPI programs should submit a completed State Meat and Poultry Program Laboratory Quality Management System Checklist form available at:

FSIS Form 5720-14 - State Meat and Poultry Inspection Program Laboratory Quality Management System Checklist

NOTE: States may also submit the information on another easy to read format.

State and contract laboratories accredited to ISO 17025, with all applicable methods under their scope of accreditation, should provide current certificates of accreditation and only complete applicable portions of the QA checklist. They should also provide the list of method SOPs along with any updated copies of methods new or revised since the previous year's submission.

The State MPI programs may contract with a laboratory that meets the same requirements and are to ensure that the contract laboratory submits the same documentation as described for State MPI program laboratories.

In the submission, State MPI program Directors should divide the document submissions into Microbiology methods, Chemistry methods, and QA records. All three sections should be submitted electronically to the FSIS Outlook mailbox: Statelabinquiry@fsis.usda.gov

NOTE: The subject line for all submissions to the FSIS Outlook mailbox should contain the name of the applicable State MPI program to allow efficient routing to assigned FSIS personnel.

If hard copies need to be submitted, please mail them to the following address:

Director, USDA, FSIS, OPHS, Laboratory Quality Assurance Staff 950 College Station Road Athens, Georgia 30605

On-Site Review of Laboratory Methods and Quality Assurance Records

The State MPI program laboratories and their contract laboratories are subject to periodic record and on-site reviews by FSIS to evaluate the QA program in comparison to submitted self-assessments and to verify the accuracy and implementation of the laboratory methods.

Records related to FSIS laboratory reviews are submitted to the FSIS Outlook mailbox: Statelabinguiry@fsis.usda.gov

Component 8: Civil Rights

Criteria for Review Determination

The State MPI programs need to provide accurate documentation to demonstrate that they are operating and will continue to operate in a manner that is "at least equal to" FSIS's Federal inspection program requirements for the next 12 months.

The State MPI program:

- · Complies with Federal civil rights laws;
- Complies with USDA civil rights regulations; and
- Achieves the intended outcome.

Outcome

State MPI programs need to be conducted in a manner that respects civil rights, ensures a non-discriminatory environment, and complies with the laws and regulations cited below.

Civil Rights authorities

State MPI programs should comply with the following civil rights laws, regulations, and policies:

Statutory

- Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000(d) (discrimination on the basis of race, color or national origin)
- Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794 (discrimination on the basis of disability)
- Age Discrimination Act (ADA) of 1975, 42 U.S.C. 6102 (discrimination on the basis of age)
- Title IX of the Education Amendments of 1972, 20 U.S.C. Section 1681 (discrimination on the basis of sex)

Regulatory and Executive Orders

- 7 CFR Part 15 Subpart A, Non-discrimination in Federally Assisted Programs
- 7 CFR Part 15 a, Education Programs or Activities Receiving or Benefitting from Federal Financial Assistance
- 7 CFR Part 15 b, Non-discrimination on the Basis of Disability Programs and Activities Receiving Federal Financial Assistance
- 45 CFR Part 91, Non-discrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance from HHS
- Executive Order 13166 on Limited English Proficiency, dated August 11, 2000

Departmental and Agency Policies

- USDA Regulation 4330-002, dated March 3, 1999, Non-discrimination in Programs and Activities Receiving Federal Financial Assistance from USDA
- USDA Regulation 4300-3, dated November 16, 1999, Equal Opportunity Public Notification Policy
- FSIS Directive 1510.1, Equal Opportunity Notification on Material for the Public, dated January 25, 2001

 FSIS Directive 5720.3, Revision 1, dated March 14, 2011, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs; and "At Least Equal to" Guidelines for State Meat and Poultry Cooperative Inspection Programs, dated July 2008

The statutes, regulations and policies listed above prohibit discrimination on the basis of a person's race, color, religion, sex (including gender identity, sexual orientation, and pregnancy), national origin, age (40 or older), disability or genetic information. It is also illegal to retaliate against a person for complaining about discrimination, filed a charge of discrimination, or participating in an employment discrimination investigation or lawsuit. Acceptance of annual Federal financial assistance under State/Federal Cooperative agreements triggers Title VI, Section 504, of the Americans with Disabilities Act (ADA). Title IX covers and authorizes compliance reviews of federally assisted program delivery (not employment practices that fall under EEO).

Areas of review

1. Civil Rights Assurances

Requires the State to submit written assurances that its Federally assisted programs and activities are conducted in compliance with Title VI and other non-discrimination authorities.

2. State Infrastructure and Program Accountability

Requires that State MPI programs identify individuals and offices responsible for ensuring program accountability and its compliance with civil rights laws, regulations, policies and guidelines.

3. Public Notification

Requires that all State MPI programs include a public notification system to inform applicants, participants, and potentially eligible persons of program availability, program rights and responsibilities, the program's policy of non-discrimination, and the procedures for filing a complaint.

4. Racial and Ethnic Data Collection and Reporting

Requires the State to obtain race and ethnic data on potentially eligible populations, applicants, and participants in their program service area.

5. Complaints of Discrimination

Assesses the complaint procedures for all complaints alleging discrimination in the delivery of State MPI programs on the basis of race, color, national origin, disability, age and sex.

NOTE: Complaints can be processed through State procedures or can be reported directly to USDA for processing.

6. Civil Rights Training

Requires State to ensure all employees involved in administering Federally-assisted MPI programs understand their obligations under civil rights related laws, regulations, procedures, and instructions.

7. Disability Compliance

Requires that State agencies ensure equal access to State MPI program personnel with disabilities.

8. Limited English Proficiency

Requires that State MPI programs provide free language access services to potentially eligible applicants and program participants who are Limited English Proficient (LEP).

9. Compliance with the Age Discrimination Act of 1975

Requires Federal agencies to annually report on steps taken to enforce the Act, including non-employment related affirmative outreach actions of its recipients of Federal financial assistance.

<u>Instructions</u>

State MPI programs need to complete FSIS Form 1520-1, *Civil Rights Compliance of State Inspected Programs* (Attachment 9, page 79-80) or provide another easy to read format.

The self-assessment Form 1520-1 or format needs to be signed by the designated State Official (such as a Director, Commissioner or Secretary) who would be deemed appropriate and responsible for signing the State-Federal Cooperative agreement and the annual application for Federal financial assistance. Signing the form consents to the assurance that the State's MPI program is conducted in compliance with all Federal statutes relating to nondiscrimination. The completed form needs to be mailed (hard copy), with an original signature, to the FSIS Civil Rights Staff by November 1st each year.

