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

FSIS DIRECTIVE

5720.3 Revision 2 11/10/16

METHODOLOGY FOR PERFORMING SCHEDULED AND TARGETED REVIEWS OF STATE MEAT AND POULTRY INSPECTION PROGRAMS

I. PURPOSE

This directive informs personnel in several Agency offices of the methodologies to use in conducting scheduled and targeted reviews of State Meat and Poultry Inspection (MPI) programs. The reviews are for the purpose of determining whether or not the State MPI programs are "at least equal to" the FSIS inspection program. Personnel involved in the reviews are from: the Federal-State Audit Branch (FSAB), Office of Investigation, Enforcement, and Audit (OIEA); the Laboratory Quality Assurance Staff (LQAS) and the Science Staff (SciS), Office of Public Health Science (OPHS); the Civil Rights Staff (CRS), Office of the Administrator (OA); and the Financial Review and Analysis Section (FRAS), Office of the Chief Financial Officer (OCFO). FSIS has rewritten this directive in its entirety to update the review components and modify the review methodology. The updates include review methodologies used by OPHS, CRS, and FRAS to evaluate the "at least equal to" status of State MPI programs.

KEY POINTS:

- FSIS policies and procedures for review of State MPI programs
- Methodologies and criteria FSIS uses to determine if State MPI programs are "At Least Equal To" FSIS's Federal inspection program

NOTE: FSIS has published the <u>"At Least Equal To" Guideline for State Meat and Poultry Inspection Programs.</u>

II. CANCELLATION

FSIS Directive 5720.3, Rev. 1, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs, 3/14/11

III. BACKGROUND

A. 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 State MPI programs. An individual State MPI program is limited to meat and poultry products that are produced and sold within the State, and needs to operate in a manner and with authorities that are "at least equal to" the programs that FSIS implements under the ante-mortem and post-mortem inspection, reinspection, sanitation, record keeping, and enforcement provisions of the FMIA (21 U.S.C. 601, et seq.) and PPIA (21 U.S.C. 451, et seq.). State MPI programs are to ensure that livestock are treated humanely by imposing humane handling requirements that are "at least equal to" those FSIS has established under

DISTRIBUTION: Electronic **OPI**: OPPD

the Humane Methods of Slaughter Act of 1978 (HMSA) (7 U.S.C. 1901-1906).

- B. The "at least equal to" standard requires that State MPI programs operate in a manner that is at least as effective as FSIS's Federal inspection program in the protection of public health. The statutes do not require that the States operate their MPI programs in a manner that is the same as or identical to FSIS's Federal inspection program, nor do they prohibit the State MPI programs from establishing safeguards that they believe to be more effective than those employed by FSIS.
- C. The FMIA and PPIA provide for FSIS to review, at least annually, each State MPI program and its requirements and enforcement activities in the slaughter, preparation, processing, storage, handling, and distribution of livestock carcasses and parts, meat and meat food products of such animals, and poultry products (21 U.S.C. 661(c)(4) and 454(c)(4)).
- D. If a State fails to administer a meat and poultry inspection program that is "at least equal to" FSIS's Federal inspection program, FSIS will move to "designate" the State in accordance with 21 U.S.C. 661(c) and 454(c).
- E. Additionally, under the FMIA and PPIA, FSIS may contribute up to 50 percent of the estimated total cost of the State's MPI program and provide administrative support as long as the State operates and maintains a program that is "at least equal to" the Federal inspection program (21 U.S.C. 661(a)(3) and 454(a)(3)).

