

**Appendix O**

**FINAL REPORT**

**Fiscal Year 2023**

**Montana**

**April 2024**

Federal-State Audit Staff  
Office of Investigation, Enforcement and Audit  
Food Safety and Inspection Service  
U.S. Department of Agriculture

## Executive Summary

This report describes the outcome of the annual review of the Montana Department of Livestock, Meat and Poultry Inspection Bureau (MDOL/MPIB), conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), including an onsite audit conducted June 5–15, 2023. The annual review process consists of two parts: (1) annual review of the State self-assessment submissions and (2) triennial onsite audits, which are used to verify whether the State meat and poultry inspection (MPI) program enforces requirements “at least equal to” the Federal requirements. The purpose of the annual review was to: (1) verify the State of Montana imposes laws, regulations, and related policies with authorities and requirements “at least equal to” those provided by the Federal Meat Inspection Act (21 U.S.C. 601, et seq.) and Poultry Products Inspection Act (21 U.S.C. 451, et seq.); (2) determine whether Montana administers a State MPI program capable of ensuring meat and poultry products produced, distributed, and sold within the State are safe, wholesome, unadulterated, and properly labeled; and (3) confirm the State MPI program carries out its regulatory oversight activities effectively and efficiently.

The annual review focused on all nine “at least equal to” components: (1) Statutory Authority and Food Safety Regulations; (2) Inspection; (3) Sampling Programs; (4) Staffing, Training, and Supervision; (5) Humane Handling; (6) Compliance; (7) Laboratory Methods and Quality Assurance Program; (8) Civil Rights; and (9) Financial Accountability.

An analysis of the audit findings within each component did not identify systemic findings that may pose an immediate threat to public health. The following findings were identified by the FSIS Auditor:

- One establishment did not meet the sanitation requirements for grounds and pest control (9 CFR 416.2).
- One establishment did not identify all deficiencies during pre-operational procedures as written in the Sanitation SOP and associated records (9 CFR 416.11 – 416.17).
- Two establishments did not meet the recordkeeping requirements (9 CFR 417.4).
- One state establishment did not meet the labeling requirements (9 CFR 317).

On July 25, 2023, MDOL/MPIB submitted an action plan to correct the findings identified during the onsite audit. The action plan identifies the underlying causes of the system-wide findings and the underlying causes of the specific findings at individual establishments. It includes a verification plan to ensure statewide correction of these findings. In addition, MDOL/MPIB provided evidentiary documents to demonstrate verification of establishment compliance with the regulatory requirements.

Based on analysis of the identified findings, FSIS concluded that MDOL/MPIB maintains an inspection system and food safety verification systems “at least equal to” the Federal requirements pending its completion of proposed corrective actions outlined in the submitted action plan.

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## **I. INTRODUCTION**

This report communicates the results of an onsite verification audit conducted by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) in Federal fiscal year (FY) 2023 to evaluate Montana's administered meat and poultry inspection program (MPI) to determine if it is "at least equal to" FSIS' requirements and is capable of ensuring that the State's supply of meat and poultry products is safe, wholesome, unadulterated, and properly labeled and packaged. This report also summarizes information examined and analyzed as part of the annual review by FSIS to determine whether the Montana MPI program is "at least equal to" the FSIS inspection system.

The "at least equal to" standard requires that State MPI programs operate in a manner that is at least as effective as FSIS' Federal inspection program in the protection of public health. Under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), FSIS may contribute up to 50 percent of the estimated total cost of the State's MPI program and provide administrative support if 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)).

## **II. OBJECTIVE, SCOPE, AND METHODOLOGY**

The review focused on the nine "at least equal to" components: (1) Statutory Authority and Food Safety Regulations; (2) Inspection; (3) Sampling Programs; (4) Staffing, Training, and Supervision; (5) Humane Handling; (6) Compliance; (7) Laboratory Methods and Quality Assurance Program; (8) Civil Rights; and (9) Financial Accountability. For each identified component, Montana Department of Livestock, Meat and Poultry Inspection Bureau (MDOL/MPIB) submitted the self-assessment documents in the State Review and Communication Tool (SRCT) that included descriptions of current program operations and procedures, and other supporting documentation pertaining to the attainment of the component requirements. FSIS verifies the above components to ensure MDOL/MPIB is implementing food safety verification activities at State-inspected establishments that comply with applicable State laws, regulations, and policies to produce safe and wholesome products. FSIS examined the submitted documentation to verify MDOL/MPIB continues to maintain regulatory operations in accordance with FMIA (21 U.S.C. 601, et seq.) and PPIA (21 U.S.C. 451, et seq.) and to check for procedural nonconformities that may prevent operations from functioning as intended. In addition, FSIS evaluated the effectiveness of current internal control and risk assessment systems and determined if there were any findings.<sup>1</sup> FSIS also conducted an onsite audit to verify accuracy and implementation of the SRCT submissions for components 1–9.