Submission Address:

FSIS Civil Rights Staff 5601 Sunnyside Avenue, Mail Drop 5261 Beltsville, MD 20705-5261 Telephone: 800-269-6912

Fax: 301-504-2141 AskCRD@fsis.usda.gov

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Civil rights Compliance of State Inspected Programs

	U.S. DEPARTMENT OF AGRICULT FOOD SAFETY AND INSPECTION S			STATE NAME
				FEDERAL FISCAL YEAR
S	ECTION I. Cooperative Agreeme	ent(s) - Civil Rights	Assurance Stater	ment:
	ate cooperative agreements by number vil Rights Assurance Statement for each			icable. Attach a copy of the current
Meat and Poultry Insp	pection			
Egg Products Inspecti	ion			
 Talmadge-Aiken agre 	ement			
	SECTION II. Civil Rig		-	
	e, and contact information of person(s)	responsible for admin	istering the following.	
 Civil rights training 				
 Discrimination compla 	ints in program delivery (not employme	nt)		
 Americans with Disabil 	lities Act (ADA)/Section 504 Coordinate	r		
2. Employee performance standa	ards include a civil rights/non-discrimina	ation element		
	SECTION III.	Public Notification	n:	,
. Check locations where the US	DA Civil Rights Poster is displayed			
State Office	In-plant inspection	n office	Other (describe)	
The following must contain a r color, national origin, age or di	non-discrimination statement providing sability. Please check to confirm compl	notification that the insiance.	pection program will b	e conducted without regard to race,
Applications for inspec	ction Official letterhead		Internet webpage for	or meat/poultry program
Information/outreach	material provided to the public		Policy statement or	n nondiscrimination, anti-harassment
	SECTION IV. Dem	ographic Data Coll	ection:	
and report demographic data on i programs can utilize to collect dei 1) requesting demographic infor peneficiaries through visual identi	n (MPI) programs are required by the C ts beneficiaries and applicants. At pres mographic information directly from app matrices of the control of the control fication methods. Demographic data in tion or directly from applicants or beneficiaries.	ent, FSIS does not ha dicants and beneficiari eficiaries; and (2) gath hay be collected from	ve an approved data of es. Therefore, State Mering demographic inf	collection form that State MPI MPI programs are prohibited from: formation from applicants and

SECTION V. Discrimination Complaints:	
Have there been allegations of discrimination involving the delivery of inspection services to program beneficiaries or a lf yes, attach a copy of the complaint log, the incoming complaint, and the disposition. No	pplicants within the last year?
SECTION VI. Civil Rights Training:	
SECTION VII. Program Accessibility to Persons With Disabilities:	
1. Does the State provide facilities and program access to disabled persons regarding: (check all that apply)	
Placarded parking Cut/raised curbing Audio or braille equipped elevators Telecommunication Relay Service number posted on website Automated/assisted door entry Program materials in alternative formats upon request (large Website compliance with Section 508 standards	
SECTION VIII. Program Accessibility to Persons with Limited English Proficiency	(LEP):
Does the State have a current LEP plan in place?	÷
Have requests been made from applicants or program beneficiaries for language interpretation or translation services?	
SECTION IX. Compliance with the Age Discrimination Act of 1975:	
 Describe the State's participation in program outreach events and activities that reach various age populations. Report the status of pending corrective action item(s) by providing documentation to show full implementation or the state provide a separate attachment if additional space is needed. 	itus of actions in progress.
SECTION X. Compliance Review Corrective Actions:	
If a compliance review of the state was conducted during the fiscal year in question, please respond to the following question	tions:
When was the compliance review conducted?	
What is the status of any action(s) that have been taken to address the recommendation(s) that were made? If necess to demonstrate the progress made on action items.	eary, provide documentation
PRINT NAME AND TITLE OF STATE OFFICIAL SIGNATURE D.	ATE

Component 9: Financial Accountability

State MPI programs need to ensure State agency conformance with USDA 7 CFR Part 3016, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments (previously known as the Common Rule). State agencies should follow FSIS Directive 3300.1, Rev. 2, "Fiscal Guidelines for Cooperative Meat and Poultry Inspection Programs."

Criteria for Review Determination -- Certification for Component 9

The following actions are necessary to complete the Component 9 certification:

- 1. Timely submission of the annual budget to FSIS's Office of Field Operations (OFO) and submission of all data requested (See Section IX, Additional Resources, *Procedures for the Preparation of the Cooperative State Meat and Poultry Inspection Program Budget Submissions*, page 112)
- 2. Timely submission of annual indirect cost proposals to the applicable Federal Agency (due within six months after close of State fiscal year). Proposals are sent to the Financial Reviews and Analysis Section (FRAS) of the Financial Management Division (FMD).
- 3. Timely submission of Federal Financial Reports (SF 425) to FSIS. Quarterly Reports are due within thirty days after the close of each quarter (e.g., 4th Quarter SF 425 is due by October 30). The Final report is due within 90 days of the end of the Federal Fiscal Year (e.g., by December 30).
- 4. Timely resolution of all corrective action on financial findings pursuant to the onsite fiscal review

<u>Documentation Needed for On-site Financial Review</u> and are to be provided to FSIS auditors prior to the onsite financial review.

- State's centralized accounting reports containing State MPI program expenditures,
- Worksheets or schedules used to reconcile the centralized accounting reports to the SF 425,
- Manual adjustments made to the accounting report expenses (vehicle mileage, terminal leave payments, etc.),
- Monthly, quarterly, or final worksheets or schedules that were used to collect, adjust, calculate indirect costs, and summarize the total costs that were reported on the Expense Reports (SF 425) for the grant years indicated,
- A reconciliation by year of Federal Financial Reports and Federal Share of Expenditures with accounting records for grant years covered by the fiscal review.
- Application for Federal Assistance (Form 424) for the grants years covered by fiscal review,

- Expenditure chart accounts for the grant years covered by the fiscal review,
- Documentation for any other FSIS cooperative agreement renewals (e.g. Public Health Data Communication Infrastructure Systems (PHDCIS), Talmadge-Aiken Overtime (TAOT), Cross Utilization (CU), and Cooperative Interstate Shipping program (CIS) employee roster with the Employee Name, Job Title ID Number, Date of Hire Hourly, Bi-weekly, or Monthly Salary,
- Single or departmental audit reports,
- Detailed organizational chart with employee names,
- Equipment inventory list as defined by State requirements,
- Contractual agreements,
- Procedures for the "Preparation and Review of the Federal Financial Report",
- List of employee retirements/terminations by quarter (e.g. April-June) with disposition of annual and sick leave balances. This is only required if a State MPI program claims indirect costs and the State's centralized accounting reports do not have object codes for terminal leave payments), and
- List if applicable names of State inspected plants, inspectors and methods separate from cooperative MPI program reimbursable costs involved in voluntary programs, or 100% State Inspection (defined as inspection of the slaughtering and/or processing of animals that are not covered by the FMIA/PPIA).

The above documents are items that State agencies are to send to the FSIS auditors prior to the onsite financial review.

Instructions for Self-Assessment

The FRAS verifies the State MPI program's compliance with financial reporting requirements throughout the Federal fiscal year. Financial reporting compliance will be determined by FRAS as outlined in this section entitled "Criteria for review determination – Certification for Component 9."

If the State agency has satisfied the elements outlined in this section, the State agency will sign the Certification Statement for Component 9 (Attachment 10, page 85) and submit the signed certification statement to the appropriate contact in FRAS in order to completely satisfy self-assessment for Component 9.

If the State has not satisfied the elements in this section, the State agency complete the following:

• Submit any outstanding documents for Component 9 Certification to FRAS. For a list of required documents for Component 9 Certification see the section above titled *Criteria for review determination — Certification for Component 9.*

- Submit a letter to FRAS indicating the reasons for the State program's delinquency.
- Upon completion of steps (1) and (2), sign the certification statement at the end
 of the section entitled "Certification Statement for Component 9," and submit the
 signed certification statement to the appropriate contact in FRAS to completely
 satisfy self-assessment for Component 9.