IV. REVIEW METHODOLOGY AND CRITERIA

- A. The FSIS review team, comprised of personnel from FSAB, OPHS, CRS, FRAS, and representatives from other program areas as needed, performs reviews and evaluations of each State MPI program to determine whether it meets the "at least equal to" criteria for the following nine components:
 - 1. **Statutory Authority and Food Safety Regulations**—State MPI programs operate under laws and regulations that provide legal authorities "at least equal to" those provided under the FMIA, PPIA, and HMSA;
 - 2. **Inspection**—State MPI program personnel conduct inspection activities to verify that establishments are complying with applicable regulations and take appropriate enforcement actions when establishments do not comply with provisions that are "at least equal to" FSIS's Federal inspection program:
 - a. State MPI program personnel carry out inspection activities to verify animals are suitable for slaughter, and carcasses and parts are eligible for human consumption; and food safety verification activities and non-food safety verification activities that ensure all meat and poultry products found in intrastate commerce are safe, unadulterated and properly labeled;
 - b. State MPI programs review exempt facilities to ensure they meet applicable laws, regulations, and policies;
 - c. State MPI programs take into account new FSIS issuances, determine their applicability to their program, and communicate instructions to inspection program personnel; and
 - d. State MPI programs maintain inspection systems that enforce their meat and poultry regulations at State-inspected establishments.

- 3. **Sampling Programs**—State MPI program personnel are to sample meat and poultry products and take appropriate actions in response to test results, including:
 - a. State MPI program personnel sample meat and poultry products to verify that they are free of adulterants, including: seven Shiga toxin-producing *Escherichia coli* (STEC) serotypes including O157, O26, O45, O103, O111, O121, and O145 in non-intact raw beef products or intact raw beef product used to produce non-intact products; *Listeria monocytogenes* (*Lm*) or *Salmonella* in ready-to-eat (RTE) products; and drug residues at violative levels:
 - b. State MPI program personnel are to verify that classes of raw meat or poultry comply with *Salmonella* Performance Standards, classes of raw poultry comply with the *Campylobacter* Performance Standards, and classes of meat and poultry products comply with other consumer protection standards; and
 - c. When State MPI program personnel learn of positive test results on State collected product samples, they are to take appropriate follow-up actions (e.g., follow-up samples, Food Safety Assessments, enforcement actions, etc.).
- 4. **Staffing, Training, and Supervision**—State MPI programs provide competent inspection coverage in each establishment on days the establishment produces products that, if found to be safe, wholesome, unadulterated, and properly labeled, are to bear the State mark of inspection.
- 5. Humane Handling—State MPI program personnel perform regulatory verification procedures to assess whether establishments humanely handle all livestock presented for slaughter and follow good commercial practices when poultry is slaughtered and processed on premises. Additionally, State MPI program personnel are to take appropriate regulatory actions in response to noncompliance.
- 6. **Compliance**—State MPI program personnel perform surveillance activities and conduct investigations of meat and poultry products in intrastate commerce and take appropriate enforcement actions when adulterated or misbranded products enter intrastate commerce.
- 7. **Laboratory Quality Assurance Program and Methods**—State MPI programs maintain laboratory methods and laboratory quality assurance programs that address food pathogen and food chemistry analytes.
- 8. **Civil Rights**—State MPI programs adhere to Federal Civil Rights laws and USDA Civil Rights regulations.
- 9. **Financial Accountability**—State MPI programs conform with 7 CFR 3016, *Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments*, and follow <u>FSIS Directive 3300.1</u>, *Fiscal Guidelines for Cooperative Inspection Programs*.

V. ANNUAL SELF-ASSESSMENT

A. FSIS expects each State MPI program to submit self-assessment documents to FSIS by November 1st of each year. The FSIS review team is to verify that the State's annual self-assessment submission demonstrates that the State MPI program operates in a manner that is "at least equal to" FSIS's Federal

inspection program in the application of its laws, regulations, policies and procedures. State MPI program self-assessment documents are to include evidence and documentation showing that its processes are in effect and current with FSIS policies.

- B. The review team is to verify that the State MPI program has internal controls in place to provide assurances that the program is functioning as intended and measure the effectiveness of the program throughout the year.
- C. The review team is to thoroughly analyze each State MPI program's self-assessment submission annually to determine if it meets and maintains the "at least equal to" criteria for all nine review components.

NOTE: State officials are to provide evidence that the State's MPI program is current with FSIS statutes, regulations, and policies, and submit any changes made to the State MPI program during the previous 12 months.