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<sup>1</sup> An issue identified by a Federal-State Audit Staff Auditor. There are two types of findings: 1. Noncompliance-failure to meet a regulatory requirement. 2. Nonconformity-State Program, or any State Official fails to implement and/or follow a policy or procedure as proffered in their Self-Assessment.

### III. BACKGROUND

The FMIA (21 U.S.C. 661) and the 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” the requirements FSIS has established under the Humane Methods of Slaughter Act of 1978 (HMSA) (7 U.S.C. 1901–1906).

The FMIA and PPIA provide for FSIS to review, at least annually, each State MPI program and its requirements and enforcement activities. If a State fails to administer a meat and poultry inspection program that is “at least equal to” FSIS’ Federal inspection program, FSIS will move to “designate” the State in accordance with 21 U.S.C. 661(c) and 454(c).

Annually, non-designated States are expected to assess and support determinations that their MPI programs operate in a manner “at least equal to” the Federal inspection program. FSIS requires State MPI programs to submit self-assessment documents through the SRCT each year and provides guidance for this process in FSIS’ “At Least Equal To” Guideline for State Meat and Poultry Inspection Programs. At a minimum, the self-assessment documentation should be representative of the current operations of the State MPI program and demonstrate the program’s ability to meet the “at least equal to” Federal requirements for the next 12 months. State MPI programs are to provide narratives in the submitted documentation for any identified administrative or operational changes made to their programs since the last FSIS review and “at least equal to” determination. As a part of the self-assessment process, State MPI programs are expected to consider the intent and assess the applicability of FSIS statutes, regulations, directives and notices in their inspection operations and compliance enforcement strategies. FSIS expects State MPI programs to submit for review copies of all applicable laws, administrative rules, regulations, and policies deemed necessary to carry out inspection programs “at least equal to” the Federal requirements.

In addition, FSIS conducts onsite audits of State MPI programs at a minimum of every 3 years to verify the accuracy and implementation of the State MPI programs’ self-assessment submissions. In years when a State MPI program is subject to FSIS’ onsite audits, the annual “at least equal to” determination will be based on analysis of results collected through FSIS’ two-part review and audit process. Otherwise, the annual “at least equal to” determination will be based solely on review and analysis of the state’s self-assessment submissions.

MDOL/MPIB, a State organization with the overall authority to administer the State MPI program, submitted the required program self-assessment documents to demonstrate administrative and program-wide compliance with all nine “at least equal to” components. FSIS evaluated the State’s self-assessment documentation and conducted an onsite verification audit of the State MPI program.

The establishment selection process for onsite audits employs a systematic approach that considers risk determinants such as sample results, recalls, production volume, and other information obtained directly from the State MPI programs through the SRCT. For this audit, a sample of 10 establishments was selected from a total of 31 State-inspected establishments.

MDOL/MPIB administers the Montana MPI program under authority of Montana Code Annotated (Title 81, Chapter 9) and Administrative Rules of Montana (Department 32, Chapter 6). MDOL/MPIB is organized on three levels: State office, State inspection, and compliance program. The program verifies compliance and enforces regulatory requirements at inspected establishments and custom exempt operators.<sup>2</sup>

FSIS verified through interviews and record reviews that all MDOL/MPIB personnel are employed by the State of Montana and are conducting verification activities as outlined in the self-assessment.

The table below details the number of inspected establishments and custom exempt operators.

Total Number of State-Inspected Establishments and Custom Exempt Operators

	<b>Establishment Type</b>	<b>Slaughter Only</b>	<b>Processing Only</b>	<b>Combination Slaughter and Processing</b>	<b>Total</b>
<b>Number of State-Inspected Establishments</b>	Meat Only	0	9	13	22
	Poultry Only	0	0	1	1
	Combination Meat and Poultry	0	6	2	8
	<b>Total</b>	0	15	16	31
<b>Number of Custom Exempt Operators</b>	Meat Only	2	44	41	87
	Poultry Only	0	0	19	19
	Combination Meat and Poultry	0	7	28	35
	<b>Total</b>	2	51	88	141

#### IV. COMPONENT 1: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The State laws or administrative rules must grant the State MPI program the legal authority to administer an inspection program. State MPI program is required to have meat and poultry inspection laws and governing regulations to impose mandatory ante-mortem and post-mortem inspection, reinspection, sanitation requirements, recordkeeping requirements, and enforcement

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<sup>2</sup> Custom exempt operators are not subject to the routine inspection requirements of the FMIA and PPIA, provided the specified operations meet the exemption requirements (21 U.S.C. 623 and 464).

authorities “at least equal to” those prescribed by the FMIA (21 U.S.C. 601, et seq.) and PPIA (21 U.S.C. 451, et seq.).