Guidance

FSIS Directive 3300.1, Rev. 2, *Fiscal Guidelines for Cooperative Meat and Poultry Inspection Programs*, contains instructions for the preparation and submission of both the Annual Budget and SF 425. Additional guidance for the submission of SF 425, and Federal Financial Reports, is contained in USDA regulation 7 CFR Part 3016.40 (b)(1). State agency grantees maintain supporting documentation for their final SF 425, and Federal Financial Reports, for three years after submission (7 CFR Part 3016.42).

Additional guidance for the analysis of budget submissions is contained in the FSIS document, titled "A Guide for the Preparation of the Cooperative State Meat and Poultry Inspection program Budget Submissions," dated September 2004 "Guidelines for the preparation and submission of Indirect Cost Proposals are contained in OMB CircularA-87, Cost Principles for State, Local, and Indian Tribal Governments, Revised 5/10/04.

Annual Assurance Statements

FMD/FRAS and OFO provide annual assurance statements to the OIEA Federal/State Audit Branch by February 1st that the State agencies are current in the financial reporting activities required throughout the Federal Fiscal Year. OFO reviews and reports on matters associated with the submission of annual budgets. FRAS will review and report regarding the submission of annual Indirect Cost Proposals, submission of Quarterly and Final SF 425, Federal Financial Reports, and timely responses to financial review findings in the form of corrective action.

State agencies need to sign the certification statement and submit it to the appropriate contacts in the FRAS to completely satisfy self-assessment for Component 9.

Please follow the general mailing procedures and specific procedures for the listed financial documents:

- Email account for FRAS is: <u>FRAS@fsis.usda.gov</u>
- Physical location mailing address for FRAS is:

Financial Reviews and Analysis Section USDA/FSIS/OA/OCFO/FMD/FASMB 5601 Sunnyside Avenue, Mail Drop 5264 Beltsville, MD 20705-5264SF-425 Expense Reports Signed electronic copies are sent to the FRAS email address only.

NOTE: Please submit electronic SF 425 only. Do not send the SF 425 to the auditor in charge of the State Agency except as a carbon copy (cc).

Indirect Cost Rate Proposals (ICP)

Electronic ICPs are sent to the FRAS email address only.

NOTE: Please submit only electronic ICPs. Hard copies are to the FRAS physical location mailing address.

Billing Rate Proposals (CU/CE/EPI)

Electronic copies with signed cover letters are sent to the FRAS email address.

NOTE: Please submit electronic billing rate proposals only. Do not email any proposals to the auditor in charge of the State Agency except as a cc.

Certification Statement for Component 9

We, the State agency entitled, calendar year ending Component 9 entails compliance with the	for the understand that self-certification for following:
 Timely submission of annual budget to 	FSIS; submission of all data requested.
 Timely submission of annual Indirect C Agency (due within six months after clean 	Cost Proposal to the Applicable Federal ose of State fiscal year).
Reports are due within thirty days afte	Il Reports (SFs 425) to FSIS. Quarterly the close of each quarter (e.g., 4 th Quarter hal report is due within 90 days of the end of mber 30).
Timely resolution of all financial finding	gs pursuant to the onsite fiscal review.
has complied with the applicable directive Safety and Inspection Service Agency for for Component 9, and certify compliance state agency.	successful and complete self-certification with all Component 9 requirements for the
Typed or Printed Name & Title	Telephone (area code, Number and extension)
Signature of Authorized Certifying Official	Date of Submission

IX. ADDITIONAL RESOURCES

"Additional Resources" provides State MPI program Directors with additional information that may be needed to perform business processes related to the budget submissions, training and Federal resources, cooperation between State and Federal Compliance Programs, and reference material for internal controls. Contributors to the new Additional Resources section are OFO, OOEET, and OIEA.

OFFICE OF FIELD OPERATIONS (OFO)

Resource Management and Financial Planning Staff (RMFPS)

<u>Procedures for the Preparation of</u> Cooperative State Meat and Poultry Inspection Program Budget Submissions

General

Budget submission guidelines for the Cooperative Meat and Poultry Inspection (MPI) State programs are contained in the <u>FSIS Directive 3300.1</u>, *Fiscal Guidelines for* <u>Cooperative Inspection Programs</u>. The procedures below provide further details on the preparation of MPI program budget submissions.

I. Current Year Budget Execution Analysis

There are two components of the current year budget analysis: a) projection of current year expenditures for determination of fund availability for the current year, and b) determination of a basis for analysis of the budget submission for the ensuing year.

A. Current Budget Execution Analysis

- 1. The analysis of the current year Cooperative State MPI program budget begins in June of each year. At that time, the Financial Reviews and Analysis Section, Financial Management Division requests that each State Agency to submit their estimated projection of the total current fiscal year obligations by object classes on the Budget Information form (SF-424A).
- 2. The data is utilized to determine a total projection of estimated fund utilization for all State MPI agencies. Annual estimates allow FSIS to determine any requirement for fund reallocation.

B. Budget Submission Base

1. Data collected serves as an annual expenditure basis for comparison and analysis of budget submissions for the following year.

II. Budget Submission for New Fiscal Year

Each August, RMFPS prepares the budget call letter for the next fiscal year.

A. Budget Call Letter

- 1. The budget call letter is addressed to the head of the State agency for each Cooperative State MPI program, and is prepared for the signature of the Assistant Administrator for OFO.
- The call letter provides specific guidance relative to operational and budgetary considerations that State agencies take into account when preparing the budget submission.
- 3. The call letter has many enclosures for presentation of the budget submission:
 - a. Application for Federal Assistance (SF-424) Attachment 2-2
 - Budget Information Non-Construction Programs (SF-424A) -Attachment 2-3
 - c. Assurances Non-Construction Programs (SF-424B) Attachment 2-4
 - d. State Assignment and Employment Report (FSIS Form 5720-5) -Attachments 2-6
 - e. State Establishment Profile (FSIS Form 5720-4) Attachments 2-5

NOTE: The attachment examples are found in <u>FSIS Directive 3300.1</u>, *Fiscal Guidelines for Cooperative Inspection Programs*

B. Budget Submission Form Requirements

FSIS forms 5720-4 and 5720-5 are prepared prior to filling out the other forms.

- 1. <u>Form SF-424 (Application for Federal Assistance)</u> Note that section 15, Estimated funding is consistent with form SF-424A.
- 2. Form SF-424A (Budget Information Non-Construction Programs) The amounts in form SF-424A are consistent with the data contained in forms 5720-5 and SF-424. The activities to be used for "Grant Program Function or Activity" are in-plant, Compliance, Laboratory and other. Costs in section B of Form SF-424A are reported by Object Class Category as follows:
 - a. Personnel costs are salaries for State permanent full time (PFT) and other than permanent (OTP) personnel including base salaries, overtime, holiday pay, differentials, lump sum payments and annual and sick leave payments. Costs for contract veterinarians should appear in "Contractual."
 - b. Fringe Benefits are costs paid on behalf of State employees, including retirement, social security, insurance, clothing allowances, relocation benefits, workmen's compensation, etc. This object class is calculated as a percentage of salary based on historical data or by using the latest payroll information available.