- D. The review team is to request clarification from a State MPI program if questions arise during the self-assessment review or if more information is needed to determine whether the State MPI program is "at least equal to" FSIS's Federal inspection program. The review team analyzes the supplemental information and continues to communicate its concerns to State MPI program officials until the review team determines if the State MPI program meets the "at least equal to" standard.
- E. The review team is to verify that the State MPI program completes the following documents, as recommended in the "At Least Equal To" Guideline for State Meat and Poultry Inspection Programs, or confirm that they have submitted all of the requested information and data in an alternative format:
 - 1. Annual Certification—"At Least Equal To" Meat and Poultry Inspection Program;
 - 2. State MPI Program Statutory Side-By-Side Comparison Table;
 - 3. State MPI Program Sampling Activity Table;
 - 4. State MPI Program Establishment Count:
 - 5. State MPI Employee Primary Roles;
 - 6. State MPI Program Summary of Statutory Authority per Business Type;
 - 7. Compliance Activity Report;
 - 8. FSIS Form 5720-15 Laboratory Method Notification Form;
 - 9. FSIS Form 5720-14 State Meat and Poultry Inspection (MPI) Program Laboratory Quality Management System Checklist;
 - 10. FSIS Form 1520-1 Civil Rights Compliance of State Inspection Programs; and
 - 11. Certification Statement for Component 9.

NOTE: States should complete the forms referenced in items 8-11.

- F. FSAB evaluates the State MPI program's responses to new FSIS issuances, including FSIS Directives and Notices, and regulations and other policies on a quarterly basis.
- G. As part of the review team, OPHS is to verify the State MPI program's laboratory capability on an annual basis and when changes are made to the methods and related procedures. On an annual basis, every State or State contracted laboratory performing analytical testing for the State MPI program should submit the following information to OPHS for review:
 - 1. FSIS Form 5720-14 State Meat and Poultry Inspection (MPI) Program Laboratory Quality Management System Checklist;

NOTE: This form includes a self-assessment of the minimum quality assurance practices, a section to list analytical methods and procedures, a section to list the names of all analysts trained on each method, and a section to list the laboratory proficiency testing (PT) programs that the laboratory participated in.

- 2. Analytical methods and related procedures not previously submitted;
- 3. Training records of laboratory analysts not previously submitted:
- 4. Proficiency testing records demonstrating current laboratory competence; and
- 5. FSIS Form 5720-15 Laboratory Method Notification Form.

NOTE: This form is used by State MPI program laboratories throughout the year for reporting new and revised laboratory method procedures.

- H. As part of the team, FRAS is to verify the State MPI program's financial reporting throughout the Federal Fiscal Year (FFY) meets at "least equal to" standards. The following actions are necessary to meet the Component 9 certification requirements:
 - 1. Submission of an annual budget to the Office of Field Operations (OFO) and submission of all data requested;
 - 2. Submission of an annual indirect cost proposal to FRAS:
 - 3. Reconciliation of Federal Financial Reports (SF-425) by FRAS for four quarters. 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 FFY (e.g., by December 30); and

NOTE: "Four quarters" means the fourth quarter of the previous FFY and the first three quarters of the current FFY.

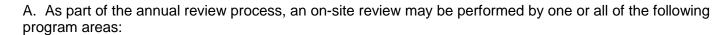
- 4. Resolution or progress toward resolution of corrective action(s) for financial findings within 45 days of the on-site fiscal review report date.
- I. At the conclusion of each self-assessment review, the FSIS review team is to determine whether the

self-assessment shows that the State MPI program is meeting the "at least equal to" standard.

J. If the self-assessment information shows the State MPI program to be meeting the "at least equal to" standard, the FSIS review team is to determine the program's "at least equal to" status on the basis of the self-assessment. If the State is scheduled for an on-site review, FSIS is to notify the State and determine the State's "at least equal to" status on the basis of the annual self-assessment and the on-site review. (Sections VI through X below cover the on-site review process)

NOTE: State MPI programs are subject to a triennial on-site review unless there is a need to conduct an on-site review outside of the established schedule.

VI. ON-SITE REVIEWS



- 1. FSAB;
- 2. OPHS;
- 3. CRS; or
- 4. FRAS
- B. An on-site review is conducted at least once every three years by each program area, and the following details the on-site review methodology for each of the program areas.