FSIS reviewed the self-assessment documentation submitted as evidence showing that Montana has enacted laws, administrative rules, and regulations that provide legal authority “at least equal to” that provided under the FMIA, PPIA, HMSA, and applicable sections of 9 CFR.

The enacted State meat and poultry inspection laws, Montana Code Annotated (MCA) impose, at a minimum, the following mandatory requirements that are “at least equal to” those under the FMIA and the PPIA:

- ante-mortem and post-mortem inspection (Section 81–9–230);
- reinspection (Section 81–9–220);
- sanitation requirements (Section 81–9–220);
- record keeping requirements (Section 81–9–220);
- humane methods of slaughter requirements (Section 81–9–219);
- adulteration (Section 81–9–217);
- misbranding (Section 81–9–217);
- prohibited acts (Section 81–9–234);
- access and examination (Section 81–9–220); and
- product control actions (Section 81–9–116 and exemption from Section 81–9–218); and
- exemption from inspection (Section 81–9–218).

The MCA grants the authority to promulgate rules and regulations (Section 81–9–220). Montana adopts by reference 9 CFR Parts 301–321.3, 325–325.21, 329.1–329.9, 352–362.5, 381–381.103, 381.115–381.182, 381.190, 381.194, 381.210–381.218, 381.300–381.524, and 416.1–500.8 in the Administrative Rule of Montana 32.6.712.

FSIS confirmed through onsite record reviews, interviews, and observations that MDOL/MPiB has statutory authority to enforce the provisions of MCA and the governing administrative rules and regulations, respectively, at State-inspected establishments and firms handling meat and poultry products within the State as outlined in the FY 2023 self-assessment submission. There were not any statutory or regulatory changes made this year that affect how MDOL/MPiB carries out its regulatory duties.

FSIS auditor did not identify any findings and determined that MDOL/MPiB operates under State laws and regulations that provide legal authority “at least equal to” that provided under the FMIA, PPIA, HMSA, and governing regulations.

## **V. COMPONENT 2: INSPECTION**

The State MPI program is required to administer a regulatory inspection program “at least equal to” that provided by FSIS. The inspection program is to include, at a minimum, inspection verification methods for verifying:

- Animals are suitable for slaughter, and carcasses and parts are eligible for human consumption;

- All meat and poultry products found in intrastate commerce are safe, unadulterated and truthfully labeled;
- All official establishments comply with sanitation performance standards (SPS), sanitation standard operating procedures (Sanitation SOP) and sanitary dressing regulatory requirements as articulated in 9 CFR 416, or equivalent governing State regulations;
- All official establishments develop, implement, and maintain written and Hazard Analysis and Critical Control Points (HACCP) systems as articulated in 9 CFR 417, or equivalent governing State regulations.

The inspection verification methods implemented by the State MPI program must include activities for evaluating compliance at official establishments with the applicable inspection and food safety verification requirements of 9 CFR 300 to End. These are to include observation of establishments' operations and employees' product handling practices, hands-on verification, and review of establishment records, with the results of verification being entered in the associated inspection records. The State MPI program also are to implement inspection verification methods for ensuring State-inspected meat and poultry products are wholesome, not economically adulterated, truthfully labeled, and meet regulatory requirements. The State MPI program must ensure inspection personnel interpret and apply relevant regulatory requirements uniformly when conducting inspection verification methods. The ultimate regulatory goal of the State MPI to protect consumers from meat or poultry products that are unwholesome, economically adulterated, or not truthfully labeled (21 U.S.C. 607 and 457).

FSIS reviewed the self-assessment documentation submitted as evidence showing that MDOL/MPIB has developed and implemented:

- An inspection system to ensure State-inspected establishments comply with applicable food safety and other consumer protection regulations (e.g., ante-mortem and post-mortem inspections, sanitation, HACCP system, and product standards and labeling;
- A generic label approval policy and process to verify labels, marks, or devices are accurate and comply with regulatory requirements prior to establishments applying them to inspected meat or poultry products;
- A risk-based methodology to analyze establishments' food safety systems to verify that the establishments can produce safe and wholesome meat or poultry products in accordance with applicable statutory and regulatory requirements;
- A system of administrative enforcement actions to bring establishments effectively under regulatory compliance in a manner that is not inferior to the comparable actions taken by FSIS; and
- An internal control system for evaluating the efficacy and effectiveness of the other systems.