- c. Travel provides for travel costs incurred by State employees in the performance of their assigned duties whether paid directly by the State or reimbursed to the employee. Some items used in determining overall travel costs are: mileage costs based on the estimated miles to be traveled times the rate per mile (the state approved mileage rate or latest approved Federal rate, whichever is lower); vehicle rental costs; motor pool costs; auto leases; repairs for State vehicles; auto insurance; and depreciation. Other allowed expenses include per diem, subsistence, and meal allowances.
- d. **Equipment** includes the purchase of durable property with an expected useful life in excess of one year and for more than \$500 per unit or in accordance with the State classification of equipment. Requests for equipment acquisitions are fully justified.
- e. **Supplies** include commodities, supplies, materials and other expendable items that are normally expended or consumed within a year of being put to use. They may also be used to form a minor part of equipment. Small equipment, costing less than \$500 per unit, may also be included. When estimating for the budget year, prior year one-time purchases are eliminated. Estimates are based on prior year costs adjusted for inflation.
- f. Contractual includes all contracts for service in support of the program. The salaries of contract veterinarians are included in this object class. This item includes any contractual laboratory costs. Budget year estimates are based on contract costs adjusted upward for inflation and anticipated changes and downward for discontinued services.
- g. **Other** includes all items of expenditure not included in the above object classes.
- 3. Form SF-424B (Assurances Non-Construction Programs)
- 4. Two copies of FSIS Form 5720-5 (State Assignment and Employment Report). The first shows data on personnel as of September 30 of the current year. The second shows data on personnel positions as projected for the ensuing budget year. In both cases, the OTP positions are shown in terms of PTF.
- 5. <u>Two copies of FSIS Form 5720-4 (State Establishment Profile)</u> The first shows data on plants as of September 30 of the current year. The second form shows a projection of plants expected to be in the cooperative inspection program during the ensuing budget year.

C. Budget Submission Justifications

State MPI program agencies fully justify and explain all changes in the budget submission compared to the current year estimated expenditures. Justifications

are in narrative form referencing the affected object class. If there is no change in level of spending or program, it must be indicated in a narrative form.

- The justification for the budget submission compares and contrasts current year estimated expenditures, staffing, and workloads with those proposed in the budget submission. Changes in staffing and workload are reflected on forms FSIS 5720-4 and FSIS 5720-5. A narrative explanation accompanies the two forms.
- 2. Justifications for increases in funding are attached to form SF-424A. The narrative justification explains, by object class, the reasons for changes in expenditure levels, including items such as pay raises, inflation, changes in staffing, and training required to maintain "at least equal to" status. If inflation factors are used to justify an increase for an object class, the rate used, as well as the publication source of the inflation index, should be provided.
- 3. Justifications for increases in salaries, benefits and other salary changes:
 - a. Provide the following information for all State employees on an attachment:
 - 1. Name of employee
 - 2. Position title
 - 3. Date employee entered on duty
 - 4. Annual salary
 - 5. Calculated salary cost for the fiscal year
 - b. Any promotions are justified by providing the following information:
 - 1. Name of employee
 - 2. Position title
 - 3. Annual salary
 - 4. Date of Promotion
 - 5. Calculated salary cost for fiscal year
 - c. For merit increases, the following is provided:
 - 1. Name of employee
 - 2. Percentages used and the amount of the increase
 - 3. Date of increase
- 4. Justifications for increases or decreases in travel items are included in the submission:
 - a. The effective date for change in mileage rate, the current rate, and the new rate
 - b. Increases in job assignments

- c. Increase in travel due to training
- d. Decrease in number of personnel traveling.
- 5. An itemized list of all equipment to be purchased during the fiscal year.

D. Talmadge-Aiken (T/A) Submission

State programs with plants inspected under the Federal-State T/A Cooperative Inspection program provide the following information attached to form SF-424A:

- 1. The number of personnel performing inspection at Federally inspected plants (T/A)
- 2. Total amount of their salaries
- 3. Staff years and estimated overtime costs(a staff year equals a full-time workload for an individual for a full year)

E. Cooperative Interstate Shipment (CIS) Budget Submission

States with plants inspected under the CIS program are to prepare a separate budget request for their CIS program. Each form submitted for base program budget request is also submitted for the CIS program. The CIS program budget request includes specific information for the State CIS program. In some instances States will footnote CIS information on the appropriate forms.

Note: The Employee Roster is expanded to include employees working in CIS establishments. If a State employee performs inspection at a CIS establishment in addition to inspection in a cooperative establishment, the appropriate percentages of the employees' time in each type of establishment noted on the roster.

OFFICE OF OUTREACH, EMPLOYEE EDUCATION AND TRAINING (OOEET)

Outreach Partnership Division (OPD)

The Outreach Partnership Division (OPD) is a part of USDA's Food Safety and Inspection Service, Office of Outreach, Employee Education and Training. OPD provides information and support to State MPI programs, as well as to operators of small and very small meat, poultry and processed egg products establishments, including State-inspected plants. OPD delivers assistance to State MPI programs and State-inspected plants through several different avenues.

Resource Library

OPD offers food defense materials, help for dealing with plant emergencies, generic HACCP models and guidebooks, informational DVDs on humane handling, control of *Listeria monocytogenes*, new plant orientation, compliance guidelines, as well a vast array of other useful food safety resources for industry. These materials are available free of charge and can be shipped on request. For a complete listing of available resources, view the "Food Safety Resources for Small and Very Small Plants" brochure at: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/resources-and-information/food-safety-resources-svsp-outreach

Small Plant Help Desk

FSIS's Small Plant Help Desk assists operators of small and very small meat, poultry and processed egg product establishments seeking help with agency requirements with direct access to knowledgeable staff specialists. The helpdesk provides assistance to State and local food regulatory agencies (FSIS's partners in keeping meat, poultry and egg products safe for consumers). The Help Desk is open from 8:00 a.m.-4:00 p.m. EST, Monday through Friday, excluding Federal holidays. To speak to a staff specialist during this time, call 1-877-FSISHelp (1-877-374-7435). Customers may also contact the help-desk by email at lnfoSource@fsis.usda.gov.

Management of State MPI Directors Contact List

OPD manages and keeps an up-to-date list of Agriculture Commissioners and MPI Directors for the 27 States that have their own meat and poultry inspection programs, as well as the States in which FSIS has entered into cooperative agreements with to conduct reviews of custom exempt slaughter and processing operations for OFO. This list is maintained on FSIS's Web site at:

www.fsis.usda.gov/wps/portal/fsis/topics/inspection/state-inspection-programs/state-inspection-and-cooperative-agreements/state-officials.

Monthly State MPI Program Directors Correlation Webinar

OPD coordinates a monthly Webinar with all 27 State MPI Directors and their personnel to discuss new FSIS policies and any other issues that States need to know to maintain "at least equal to" status to FSIS's Federal meat and poultry inspection programs. OPD, in conjunction with FSAB and other FSIS programs encourage States to provide issues or topics that need further clarification before the monthly scheduled Webinar so that the appropriate FSIS subject matter experts can provide updates and answer questions. OPD solicits topics from the State MPI Directors for upcoming Webinars; however, State personnel are also welcome to submit suggestions for Webinar topics through the Small Plant Help Desk.