VII. FSAB ON-SITE REVIEW

- A. FSAB has the responsibility for reviewing components 1-6 listed in Section IV above.
- B. FSAB begins preparing for the on-site review with a thorough assessment of the State MPI program's most recent self-assessment submission.
- C. At least 30 days before the scheduled start of the review, FSAB is to agree with State MPI program officials on the dates for conducting the on-site review. The FSAB review team leader is to follow up with a written notification to the State MPI program Director to confirm the upcoming on-site review.
- D. Before traveling to the on-site review location, FSAB is to arrange an entrance meeting teleconference with State MPI program officials. During this teleconference, FSAB is to explain the review process, answer any questions, and request that State MPI program officials submit the following information within 10 business days of the teleconference:
 - 1. Descriptions of any changes that have occurred in the MPI program since the most recent selfassessment submission:
 - 2. A current list of establishments receiving inspection from the State MPI program and their operating schedules. ID Warehouses and establishments that slaughter or process only species non-amenable to the FMIA and PPIA are excluded;
 - 3. A description of each State field supervisor's area of responsibility;

- 4. The Hazard Analysis and Critical Control Point (HACCP) processing categories for each State-inspected establishment, and a ranking of the highest-volume producers for each HACCP processing category;
- A list of all State-inspected establishments reviewed by the State MPI program (e.g., through a review similar to an FSIS food safety assessment or other State review) within the previous 12 months; and
- 6. A list of all State-inspected establishments that have had a history of any of the following within the preceding 12 months:
 - a. Positive sample results for adulterants (e.g., STEC in non-intact, raw beef products or intact raw beef products to be used to produce raw, non-intact products; or *Lm* or *Salmonella* in RTE products);
 - b. Salmonella and Campylobacter verification sample set results that exceed the performance standard or guideline established by FSIS;
 - c. Enforcement actions;
 - d. Recalls; and
 - e. Structural damage to State-inspection establishments caused by a natural or other disaster.
- E. FSAB is to select the number of establishments for the on-site review and selects specific establishments for review based on a statistical methodology as well as adverse public health risks and Agency mission considerations.
- F. FSAB is to provide State MPI program officials with a list of the selected establishments at least one week before the on-site review.
- G. FSAB is to begin each establishment review with an entrance meeting with State MPI program officials and establishment management. FSAB is to explain the purpose and methodology for the review and answers any questions.
- H. During the on-site review of the selected establishments, FSAB is to observe State MPI program personnel as they execute the State MPI program's inspection procedures, verification tasks, and oversight functions.
- I. At each establishment, FSAB is to review the State MPI program's verification of compliance with applicable State requirements on Sanitation Standard Operating Procedures (Sanitation SOPs), HACCP, non-food safety related consumer protection, control of specified risk materials, humane handling, and separation of custom exempt/retail exempt processes and products.
- J. FSAB is to observe State MPI program inspectors as they perform ante-mortem and post-mortem inspection procedures.
- K. Using the records review and observations, FSAB is to document on FSIS Form 5720-3, State On-Site Audit Checklist, any establishment noncompliance that the State MPI program failed to identify or for

which the State MPI program failed to take appropriate regulatory action. FSAB is also to document on FSIS Form 5720-3 other findings that indicate that the State MPI program is not "at least equal to" the Federal inspection program (e.g., State MPI program personnel do not perform inspection or humane handling verification tasks "at least equal to" the Federal inspection program).