MDOL/MPIB uses the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. MDOL/MPIB administers inspection for any meat or poultry product intended for human consumption, wholly or in part, from the carcass or parts of any animal defined as "livestock" or "poultry" in the MCA (Section 81–9–220) and governing rules, regulations and policies. The State inspection program maintains assurances that animals intended to be used in meat and poultry products sold commercially are



slaughtered and processed in the presence of State inspection personnel, and the resulting products are inspected and passed for human consumption. MDOL/MPIB adopts and implements all relevant FSIS issuances as its policies for carrying out inspection and food safety verification activities.

MDOL/MPIB schedules and performs a comprehensive Food Safety Assessment (FSA) at each inspected establishment on a 3-year cycle and follows FSIS Directive 5100.1, Enforcement, Investigations and Analysis Officer (EIAO) Food Safety Assessment (FSA) Methodology when conducting the FSA. These FSAs examine the design and validity of establishments' food safety systems, which include hazard analyses, HACCP plans, Sanitation Standard Operational Procedures (SSOPs), prerequisite programs, sampling programs, supporting documentation and records, and any other programs that constitute the establishments' food safety systems. In addition to the scheduled FSAs, supervisors conduct a plant review twice per year to verify the inspection staff is performing tasks as required. MDOL/MPIB follows FSIS Directive 5100.4, Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology. The PHRE and FSA records support the conclusion that State inspection personnel recognize and document noncompliance and initiate appropriate regulatory actions.

FSIS audited the conditions and documents onsite. The onsite documents audited included, but were not limited to, Sanitation SOPs and associated records; HACCP plans and associated records; generic *Escherichia coli* (*E. coli*) sampling procedures and associated records; procedures for the removal, segregation, and disposition of specified risk materials and associated records; custom exempt records; noncompliance records; and enforcement letters. In addition, FSIS audited the non-food safety consumer protection documents and procedures to determine whether MDOL/MPIB enforces non-food safety consumer protection regulatory standards "at least equal to" the Federal requirements. This audit included, but was not limited to, ongoing regulatory verification tasks, label approvals, labels, and product formulations.

FSIS evaluated MDOL/MPIB inspection at ten establishments during the onsite audit. MDOL/MPIB personnel identified several establishment noncompliances with Sanitation SOP, Sanitation Performance Standards (SPS), HACCP design and validity, non-food safety consumer protection requirements, labeling, and generic *E. coli* sampling requirements.

The FSIS program auditor identified the following noncompliances, which were not identified by MDOL/MPIB:

- One establishment did not meet the sanitation requirements for grounds and pest control (9 CFR 416.2).
- One establishment did not identify all deficiencies during pre-operational procedures as written in the Sanitation SOP and associated records (9 CFR 416.11 – 416.17).
- One establishment did not identify calibration of instruments as an ongoing verification procedure (9 CFR 417.4).
- One establishment did not conduct record reviews (9 CFR 417.4).

In response to the above findings, MDOL/MPIB officials initiated corrective actions and provided evidentiary documentation demonstrating the establishments were brought back into

compliance. In addition to the above, FSIS identified inspected and passed product which did not bear the mark of inspection.

- An establishment freezer contained product that was slaughtered and processed under State inspection and had all general labeling requirements except the mark of inspection and net weight. Discussions with the establishment owner indicated the products were intended for resale, and the missing label features were intentionally not applied for business reasons. State inspection personnel did not identify the misbranding noncompliance (9 CFR 317).

This finding was consistent with an onsite audit finding in FY2021, which documented MDOL/MPIB not enforcing all labeling requirements, such as applying the state mark of inspection, net weight, and establishment number. Following the FY 2021 finding, MDOL/MPIB submitted corrective actions, which included employee training and additional labeling tasks. In response to the current findings, the State Director assigned additional PHIS labeling tasks and supervisory oversight to verify compliance with labeling requirements. During the audit, FSIS verified all products were produced under State inspection, all HACCP requirements were met, product were properly labeled, and determined the findings did not pose an immediate risk to public health.

Based on analysis of the identified findings, FSIS determined that MDOL/MPIB maintains inspection and food safety verification systems “at least equal to” the Federal requirements.

## **VI. COMPONENT 3: SAMPLING PROGRAMS**

The State MPI program is required to assess establishments’ control of microbial pathogens, violative levels of veterinary drugs, pesticides, contaminants, and other adulterants through product sampling. The State MPI program must have access to laboratory services to conduct chemical, microbiological, physical, and pathological testing. Laboratories conducting official analyses for State inspection programs must ensure test results are accurate, reliable, and reproducible.

FSIS reviewed MDOL/MPIB’s product sampling documents, protocols, procedures, and results presented in the FY 2023 self-assessment submission. FSIS verified through interviews and record reviews that MDOL/MPIB maintains sampling programs, based on sound rationale and goals, for the following:

- *E. coli* O157:H7 in raw non-intact beef products and raw ground beef components;
- Non-O157 Shiga toxin-producing *E. coli* (non-O157 STEC) in beef manufacturing trimmings;
- *Listeria monocytogenes* (*L. monocytogenes*) and *Salmonella* in ready-to-eat (RTE) products; and
- Other consumer protection standards.