Management and Renewal of Federal and State Cooperative Agreements

The FMIA and PPIA allow FSIS to cooperate with State agencies in developing and administering their own MPI programs. OPD administers the base cooperative agreements between FSIS and the individual States to operate their "at least equal to" meat and poultry inspection programs. Provided the State continues to operate it's "at least equal to" program in good standing, these cooperative agreements are renewed on an annual basis through OPD.

OPD administers, and renews, the Tallmadge-Aiken (TA) and Cross Utilization (CU) agreements with States that provide inspection coverage for FSIS-regulated establishments, as well as the Cooperative Interstate Shipment (CIS) agreements where State-inspected establishments can sell product outside of their respective State boundaries and in foreign commerce. OFO has direct oversight of these three programs, and ensures that State inspection personnel assigned to any TA, CU or CIS establishment have received FSIS-conducted training. OPD assists the States that have these programs by ensuring their personnel are registered in the required FSIS-conducted training courses and providing both the States and OFO with the pass/fail results of the State employees.

There are several other unique cooperative agreements that OPD administers and renews based on OFO's needs. There is a cooperative agreement with Utah's Egg and Poultry Grading Program to have Utah State Inspectors provide continuous inspection in several of FSIS's egg products inspection plants. Furthermore FSIS has cooperative agreements with California and Colorado for their personnel to conduct reviews of custom exempt slaughter and processing operations within those respective States, which are procedures that OFO would normally perform.

Directors seeking advice or assistance with State MPI programs, or wishing to obtain copies of current and archived cooperative agreements, are welcome to contact OPD through the Small Plant Help Desk.

Training

OPD provides assistance to the State programs by ensuring they receive course announcements from FSIS and any assistance to State personnel in securing enrollment in the classes they might need. This service is especially essential for the States that have TA, CU or CIS programs where their personnel must have successfully completed FSIS trainer-led courses in order to conduct inspection activities within TA, CU or CIS establishments. OPD provides both the States and OFO with the pass/fail results of the State employees. Furthermore, OPD assists States by providing CDs, DVDs, or other hard copy resources on food safety and public health-related training materials for reference offered through FSIS's Center for Learning. Many of these titles are interactive computer-based training on disk. State personnel can request a copy of the catalog and submit any orders through the Small Plant Help Desk, since the online catalog is only available through FSIS's Intranet site, which the States cannot access.

OFFICE OF INVESTIGATION, ENFORCEMENT AND AUDIT (OIEA)

Compliance Investigation Division (CID)

<u>Cooperation Between Compliance Investigation Division (CID)</u> <u>and State Compliance Programs</u>

Federal and State Compliance programs are encouraged to integrate and coordinate their respective programs to the maximum extent possible to eliminate or avoid duplication of efforts. CID assists and encourages State Compliance programs in assuming full responsibility for and jurisdiction over the enforcement of meat and poultry laws within States. State Compliance programs assist CID in coordinating and channeling various State efforts into a comprehensive national compliance program. The coordination of CID and State Compliance programs necessitate close communications in administration of the respective programs.

The compliance personnel of CID and State Compliance programs are cross-utilized fully to inquire into alleged violations, conduct compliance reviews, develop evaluation material, and make necessary contacts with the various Federal, State, County, or Municipal officials and informants. When there is overlapping jurisdiction and authority, compliance personnel of either CID or State Compliance programs are authorized to handle the matter and represent fully both Federal and State interests. CID and State Compliance programs are encouraged to refer cases dependent on resources to obtain optimal results. These operational details are resolved on a case-by-case basis between CID and State Compliance programs.

CID training programs are open for participation by members of both groups to the extent possible and feasible.

CID Regions and Contact Information

Western Region (CA, HI, AZ, AK, NM, NV, UT, CO, OR, WA, ID, WY, MT) 620 Central Avenue
Building 2B, 2nd Floor
Alameda, CA 94501

Telephone: 510-769-5733

Southwest Region (TX, OK, KS, MO, NE, IA, SD, ND, IL, MN) 1100 Commerce Street, Room 557 Dallas, TX 75242

Telephone: 214-767-2783

Southeast Region (FL, PR, AR, LA, GA, AL, TN, MS, MD, VA, KY, SC, NC, WV, DE, DC)

100 Alabama Street, SW 1924 Building Suite 3R95 Atlanta, GA 30303-3104 Telephone: 404-562-5962

Northeast Region (PA, NJ, CT, NY, MI, WI, IN, OH, MA, ME, NH, VT, RI) BNY Mellon Independence Center 701 Market Street, Suite 4100 C Philadelphia, PA 19106

Management Control and Audit Division (MCAD)

Development of a Federal Program Management Control System

Background

The Federal Managers' Financial Integrity Act of 1982 (FMFIA) requires the General Accounting Office (GAO) to issue standards for internal control in government. The standards provide the overall framework for establishing and maintaining internal control and for identifying and addressing major performance and management challenges in areas at greatest risk of fraud, waste, abuse, and mismanagement. Office of Management and Budget (OMB) Circular A-123, Management Accountability and Control, revised June 21, 1995, provides the specific requirements for assessing and reporting on controls.

As a result, Federal program managers continually seek better ways to achieve agencies' missions and program results. In other words, they seek ways to improve accountability. A key factor in helping achieve such outcomes and minimize operational problems is to implement appropriate internal control. Effective internal control helps manage change to cope with shifting environments and evolving demands and priorities.

The term internal control is synonymous with the term management control (as used in OMB Circular A-123) that covers all aspects of an agency's operations (programmatic, financial, and compliance). Recently, other laws have prompted renewed focus on internal control. The Government Performance and Results Act of 1993 requires agencies to clarify their missions, set strategic and annual performance goals, and measure and report on performance toward those goals.

The internal control system helps the program's management to provide reasonable assurance of the effectiveness and efficiency of operations, of reliability of financial reporting, and of compliance with applicable laws and regulations.

Terminology

The following includes definitions for commonly used terms of the Federal management control systems:

Risk Assessment - Internal control provide for an assessment of the risks the agency faces from both external and internal sources. A precondition for risk assessment is the establishment of clear and consistent agency objectives. Risk assessment is the identification and analysis of relevant risks associated with achieving the objectives, such as those defined in strategic and annual performance plans developed under the Government Performance and Results Act, and forming a basis for determining how risks is managed.

Internal Control (Management Control) - An internal control is comprised of control activities, control document (control), and performance measures (i.e., performance standards or action level).

Control - Control documents (control) provide direction to program personnel for the execution of the control activity to meet the expectation of the program's management. Controls are policies, procedures, techniques, and mechanisms that enforce management's directives, such as the process of adhering to requirements for budget development and execution. Controls are clearly documented, and the documentation is readily available for examination. The control document is measurable and appears in management directives, administrative policies, or operating manuals and may be in paper or electronic form. All documentation and records are properly managed and maintained.

Control Activity – Internal control activities help ensure that management's directives (mission and strategic goals) are carried out. Control activities are effective and efficient in accomplishing the agency's control objectives. They help ensure that actions are taken to address risks.

Objective of Control Activity - Objective of control activity specifies the purpose for program in executing a control activity. The purpose of the control activity directly relates to and supports the program's mission and strategic goals.

Implementation (Monitoring) - Internal control monitoring assesses the quality of the control activity performance over time and ensures the findings of audits and other reviews are promptly resolved.