- L. At the conclusion of each establishment on-site review, FSAB is to report findings to the State MPI program officials.
- M. FSAB is to observe the State MPI program officials as they lead the exit conference with establishment management. During this time, FSAB is to discuss with State MPI program officials and establishment management the findings of the establishment review, including any noncompliances identified by FSIS and the State MPI program officials.
- N. Before leaving an establishment, FSAB is to ensure that State MPI program officials take appropriate regulatory actions for all noncompliances observed during the establishment review.
- O. In addition to the establishment reviews, FSAB is to assess product sampling, staffing, training, compliance program records (e.g., surveillance, investigations, and enforcement records), and management control documents at the State MPI program office. The document assessment is to include a representative sample of current records that assist the review team in determining whether the State MPI program implements its inspection consistently with its self-assessment documents. The review of the records is to verify that the State MPI program is carrying out these functions and maintaining its inspection activities in a manner that is "at least equal to" FSIS's Federal inspection program.
- P. After completing the on-site review, FSAB is to analyze the information collected during the review and the current fiscal year's self-assessment review results. FSAB may need to ask follow-up questions and request additional information to determine the supportability of findings and program deficiencies identified during the on-site review. FSAB's findings are to focus on the implementation of food safety policy and procedures, and if the program meets the criteria for the six components reviewed by FSAB and listed in Section IV.
- Q. The FSAB review team leader is to:
 - 1. Schedule an exit meeting with State MPI program officials within 10 business days of completion of the on-site review;
 - 2. Present the review team's findings to State MPI program officials at the exit meeting. The review team leader sends the findings by e-mail before the exit meeting;
 - 3. Request that the State MPI program officials submit a written action plan detailing how they will address all of the State MPI program's findings and FSAB's findings within 10 business days of the date of the exit meeting;
 - 4. Explain to the State MPI program officials that the State's action plan is to:
 - a. Identify the underlying causes of the findings and include any corrective actions needed to resolve the establishment noncompliances and review findings;
 - b. Identify the verification plan and management controls that the State MPI program will use to confirm that the action plan resolved the review findings and achieved its intended

goals, including verification that establishments corrected the noncompliances identified during the review; and

c. Identify the timeframe for completion of the action plan.

VIII. OPHS ON-SITE REVIEW

- A. OPHS has the responsibility of reviewing component 7, "Laboratory Quality Assurance Program and Methods."
- B. OPHS is to perform an on-site review of each laboratory that performs testing for State MPI programs. The review is to verify that the laboratory is "at least equal to" FSIS's laboratories, based on preliminary record review, on-site record review, and observation of method performance.
- C. OPHS microbiologists and chemists are to be assigned to each scheduled State laboratory review, with one auditor assigned as the lead auditor for each State or contract laboratory visited. Assigned auditors are to conduct a record review of the Component 7 self-assessment submission, described in Section V. G. Methods are to be reviewed to determine if they are "at least equal to" FSIS's laboratory methods. If additional information or clarification is needed to complete the preliminary review, the auditor is to contact the laboratory contacts by e-mail or phone.
- D. The OPHS lead auditor is to contact the laboratory to arrange acceptable dates for the on-site review. The audit is typically scheduled for two or three days.
- E. During the on-site review at each laboratory performing State MPI program testing, OPHS is to verify that the laboratory follows the required quality assurance activities, utilizes trained analysts to perform the submitted analytical methods as written, and maintains the capability to perform applicable analyses. Nonconformances to quality assurance and method requirements are to be discussed with the laboratory during the audit. A closing meeting is to be held at the laboratory to ensure that the laboratory contacts have a clear understanding those nonconformances.
- F. Following approval of the content by assigned OPHS reviewers, and within 30 days of the on-site audit, an audit report is to be distributed to laboratory directors or other contacts, with copies supplied to the State MPI program Director, FSAB, and OPHS personnel.
- G. The laboratory is to be given 30 days to provide corrective action responses (CARs) and objective evidence to support the described actions for all nonconformances identified in the audit report.
- H. The OPHS auditors are to review the submitted CARs, verify that all nonconformances have been addressed, and, when necessary, to prepare requests for additional records or information. Additional requests are to be provided to the laboratory within 30 days of the CAR receipt, unless additional time is requested.
- I. Within 30 days of receiving the final CARs, the OPHS audit team is to review the CARs, and the lead auditor is to distribute an audit closure letter.
- J. The OPHS lead auditor is to provide the Component 7 review determination to FSAB once the laboratory audit is concluded and before the end of the FFY.

IX. CRS ON-SITE REVIEW

- A. CRS has the responsibility for reviewing component 8, "Civil Rights."
- B. CRS is to assess each State MPI program's Civil Rights management controls for preventing discrimination in the delivery of program services to determine whether they are "at least equal to" FSIS's management controls, which are designed to prevent discrimination in the delivery of program services.

NOTE: Civil Rights compliance is based on the requirements set forth in Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975. These laws prohibit discrimination in all federally-assisted programs on the basis of race, color, national origin, age, sex and disability.