MDOL/MPIB implements developed sampling procedures for collecting samples, maintaining sample integrity, determining sampling frequencies, conducting sample analyses, responding to positive results, and preventing adulterated product from entering commerce. Additionally,

MDOL/MPIB participates in the National Residue Program and collects and analyzes inspector-generated samples for violative drug residues.

MDOL/MPIB adopts and implements all relevant FSIS issuances as its own policies for carrying out inspection and food safety verification activities. MDOL/MPIB determines sample frequency based on the FSIS Guidance to States on Frequency of Microbiological Testing for the fiscal year sent out by FSIS. Inspectors and supervisors receive sample request letters generated by the State office at the beginning of each month. All sample requests and sample results are tracked and documented at the MDOL/MPIB State office and in-plant inspection files.

FSIS auditor did not have any findings and determined that MDOL/MPIB maintains verification testing to address adulterants, other measures of properly operating food safety systems, and other consumer protection standards “at least equal to” the Federal requirements. Control measures are in effect to ensure that the sampling programs function as intended.

## **VII. COMPONENT 4: STAFFING, TRAINING, AND SUPERVISION**

The State MPI program must maintain enough staff to carry out its responsibilities. The State MPI program is to organize a sufficient number of trained veterinarians, inspectors, and enforcement staff to carry out the inspection and regulatory duties of the MPI program well. The State MPI program ensures its personnel receive the professional, technical, inspection, and managerial training necessary to maintain a competent and effective workforce. The State MPI program is to provide instructions to MPI personnel on performing daily inspection tasks and compliance enforcement activities.

FSIS reviewed MDOL/MPIB’s submitted documents and confirmed MDOL/MPIB implements administrative programs to ensure a competent workforce provides daily inspection coverage in each State-inspected meat and poultry establishment where the State inspection marks are applied to products. In addition, the documentation outlines a training program that includes both formal and informal job-related courses. The State’s supervisory system aligns individual workloads with Alabama’s public health and regulatory goals and sets standards for assessing job performance that includes measures to correct of unsatisfactory performance.

In FY 2022, the State MPI program was lacking an EIAO to conduct FSAs on the 3-year cycle. Therefore, FSAs were not being conducted per MDOL/MPIB submission. The State Director prioritized for cause FSAs. On the occasion there is a for cause FSA, the State Director will conduct the FSAs herself. MDOL/MPIB hired an EIAO in May of FY 2023. He has been trained and has begun conducting FSAs.

Currently MDOL/MPIB has enough staff to carry out its responsibilities. The State MPI program ensures that there is a sufficient number of trained veterinarians, inspectors, and enforcement staff to handle the inspection and regulatory duties of the program properly. The State MPI program ensures that its personnel receive the professional, technical, inspection, and managerial training necessary to maintain a competent and effective workforce. State MPI programs provide

direction on daily State inspection and compliance enforcement activities performed by State MPI program personnel.

MDOL/MPIB developed methods to determine staffing requirements. The requirements consider each inspector's workload and the number of inspectors required to provide daily inspection coverage in each establishment on days when the establishment produces products bearing the State mark of inspection. Procedures are in effect to document staffing in each establishment, identify failures to meet staffing requirements, and correct staffing deficiencies. Inspectors are assigned specific circuits, with area supervisors coordinating routine and emergency leave as needed. Inspectors complete and submit weekly activity reports. The field supervisors review the activity reports to verify daily inspection coverage and arrange relief inspection during routine and emergency leave situations.

After further analysis of data from MDOL/MPIB office and establishment audits, FSIS concluded that MDOL/MPIB has an adequate number of trained persons to provide the required inspection coverage in the establishments, perform compliance verification activities, and provide supervisory oversight, and has implemented procedures to ensure daily inspection coverage in operating establishments. Inspection personnel apply MDOL/MPIB's inspection methodology and make decisions based upon the correct application of inspection methodology, document findings, and initiate regulatory action, if needed.

MDOL/MPIB continues to implement a training program for new entry-level inspection personnel. The training covers basic slaughter techniques and all inspection techniques required to perform slaughter duties, including basic Sanitation SOPs and HACCP procedures. The MDOL/MPIB has one designated trainer who also functions as the EIAO. The training subjects include livestock inspection, slaughter inspection, processing inspection, HACCP, SSOPs, and sanitation performance standards. With the transition to virtual delivery of FSIS Inspection Methods training, MDOL/MPIB has made a goal of sending all inspection program personnel (IPP) to Inspection Methods training, and currently has several inspectors who have completed virtual Inspection Methods training. MDOL/MPIB maintains a record keeping system to track participation and completion of training.