Performance Measure - A performance measure (i.e., performance standard or action level) is an indicator of the effectiveness and efficiency of a control activity. Programs need to establish activities to monitor performance measures. These activities may include comparisons and assessments of different sets of data to one another and the performance measures to analyze the relationships so conclusions can be made and appropriate actions taken. Controls are aimed at validating the correctness and integrity of the performance measures.

Management Control Helper Questions

Key Function (Functional Area)

 Why do we exist? How do we accomplish our program's mission and strategic goals? Does our existence require us to produce any products?

Risk Assessment

- What can happen if we do not meet our objective?
- How will our failures to meet our objectives affect the program's function or existence?
- How will our failures affect the program's accomplishment of its mission and strategic objectives?

Control Activity

 What must be done consistently and well for the program to continue to function successfully? (NOTE: This does not relate to how it is done)

Objective (Desired Outcome)

What is the objective of the control activity?

Management Control

- What procedures or activities will provide personnel clear instructions for implementing the control activity and ensure the attainment of the objective?
- How can we demonstrate our implementation of the controls? (proof)
- What is our proof of implementation? (**NOTE:** The proof is management control, because it is measurable—e.g., a form, tracking log, etc.)

NOTE: Reference for performing the control – e.g., 9 CFR, Directives, Notices, State Policies

Performance Measure

- How do we define a success?
- How can we measure successful completion of the objective?
- What is our tolerance level of risk for the control activity?

Reference Table of Related FSIS Policy Documents

Component 2 – Inspection Related FSIS Directives		
Slaughter Inspe	ection	
5100.3	Administrative Enforcement Reporting (AER) System - Revision 2 (Oct 18, 2011; 18 pp)	
6000.1	Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions - Revision 1 (Aug 3, 2005; 6 pp)	
6030.1	Religious Exemption for the Slaughter and Processing of Poultry - Revision 1 (Aug 10, 2005; 11 pp)	
6100.1	Ante-Mortem Livestock Inspection - Revision 2 (Jul 24, 2014; 18 pp) Bovine Spongiform Encephalopathy (BSE) and Specified Risk Material (SRM) Guidance Materials and Resources	
6100.2	Post-Mortem Livestock Inspection (Sep 17, 2007; 31 pp)	
6100.3	Ante-Mortem and Post-Mortem Poultry Inspection - Revision 1 (Apr 30, 2009; 16 pp)	
6100.4	Verification Instructions Related to Specified Risk Materials (Sep 13, 2007; 22 pp) Questions and Answers Verification of SRM Removal Including Tonsils	
6240.1	Inspection, Sampling, and Disposition of Animals for Tuberculosis - Revision 1 (Jan 29, 2009; 10 pp) PHV Training: Multi-species Disposition Basics with a Public Health Focus FSIS Guideline No. 4, Inspection of Tuberculin Reactors Tuberculosis Sample Submission Manual for Meat Inspection Personnel (USDA-APHIS)	
6410.1	Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age - Revision 1 (Nov 3, 2011; 23 pp)	

6420.2	Verification of Procedures for Controlling Fecal Material, Ingesta and Milk in Slaughter Operations (Mar 31, 2004; 14 pp) PHIS FSIS Directive 6420.1 Questions and Answers on FSIS Directives 10,010.1, Revision 1, 5000.2, and 6420.2 Questions and Answers Regarding Directives 5000.2, 6420.2 and 10,010.1, Revision 1, and the Compliance Guidelines on E. coli O157:H7 Workshops on E. coli O157:H7 Regulations
Food Safety Ve	
5000.1	Verifying an Establishment's Food Safety System - Revision 4 (Mar 4, 2014; 76 pp) Meat and Poultry Hazards and Controls Guide (Oct 4, 2005)
5000.2	Review of Establishment Data by Inspection Personnel - Revision 2 (Dec 4, 2008; 6 pp) Questions and Answers on FSIS Directives 10,010.1, Revision 1, 5000.2, and 6420.2 Questions and Answers Regarding Directives 5000.2, 6420.2 and 10,010.1, Revision 1, and the Compliance Guidelines on E. coli O157:H7 Compliance Guidelines For Establishments On The FSIS Microbiological Testing Program And Other Verification Activities For Escherichia coli O157:H7
5000.3	Identification and Segregation of Products (Dec 21, 2006; 3 pp)
5000.4	Performing the Review Component of PBIS 01b02 Procedure and PHIS Pre-Op Sanitation SOP Review and Observation Task in Federally Inspected Processing, Slaughter and Import Establishments-Revision 1 (Sep 28, 2011; 12 pp)
5000.5	Verification of Less Than Daily (LTD) Sanitation Procedures In Processing Operations- Revision 1 (Sep 28, 2011; 19 pp) Less than Daily Sanitation Procedures Compliance Guideline (Oct 19, 2009
5000.6	Performance of the Hazard Analysis Verification (HAV) Task - Revision 1 (Mar 4, 2014; 29 pp) Questions and Answers Related to Performance of the Hazard Analysis Verification (HAV) Task (Aug 14, 2012) 9 CFR Part 417 Docket No. 00-022N - E. coli O157:H7 Contamination of Beef Products FSIS Directive 5020.1 - Verification of Salmonella Initiative Program

	FSIS PHIS Directive 5300.1 - Managing the Establishment Profile in the Public Health Information System (PHIS) FSIS PHIS Directive 13000.1 - Scheduling In-plant Inspection Tasks in the Public Health Information System Meat and Poultry Hazards and Controls Guide (Oct 4, 2005)
5000.8	Verifying Compliance with Requirements for Written Recall Procedures (Dec 18, 2013; 2 pp)
5000.9	Verifying Video or Other Electronic Monitoring Records (Aug 26, 2011; 5 pp) Compliance Guidelines for Use of Video or Other Electronic Monitoring or Recording Equipment in Federally Inspected Establishments (Aug 26, 2011)
5010.1	Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management - Revision 2 (Apr 17, 2014; 6 pp)
5020.1	Verification of Salmonella Initiative Program (Aug 12, 2011; 10 pp)
5100.1	Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology - Revision 4 (May 29, 2015; 23 pp) Food Safety Assessment Tools
5100.2	Enforcement, Investigations, and Analysis Officer (EIAO) Responsibilities Related to Recalls and Consumer Complaints (Oct 4, 2005; 6 pp) Meat and Poultry Hazards and Controls Guide
5100.3	Administrative Enforcement Reporting (AER) System - Revision 2 (Oct 18, 2011; 18 pp)
5100.4	Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology - Revision 1 (May 22, 2015; 8 pp)
5220.1	Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS - Revision 1 (Jan 30, 2013; 21 pp)
5220.3	Issuance of a Ten-Day Letter for Inactive Operations (Apr 11, 2011; 3 pp)
5300.1	Managing the Establishment Profile in the Public Health Information System (PHIS) (Apr 13, 2011; 22 pp)