- C. The CRS reviewer is to begin preparation for the on-site review with a thorough assessment of the State MPI program's most recent self-assessment submission, which may be on FSIS Form 1520-1, "Civil Rights Compliance of State Inspection Programs".
- D. CRS is to issue a letter of determination based on the information reported in the self-assessment for State MPI programs not scheduled for an on-site review during the current fiscal year.
- E. At least 60 days before the scheduled start of the review, the CRS reviewer is to issue a notification announcing the date(s) and time(s) of the upcoming review. With the notification, CRS is to include a document request and questionnaire to which the State MPI program is to respond to within 30 days of receiving the notification. The document request is to be made and the questionnaire is to be used in assessing nine separate elements of Civil Rights compliance, including:
 - 1. Civil Rights Assurance Statements;
 - 2. Civil Rights Program Accountability;
 - 3. Public Notification;
 - 4. Demographic Data Collection;
 - 5. Discrimination Complaints;
 - 6. Civil Rights Training;
 - 7. Program Accessibility to Persons with Disabilities;
 - 8. Program Accessibility to Persons with Limited English Proficiency (LEP); and
 - 9. Compliance with Age Discrimination Act 1975.

NOTE: Because of fiscal restrictions, CRS may conduct some reviews by telephone, and if so, this information is to be provided in the notification announcing the upcoming review.

F. Using the information received in response to the document request and questionnaire, the CRS reviewer is to analyze and assess all information and data in preparation for the on-site visit. If the document request or questionnaire is found to be incomplete or if the reviewer needs additional clarification, CRS is to contact the State MPI program officials to request the missing or additional information.

- G. At least one week before the on-site review, the CRS reviewer is to work with the State MPI program to confirm all logistics and the details of the review process. The reviewer also is to provide State MPI program officials with a list of the selected establishments where interviews will be conducted.
- H. The CRS reviewer is to begin each State MPI program review with an introduction explaining the purpose and methodology for the review process to State MPI program officials. Following the introduction, the reviewer is to address each question or item in the completed questionnaire and is to discuss the corresponding Civil Rights program or management controls the State has in place to ensure compliance with all USDA and FSIS Civil Rights program policies. During the discussion, the reviewer is to answer any questions raised by the State MPI program officials, report any areas of noncompliance, and provide preliminary recommendations to correct noncompliance issues.
- I. During the on-site review at the State MPI program office, the CRS reviewer is to conduct a facility assessment to determine the building's accessibility for persons with disabilities, and is to determine whether the State has prominently posted the Civil Rights notifications and posters subscribed for in USDA and FSIS Civil Rights program policies.
- J. The CRS reviewer is to visit the selected establishments to interview establishment owners or operators following the on-site review at the State MPI program office. Interviews are to be used in assessing whether the establishment owner or operator has received State-inspection services in a nondiscriminatory manner.

NOTE: Some interviews with establishments are conducted by telephone.

- K. After completing the on-site review, the CRS reviewer is to analyze the information received in response to the document request, questionnaire, and any matters discussed during the on-site review. The reviewer may need to ask follow-up questions and request additional information to identify findings and program deficiencies after completion of the on-site review. The reviewer's findings are to focus on implementation of the State MPI program's Civil Rights programs and controls, whether the program is in compliance with all USDA and FSIS Civil Rights program policies, and whether the program meets the criteria for the nine elements reviewed by CRS.
- L. Within 120 days of the on-site review, CRS is to provide a written report documenting the review findings and whether the program is in compliance with all nine elements reviewed by CRS. If there are areas in need of improvement, the reviewer is to identify the action items for the State MPI program to implement.
- M. To ensure follow-up on the implementation of directed action items, CRS requires the State MPI program to report the status of all action items in the next annual self-assessment submission, FSIS 1520-1 Form "Civil Rights Compliance of State Inspection Programs". Upon receiving the self-assessment, CRS issues a letter of determination based on the information provided in the self-assessment.

X. FRAS ON-SITE REVIEW

- A. FRAS has the responsibility for review component 9, "Financial Accountability."
- B. The FRAS auditor is to begin preparing for the on-site review with a thorough assessment of the State MPI program's most recent self-assessment submission, including the successful reconciliation of quarterly and final Federal Financial Reports (SF-425).