MDOL/MPIB incorporates the guidance in FSIS Directive 4430.3, In-Plant Performance System (IPPS), to set performance standards, and complete and record ongoing performance evaluations. The supervisors are to perform at least two IPPS assessments for each inspector annually. MDOL/MPIB maintains control measures to examine the IPPS assessments for quality, completeness, and accuracy. In addition, Montana mandates a performance plan and evaluation system for all State employees. This system communicates to its employees their work responsibilities, performance goals and objectives, and the results of their annual performance evaluations.

The FSIS determined MDOL/MPIB maintains sufficient resources to provide the required inspection coverage at State-inspected establishments to ensure that only safe, wholesome, unadulterated, and properly labeled meat and poultry products receive the State mark of inspection.

In addition, the information supports the determination that inspection personnel have the education and training needed to apply MDOL/MPIB's inspection methodology, to document findings, and to initiate regulatory actions when necessary. Control measures are in effect to ensure that the staffing, training, and supervision systems function as intended.

## **VIII. COMPONENT 5: HUMANE HANDLING**

The State MPI program is required to ensure the slaughter and handling of livestock is done humanely in accordance with the HMSA 1978 (7 U.S.C. 1901–1906) and FMIA 21 U.S.C. 603 (b) and 610 (b)). The State MPI program is expected to impose laws “at least equal to” the HMSA and the requirements outlined in FSIS Directives 6900.1 and 6900.2. When livestock are slaughtered humanely, they are to be rendered insensible to pain by means that are rapid and effective before being shackled, hoisted, thrown, cast, or cut. The HMSA requires establishments to comply with a prescribed method of slaughter in which the animal loses consciousness by severing its carotid arteries simultaneously and instantly with a sharp instrument when slaughtered livestock in accordance the ritual requirements of with Jewish faith and any other religious faiths.

The State MPI Program is required to ensure poultry operators comply with Good Commercial Practices (GCP). The Poultry Products Inspection Act (PPIA) (21 U.S.C. 453(g)(5)) and the regulations (9 CFR 381.90) provide that poultry carcasses showing evidence of having died from causes other than slaughter are considered adulterated and must be condemned. The regulations (9 CFR 381.65(b)) also require that poultry be slaughtered in accordance with GCP. Poultry are to be slaughtered in a manner that ensures that breathing has stopped before scalding, so that the birds do not drown, and that slaughter results in thorough bleeding of the poultry carcass. Compliance with these practices helps ensure that poultry are treated humanely.

FSIS reviewed submitted humane handling policies, ante-mortem inspection reports, noncompliance records, and periodic supervisory review records. The results of the reviews revealed MDOL/MPIB schedules and performs regulatory verification procedures to assess whether establishment personnel humanely handle all livestock throughout the time the livestock are on official establishment premises, and it takes appropriate regulatory action in response to noncompliance.

FSIS audited the humane handling program and documents presented onsite to determine whether MDOL/MPIB adequately enforces the humane slaughter of livestock regulatory standards to ensure that animals presented for slaughter are humanely handled throughout the time they are on official establishment premises. These documents included, but were not limited to, noncompliance records and procedure schedules. When conducting establishment audits, FSIS observed humane handling of livestock, stunning methods, and the condition of livestock pens, driveways, and ramps.

MDOL/MPIB uses FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. Inspectors document humane handling verifications in PHIS and on Weekly Activity Reports. During semi-annual visits, Area

Supervisors evaluate establishments' humane handling procedures and inspectors' humane handling task performance. MDOL/MPIB Area Supervisors perform semi-annual humane handling reviews at slaughter facilities in accordance with FSIS Directive 6910.1, District Veterinary Medical Specialist (DVMS) – Work Methods.

The information supports the conclusion that MDOL/MPIB verifies compliance with the humane handling requirements and takes regulatory action “at least equal to” the Federal program. Control measures are in effect to confirm that the humane handling verification system functions as intended.

FSIS did not any findings and determined that MDOL/MPIB operates under State laws and regulations that provide legal authority “at least equal to” that provided under the FMIA, PPIA, HMSA, and governing regulations.

## **IX. COMPONENT 6: COMPLIANCE**

The State MPI program is required to enforce compliance with all applicable laws and regulations and to take appropriate action in the event of noncompliance. The State MPI program must have the ability to:

- Detain adulterated or misbranded product (21 U.S.C. 672 and 467 (a));
- Take appropriate control in intrastate commerce of adulterated or misbranded product and to ensure proper disposition of such product, including seizure, condemnation, and destruction where appropriate (21 U.S.C. 673 and 467 (b));
- Ensure establishments maintain written recall procedures for all meat and poultry products produced and shipped (21 U.S.C. 613 and 459(c)(1));
- Conduct surveillance activities to ensure animal carcasses, and carcass parts that are not intended for use as human food are not diverted to such uses; and
- Refuse or withdrawal inspection services as warranted (21 U.S.C. 671, 467, and 457 (b)). The State must maintain a statutory process to prosecute anyone who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with officials in the performance of their official duties (21 U.S.C. 675 and 461 (c)).