6410.1	Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age - Revision 1 (Nov 3, 2011; 23 pp)
6420.2	Verification of Procedures for Controlling Fecal Material, Ingesta and Milk in Slaughter Operations (Mar 31, 2004; 14 pp) PHIS FSIS Directive 6420.1 Questions and Answers on FSIS Directives 10,010.1, Revision 1, 5000.2, and 6420.2 Questions and Answers Regarding Directives 5000.2, 6420.2 and 10,010.1, Revision 1, and the Compliance Guidelines on E. coli O157:H7 Workshops on E. coli O157:H7 Regulations
7520.2	Procedures for Condition of Canned Product Container Examination (May 12, 1988; 10 pp)
7530.1	Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product - Revision 2 (Mar 25, 2010; 15 pp)
7530.2	Verification Activities in Canning Operations that Choose to Follow the Canning Regulations (Oct 20, 2005; 22 pp)
10,010.1	Sampling Verification Activities for Shiga Toxin-Producing <i>Escherichia coli</i> (STEC) in Raw Beef Products (Aug 20, 2015; 88 pp)
10,010.2	Verification Activities for Shiga Toxin-Producing <i>Escherichia Coli</i> (STEC) in Raw Beef Products (Aug 20, 2015; 22 pp)
10,010.3	Traceback Methodology for Escherichia Coli (E. Coli) 0157:H7 in Raw Ground Beef Products and Bench Trim (Jan 21, 2015; 16 pp)
Non-Food Safety	y Verification
5100.3	Administrative Enforcement Reporting (AER) System - Revision 2 (Oct 18, 2011; 18 pp)
7000.1	Verification of Non-Food Safety Consumer Protection Regulatory Requirements (Dec 11, 2006; 24 pp)
7000.4	Verifying Certain Transferred Labeling (Dec 8, 2008; 4 pp) Questions and Answers (Jan 7, 2009)
7110.1	Guidelines for Specified Cuts of Poultry (Feb 26, 1986; 2 pp)

7110.3	Time/Temperature Guidelines for Cooling Heated Products-Revision 1 (Jan 24, 1989; 10 pp)
7111.1	Performance Standards for the Production of Certain Meat and Poultry Products (Mar 3, 1999; 15 pp)
7120.1	Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products - Revision 20 (Sep 8, 2014; 69 pp) Access additional information
7124.1	Standards of Identify or CompositionUse of Cooked or Cured Product (Jul 28, 1986; 3 pp)
7220.1	Food Labeling Division Policy Memoranda (Aug 2, 2005; 133 pp)
7221.1	Prior Labeling approval - Revision 1 (Jan 6, 2014; 5 pp)
7235.1	Mandatory Safe Handling Statements on Labeling of Raw and Partially Cooked Meat and Poultry Products (May 11, 1994; 10 pp)
7237.1	Labeling of Ingredients - Revision 1 Amendment 1 (Aug 9, 1994; 4 pp)
7270.1	Sampling and Testing Procedures for Raw Poultry Products Labeled "Fresh"-Revision 1 (Aug 13, 1998; 5 pp)
7310.5	Presence of Foreign Material in Meat or Poultry Products - Revision 3 (May 30, 2003)
7320.1	Treatment of Certain Meat and Poultry Products Containing Pork to Destroy Trichinae (Apr 27, 1993; 2 pp)
7355.1	Use of Sample Seals for Program Samples and Other Applications - Revision 2 (Dec 3, 2002; 13 pp)
7620.3	Processing Inspectors' Calculations Handbook (Revised 1995; 138 pp)
Exempt Facility	Review
5930.1	Custom Exempt Review Process - Revision 4 (Jul 15, 2009; 17 pp) Poultry Slaughter Exemption Guideline
8010.1	Methodology for Conducting In-Commerce Surveillance Activities – Revision 4 (Apr 24, 2014; 27 pp)
Component 3 –	Program Sampling Related FSIS Directives and Compliance Guidelines

FSIS Directives	
10,010.1	Sampling Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef Products (Aug 20, 2015; 88 pp)
10,010.2	Verification Activities for Shiga Toxin-Producing <i>Escherichia Coli</i> (STEC) in Raw Beef Products (Aug 20, 2015; 22 pp)
10,010.3	Traceback Methodology for <i>Escherichia Coli</i> (<i>E. Coli</i>) 0157:H7 in Raw Ground Beef Products and Bench Trim (Jan 21, 2015; 16 pp)
10,200.1	Accessing Laboratory Sample Information via LEARN (Jul 19, 2001, 7 pp)
10,210.1	Unified Sampling Form - Amendment 1 (Jun 10, 1999; 31 pp) Amendment 6 - Change Transmittal Sheet (Dec 18, 2003; 63 pp) Amendment 5 - Change Transmittal Sheet (Feb 11, 2003; 9 pp) Amendment 4 - Change Transmittal Sheet (Dec 19, 2002; 7 pp) Amendment 3 - Change Transmittal Sheet (May 22, 2002; 25 pp) Amendment 2 - Change Transmittal Sheet (Dec 12, 2001; 9 pp)
10,230.2	Procedures for Collecting and Submitting Domestic Samples for Microbiological Analysis (Aug 6, 1992; 14 pp)
10,230.4	Salmonella Surveillance Program for Liquid and Frozen Egg Products (Aug 6, 1992; 4 pp)
10,230.6	Submitting Tissue Specimens for Pathological or Diagnostic Microbiological Evaluation to the Laboratory (Jan 10, 2006; 9 pp)
10,240.4	Verification Activities for the <i>Listeria monocytogenes</i> (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program - Revision 3 (Jan 10, 2014; 48 pp) Attachments and Related Documents
10,240.5	Verification Procedures for Enforcement, Investigations and Analysis Officers (EIAOs) for the <i>Listeria monocytogenes</i> (Lm) Regulation and Routine Risk-Based <i>Listeria monocytogenes</i> (RLm) Sampling Program - Revision 3 (Mar 28, 2013; 17 pp)
10,250.1	Salmonella and Campylobacter Verification Program for Raw Meat and Poultry Products (Sep 20, 2013; 70pp) FSIS Establishment Eligibility Criteria for the Salmonella Verification Sampling Program and FSIS Scheduling Algorithm for the Salmonella Verification Sampling Program for Raw Meat and Poultry (Feb 2013; 4 pp)

10,300.1	Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria Monocytogenes - Revision 1 (Mar 28, 2013; 19 pp)
10,400.1	Sample Collection from Cattle Under the Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Program (Apr 11, 2013; 6 pp)
10,630.1	Federal and Contract Servicing Laboratories for Domestic Food Chemistry Samples (May 13, 1991; 4 pp)
10,700.1	Procedures for New Technology and Experimental Protocols for In- Plant Trails (Jun 24, 2003, 10 pp) <u>Guidance Procedures for Notification and Protocol Submission of New Technology PDF</u> (16 pp) <u>Other Related Documents</u>
10,800.1	Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products - Revision 1 (Mar 3, 2014; 43 pp) KISTM Test Instructions (Oct 13, 2011) Examples of Official Ear Tags Additional Related Documents

FSIS Compliance Guidelines

FSIS Revised Action Plan for Control of *Listeria monocytogenes* for the Prevention of Foodborne Listeriosis (2000)

<u>Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens</u>

FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products (Updated Jan 2014; PDF Only)

FSIS Scheduling Criteria for Routine *Lm* Risk-Based (RLm) Sampling Program (Mar 21, 2008; PDF Only)

<u>Verification Procedures for the Listeria monocytogenes Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification - FSIS Directive 10240.4 (Feb 3, 2009; PDF Only)</u>

FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products (Jun 2013; PDF Only)

<u>Docket No. FSIS-2008-0017</u> | <u>PDF</u> (Aug 9, 2013)

Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing

Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products (Feb 2012; PDF Only)

View Comments on regulations.gov

<u>FSIS Compliance Guideline for Controlling Meat and Poultry Products Pending FSIS</u> Test Results (Feb 1, 2013; PDF)

FAQs: FSIS Hold and Test Conference Call with Industry held February 7, 2013 (PDF Only)

<u>Docket No. FSIS-2005-0044</u> - Not Applying the Mark of Inspection Pending Certain Test Results | <u>PDF</u> (Dec 10, 2012)

Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory (Revised Jun 2013; PDF Only)

Foodborne Pathogen Test Kits Validated by Independent Organizations | PDF

FSIS Guidance for Evaluating Test Kit Performance (PDF Only)

Compliance Guideline for Controlling Salmonella in Market Hogs

Docket No. FSIS-2012-0026 | PDF (Jan 6, 2014)

Baseline Data Reports

<u>Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry</u> <u>Establishments that Produce Ready-to-Eat (RTE) Products (Sep 19, 2012; PDF Only)</u>

Compliance Guideline for Controlling Salmonella and Campylobacter in Poultry Third Edition May 2010 (May 10, 2010; PDF Only)

Review of FSIS Compliance Guidelines for Controlling Salmonella in Small and Very Small Plants that Produce Raw Poultry Products (PDF Only)

Chemical Antimicrobials (Jun 29, 2009; PDF Only)

Component 4 – Administrative FSIS Directives			
Staffing			
12,700.1	Operations Occurring Outside Approved Hours - Revision 1 (Nov 25, 2008; 4 pp)		
Training	Training		
4200.2	New Employee Orientation (Jul 12, 2007; 9 pp)		
4338.1	Training as a Condition of Employment - Amendment 2 (Mar 1, 2013; 36 pp)		
Supervision			
2610.1	FSIS Issuance System - Revision 6 (Apr 23, 2012; 18 pp)		

4200.2	New Employee Orientation (Jul 12, 2007; 9 pp)
4315.2	Probationary Period (Mar 3, 1982; 4 pp)
4315.3	Probationary Period for Newly Appointed Supervisors and Managers - Revision 1 (May 3, 1989; 17 pp)
4335.1	Merit Promotion Plan - Revision 2 (May 6, 1999; 84 pp)
4338.1	Training as a Condition of Employment - Amendment 2 (Mar 1, 2013; 36 pp)
4410.1	Employee Development- Revision 1 Amendment 2 (Dec 14, 2007; 15 pp)
4410.2	Career Development Program (Oct 18, 1982; 12 pp)
4430.1	Performance Evaluation Plan - Revision 6 (Dec 15, 2009; 31 pp)
4430.3	In-Plant Performance System (IPPS) - Revision 2 (Feb 19, 2010; 23 pp)
Component 5 -	- Humane Handling Related FSIS Directives
6030.1	Religious Exemption for the Slaughter and Processing of Poultry - Revision 1 (Aug 10, 2005; 11 pp)
6900.2	Humane Handling and Slaughter of Livestock - Revision 2 (Aug 15, 2011; 40 pp)
6910.1	District Veterinary Medical Specialist (DVMS) - Work Methods - Revision 1 (Dec 7, 2009;18 pp)
Component 6 –	- Compliance Related FSIS Directives
8010.1	Methodology for Conducting In-Commerce Surveillance Activities - Revision 4 (Apr 24, 2014; 27 pp)
8010.2	Investigative Methodology - Revision 4 (Apr 24, 2014; 16 pp)
8010.3	Procedures for Evidence Collection, Safeguarding and Disposal - Revision 4 (Apr 24, 2014; 18 pp)
8010.4	Report of Investigation - Revision 5 (Apr 24, 2014; 6 pp)

8010.5	Case Referral and Disposition - Revision 4 (Apr 24, 2014; 6 pp)
8080.1	Recall of Meat and Poultry Products - Revision 7 (Sep 9, 2013; PDF; 41 pp)
8410.1	Detention and Seizure - Revision 6 (Apr 24, 2014; 12 pp)
8420.1	Transportation Accidents (Nov 7, 1985; 2 pp)

Component 7 - Relevant FSIS Laboratory Quality Assurance Compliance Guidelines

FSIS Form 5720-14, State Meat and Poultry Inspection Program Laboratory Quality Management System Checklist

FSIS Form 5720-15, Laboratory Method Notification Form

FSIS Accredited Laboratory Program

USDA FSIS Chemistry Laboratory Guidebook

USDA FSIS Microbiology Laboratory Guidebook

FDA Bacteriological Analytical Manual

ISO Standards

AOAC Official Methods of Analysis

<u>Establishment Guidance for the Selection of a Commercial or Private Microbiological</u> <u>Testing Laboratory</u> (Revised Jun 2013; PDF Only)

Foodborne Pathogen Test Kits Validated by Independent Organizations | PDF

FSIS Guidance for Evaluating Test Kit Performance (PDF Only)

FSIS Directive 10,800.1, Residue Sampling, Testing and Other Verification Procedures Under The National Residue Program For Meat and Poultry Products

KISTM Test Instructions (Oct 13, 2011)

Examples of Official Ear Tags

Additional Related Documents

Component 8 – Federal Civil Rights Statutes, Regulations and Policies

Federal Statutes

Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000d (discrimination on the basis of race, color or national origin)

Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794 (discrimination on the basis of disability)

Age Discrimination Act (ADA) of 1975, 42 U.S.C. 6102 (discrimination on the basis of age)

Title IX of the Education Amendments of 1972, **20 U.S.C. Section 1681** (discrimination on the basis of sex)

Regulatory and Executive Orders

7 CFR Part 15 Subpart A, Non-discrimination in Federally Assisted Programs

7 CFR Part 15 a, Education Programs or Activities Receiving or Benefitting from Federal Financial Assistance

7 CFR Part 15 b, Non-discrimination on the Basis of Disability Programs and Activities Receiving Federal Financial Assistance

45 CFR Part 91, Non-discrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance from HHS

Executive Order 13166 on Limited English Proficiency, dated August 11, 2000

Departmental and Agency Policies

USDA Regulation 4330-002, dated March 3, 1999, Non-discrimination in Programs and Activities Receiving Federal Financial Assistance from USDA

USDA Regulation 4300-3, dated November 16, 1999, Equal Opportunity Public Notification Policy

FSIS Directive 1510.1, Equal Opportunity Notification on Material for the Public, dated January 25, 2001

FSIS Directive 5720.3, Revision 1, dated March 14, 2011, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs; and "At Least Equal to" Guidelines for State Meat and Poultry Cooperative Inspection Programs, dated July 2008

Component 9 - Relevant Financial FSIS/USDA Regulations and Policies

Departmental and Agency Regulations

	<u> </u>
7 CFR Part	Uniform Administrative Requirements for Grants and Cooperative
3016	Agreements to State and Local Governments (previously known as the
	Common Rule)

FSIS Directive		
3300.1	Fiscal Guidelines for Cooperative Meat and Poultry Inspection Programs – Revision 2	
Additional Compliance Guidelines		
A Guide for the Preparation of the Cooperative State Meat and Poultry Inspect Program Budget Submissions, dated September 2004		
	Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, ed 5/10/04 - Guidelines for the preparation and submission of Indirect Cost osals	