- C. On-site financial reviews are to be scheduled on a three-year rotation to include analyses of financial data from the three most recent FFY's. By November 15th of each year, FRAS is to schedule on-site visits and send review engagement letters to the State Agencies (SAs) administering the State MPI programs that are subject to on-site reviews during the FFY.
- D. When an on-site financial review is to be performed, SAs provide FRAS with the following types of documents:

NOTE: Documents are to be from the grant years covered by the fiscal review.

1. Financial Records

- a. Accounting Reports (ARs), including the general ledger (GL) trial balances and detailed transaction listing by GL account containing the Meat and Poultry Inspection (MPI) Program's expenditures (preferably in Excel format);
- b. Supporting documentation for any manual adjustments made to the AR expenses (vehicle mileage, terminal leave payments);
- c. SF-425 Preparation and Review Procedures;
- d. Monthly, quarterly, and/or final worksheets and schedules that are used to collect, adjust, calculate indirect costs, and summarize the total costs that are reported on the Expense Reports (SF-425);
- e. Reconciliation by year of Federal Financial Report's, SF-425; line 10.e. Federal Share of Expenditures with accounting records;
- f. Documentation supporting expenditures related to other Food Safety and Inspection Service (FSIS) Awards (e.g., Talmadge/Aiken (T/A) Overtime, Public Health Data Communications Infrastructure System (PHDCIS), Egg Product Inspection, Custom Exempt, or Cross Utilization (CU));
- g. Copy of the Application for Federal Assistance (SF-424); and
- h. Expenditure chart accounts.

2. Personnel Records

- a. Payroll report or journal for each grant year under review:
- b. Detailed organizational chart of MPI program with employee names;
- c. Time and Attendance Report with all supporting forms and worksheets (from inspector to input into its central accounting system) for the last payroll for each grant year;
- d. Employee roster with the following information:
 - i. Employee Name;
 - ii. Job Title:

- iii. ID Number;
- iv. Date of Hire; and
- v. Hourly, Bi-weekly, or Monthly Salary.
- e. List of employee terminations and transfers and disposition of leave balances for these employees (only if terminal leave payments are made by the SA and there are no separate object codes for those payments), by:
 - i. Employee name;
 - ii. Date of retirement or departure from State service; and
 - iii. Payment amount (if any) for used annual and/or sick leave.
- 3. If State inspectors perform voluntary inspection, the following information:

NOTE: Voluntary, 100% State Inspection is defined as inspection of the slaughtering or processing of animals that are not covered by the FMIA or PPIA.

- a. Names of State plants;
- b. Names of State Inspectors; and
- c. Methodology used for keeping the Voluntary Inspection costs separate from the Cooperative MPI Program reimbursable costs.
- 4. Equipment Inventory Listing
 - a. Acquisition date and total acquisition cost; and
 - b. Identification of Federally funded items.
- 5. Internal Controls
 - a. Audit Reports; and
 - b. Policies and procedures for:
 - i. Personnel;
 - ii. Travel;
 - iii. Laboratory Services;
 - iv. Contractual Services; and
 - v. Equipment.

- E. The FRAS auditor is to begin each State MPI program review with an entrance conference with State MPI program officials. The auditor is to explain the purpose, scope, and procedures for the review.
- F. During the on-site review, the FRAS auditor is to:
 - 1. Review documents provided by the SA in response to documentation requirements listed in paragraph D and obtain any documentation that may have been omitted;
 - 2. Review the internal control structure of the SA;
 - 3. Prepare a detailed reconciliation of the proposal costs to the accounting records;
 - 4. Review management's classifications of exclusions, unallowable costs, indirect and direct costs;
 - 5. Through inquiry, and limited transaction testing, determine the reasonableness, allowability and allocability of exclusions, indirect and direct costs; and
 - 6. Review equipment or building usage costs.
- G. Before completing the on-site review, the FRAS auditor is to brief State MPI program officials on the preliminary results of the review and obtains the names and position titles of State employees who provide assistance during the review.
- H. After completing the on-site review, the FRAS auditor is to:
 - 1. Brief his or her supervisor on the preliminary results of the review and discuss any major findings;
 - 2. Prepare detailed reports for the Director of the Financial Management Division and SA; and
 - 3. Provide the Progress Report to the SA.
- I. The FRAS auditor is to work with the SA to address FRAS's findings and establish corrective actions. Once the findings are resolved, a closeout letter is sent to the SA.