FSIS reviewed submitted self-assessment documents and confirmed MDOL/MPIB maintains a compliance system to enforce food safety, food defense, inspection exemption, and other consumer protection statutory requirements in intrastate commerce. MDOL/MPIB follows State compliance policies or adopted FSIS directives to:

- Conduct surveillance activities and investigations, as warranted, of firms producing meat and poultry products in intrastate commerce;
- Control unsafe or violative products through detentions, seizures, and voluntary recalls;
- Take appropriate enforcement actions when adulterated or misbranded products are found in intrastate commerce; and
- Develop case files to ensure all enforcement actions imposed are legally supported by applicable State laws.

FSIS audited the documents presented onsite. These included, but were not limited to, Reports of Investigation, Daily Activity Reports, Programmed Compliance Plans, Incident Reports, Case Reports, Reports of Apparent Violations, and Notices of Warning.

MDOL/MPIB personnel conduct in-commerce surveillance of persons or firms that prepare, transport, sell, or offer for sale meat and poultry products in intrastate commerce to verify compliance with State statutory and regulatory requirements, and to verify that meat and poultry products in intrastate commerce are wholesome; correctly packaged and labeled; and are secure from threats or intentional acts of contamination.

MDOL/MPIB investigates alleged or actual statutory or regulatory violations; controls products when there is reason to believe that the products are adulterated, misbranded or otherwise in violation of the Montana Code Annotated (Title 81, Chapter 9); and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the Montana Code Annotated. MDOL/MPIB has procedures to maintain and preserve the legal integrity of documentary and other evidence to support legal action, and to report transportation accidents that involve State-inspected and passed meat and poultry products.

The MDOL/MPIB Bureau Chief reviews all compliance reports for correctness, reviews all violations and relevant evidence, and then determines the appropriate case disposition and course of action.

MDOL/MPIB maintains procedures for the recall of meat and poultry products subject to its jurisdiction that are “at least equal to” the procedures described in FSIS Directive 8080.1, Recall of Meat and Poultry Products. These procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. Firms are to notify MDOL/MPIB within 24 hours of initiating a recall. MDOL/MPIB oversees the recall activities, coordinates actions to determine whether adulterated product was removed from commerce, and issues news releases as necessary to serve the interest of public health.

MDOL/MPIB established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. Compliance personnel either investigate these complaints or refer them to the local health authority. The investigative methods include procedures to collect and safeguard evidence; conduct interviews; submit product samples to the laboratory; initiate recall procedures and/or regulatory and enforcement actions; and report potential food safety threats.

MDOL/MPIB has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. MDOL/MPIB IPP conduct custom exempt reviews at least twice annually at all exempt operators, and meat depots once annually. Meat depots are defined in ARM 32.6.701 as a facility where meat or poultry food products, or meat or poultry by-products, capable for use as human food and intended for sale, are stored. MDOL/MPIB classifies findings from custom exempt operator reviews as either critical, major, or minor. Critical findings are defined as conditions in which definite product adulteration has occurred and the facility will be reviewed again within 5 days and again the next quarter. Major findings are defined as those that are a likely cause of product adulteration and the facility will

be reviewed again within 9 days. Minor findings are defined as those that may potentially cause product adulteration, and the facility will be reviewed again within 6 months.

FSIS did not have any findings and determined that MDOL/MPIB maintains sufficient resources to conduct surveillance reviews at registered firms, which may lead to investigations and enforcement actions. The information supports individuals, firms, and corporations in complying with applicable State statutes when producing, transporting, storing, and distributing meat and poultry products in intrastate commerce. The information supports the conclusion that inspection personnel have the education and training needed to apply MDOL/MPIB's inspection methodology, to document findings, and to initiate regulatory actions when necessary. Control measures are in effect to ensure that the compliance systems function as intended.

## **X. COMPONENT 7: LABORATORY METHODS AND QUALITY ASSURANCE PROGRAM**

The State MPI program must use product sampling and laboratory methods with capabilities and safeguards "at least equal to" FSIS' product sampling and laboratory methods. State MPI program is to update and maintain as necessary its laboratory microbiological and chemical detection methods to keep pace with the applicable FSIS methods detailed in the FSIS Microbiology Laboratory Guidebook and USDA FSIS Chemistry Laboratory Guidebook.

An onsite audit of the Montana Public Health Laboratory (MPHL) was performed during FY 2023 to evaluate laboratory quality assurance programs and method equivalence under the State MPI Program.