XI. PROCESS FOR DETERMINING "AT LEAST EQUAL TO" STATUS

- A. Each year, FSIS determines whether each State MPI program meets the "at least equal to" standard. If the State MPI program is not scheduled for an on-site review during the fiscal year, FSIS makes an annual determination based on the results of the self-assessment review. If the State MPI program is scheduled for an on-site review during the fiscal year, FSIS makes an annual determination based on results of both the self-assessment and on-site review.
- B. FSIS makes one of the following three determinations for each component and on the State's overall ability to maintain its MPI program for the next 12 months.
 - 1. "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 the review findings; or

- 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.
- C. If the determination of the self-assessment or the on-site review is "at least equal to" FSIS's Federal inspection program, the FSIS program area promptly notifies the State MPI program officials in writing of this fact.
- D. If a State MPI program's corrective actions cannot be immediately implemented, but the State is committed to making the corrections and has the resources to support the changes, the FSIS program area may issue an "at least equal to" determination, provided that the corrective actions are completed by an agreed-upon date. FSIS may perform a targeted review or conduct a review of the relevant documents to verify that the State MPI program has corrected the findings before finalizing the "at least equal to" determination.
- E. If an FSIS program area determines that a State MPI program is not "at least equal to" FSIS's inspection program, an official of that program is to contact the FSAB Chief, who is to notify the Assistant Administrator of OIEA, and recommend designation of the State (<u>FSIS Directive 5710.1</u>, *Designation of a State or Individual State-Inspected Establishment for FSIS Inspection*).

XII. TARGETED REVIEWS OF STATE MPI PROGRAMS

A. Information from the States' annual self-assessment submissions, outbreak investigations, on-site reviews, or other available information may indicate the need for a targeted review of a State MPI program. FSIS may assign a review team to conduct a targeted review when there is evidence of one or more of the following conditions:

- 1. A foodborne disease outbreak incident associated with or attributed to a State-inspected product;
- 2. Adverse trends in inspection activities, such as insufficient staffing situations or inspection personnel's ineffective implementation of verification activities;
- 3. Food safety concerns identified during the self-assessment review or on-site review;
- 4. A rise in the number of product recalls;
- 5. An increase in surveillance and enforcement cases;
- 6. An increase in positive pathogen results;
- 7. The presence of any other incident or condition that imposes a clear risk to public health; or
- 8. Provisions from previous reviews that may influence the "at least equal to" determination.
- B. The review team assigned to conduct targeted reviews may be composed of the same staff members as described in Section IV, a smaller team (e.g., with only one program auditor or a subject matter expert from another program area), or a larger team, depending on the scope and urgency of the review.

- C. For targeted on-site reviews, the review team follows the methodology in Sections VII-X including:
 - 1. Focus the scope and activities of the review on the conditions and evidence that triggered the need for the review;
 - Inform the State MPI program officials of the upcoming targeted review, explain the scope and activities, request any needed information and materials, and schedule acceptable review dates; and
 - 3. Identify the review findings, determine if the State MPI program is imposing requirements "at least equal to" FSIS's Federal inspection program, and present the results of the review, along with any other information that accurately summarizes the program's "at least equal to" status, to appropriate State officials.

XIII. REPORTING

After receiving the routine and targeted review determinations from all program areas, FSAB develops an overall end-of-year summary report that includes the findings and final determinations for all State MPI Programs. FSIS posts this report on the FSIS Web site on an annual basis.

XIV. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff through <u>askFSIS</u>, by telephone at 1-800-233-3935, or through Supervisory channels. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 5720.3**

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 Program 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 FSIS Directive 5620.1, Using askFSIS, for additional information on submitting questions.

Assistant Administrator

Office of Policy and Program Development