MPHL has an agreement with South Dakota State University-Animal Disease Research and Diagnostic Laboratory (South Dakota) for the Cooperative Interstate Shipment "same as" program to conduct FSIS Microbiology Laboratory Guidebook methods for the microbiological analyses of *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, and non-O157 STEC on its behalf.

As a participant in the State MPI program, MPHL conducts microbiological testing for *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, and non-O157 STEC.

MPHL has an agreement with USDA/FSIS/Eastern Laboratory (EL) to conduct chemistry testing for the Cooperative Interstate Shipment and MPI programs on its behalf to include moisture, protein, fat and salt.

FSIS compared the MPHL Laboratory Quality Assurance Program to the State MPI Program Laboratory Quality Management System Checklist and evidence of laboratory proficiency and analyst training was evaluated. MPHL met all laboratory quality assurance (QA) requirements. South Dakota met all laboratory QA requirements.

EL has adequate food chemistry capability for the measurement of moisture, protein, fat, and salt. MPHL and South Dakota have demonstrated adequate microbiological capabilities for detection of *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, and non-O157 STEC.



Based on the Component 7 methods and quality assurance program review, MDOL/MPIB will be eligible to perform inspection:

- At beef establishments producing raw ground beef and bench trim, provided that the State collects and submits the appropriate number of samples that are tested for *Salmonella* and *E. coli* O157:H7, and at beef slaughter establishments producing manufactured trim, where the State is required to collect and submit the appropriate number of samples that are tested for *Salmonella*, *E. coli* O157:H7, and non-O157 STEC.
- At ready-to-eat (RTE) meat and poultry establishments, provided that the State collects and submits the appropriate number of samples that are tested for *Salmonella* and *L. monocytogenes*.
- At poultry slaughter establishments, provided that the State collects and submits the appropriate number of samples that are tested for *Salmonella* and *Campylobacter*. MPI States with no participating facilities slaughtering at least 20,000 chickens and/or 20,000 turkeys per year are not required to test that raw product for *Salmonella* and *Campylobacter* since it is not required at similar federally inspected plants. Note: Analytical methods for *Salmonella* and *Campylobacter* in raw poultry products were not evaluated as MDOL/MPIB is not currently inspecting poultry establishments slaughtering at least 20,000 chickens and/or turkeys per year.

On September 18, 2023, FSIS determined the analytical methods used for microbiological and chemical analyses are “at least equal to” the FSIS methods.

## **XI. COMPONENT 8: CIVIL RIGHTS**

The State MPI program is to adhere to 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.) and applicable USDA Civil Rights regulations.

In November 2022, MDOL/MPIB submitted the required FSIS Form 1520-1, *Civil Rights Compliance of State Inspection Programs*, to demonstrate adherence to Federal civil rights laws and USDA civil rights regulations.

FSIS conducted a Civil Rights compliance review of MDOL/MPIB. The review was conducted to determine compliance with applicable Civil Rights statutes, USDA regulations, and FSIS policies and, where necessary, provide recommendations for program improvement. The review focused on the State’s compliance in eight components: (1) Civil Rights Assurances; (2) State Infrastructure and Program Accountability; (3) Public Notification; (4) Complaints of Discrimination; (5) Civil Rights Training; (6) Civil Rights Compliance, (7) Program Accessibility to Individuals with Limited English Proficiency; and (8) Compliance with the Age Discrimination Act of 1975.

On June 29, 2023, FSIS determined the Montana’s Civil Rights program to be in compliance with “at least equal to” standards for applicable civil rights laws, USDA regulations, and FSIS policies.

## **XII. COMPONENT 9: FINANCIAL ACCOUNTABILITY**

The State is to appropriate funds commensurate with those provided by FSIS as specified in the Cooperative Agreement. Funding is sufficient to ensure the operation of an inspection program consistent with the criteria of the Cooperative Agreement and the satisfactory and uninterrupted operation of State inspection program activities. The State is to ensure that there is appropriate use of Federal funds, adequate accounting support for the State inspection program, and timely and accurate submission of expense reports.

MDOL/MPIB submitted quarterly and final Federal Financial Reports (SF-425), and an annual Indirect Cost Proposal to demonstrate it conforms to 2 CFR Part 400 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, and follows FSIS Directive 3300.1, Fiscal Guidelines for Cooperative Inspection Programs.

FSIS determined that MDOL/MPIB is “at least equal to” Federal standards for financial accountability for FY 2023.

## **XIII. DETERMINATION FOR MONTANA**

Based on the evidence and results described above, FSIS determined that MDOL/MPIB operates its MPI program “at least equal to” the Federal requirements for all components and enforces requirements “at least equal to” those imposed under the Federal Acts.