VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS CONSUMER PROTECTION AND FOOD SAFETY

Meat Inspection Service MONTPELIER, VT Anson Tebbetts, Secretary

MIS DIRECTIVE	5220.1 Rev 1	12/31/22
Adopted from FSIS Directive 5220.1 Rev 1		

GRANT OF INSPECTION MANAGEMENT IN PHIS; PROCESS FOR LICENSING

I. PURPOSE

This directive provides instructions for issuing a commercial licenses, to have the license voluntarily suspended or withdrawn; and to reinstate the license after voluntary suspension or voluntary withdrawal. Finally, this directive provides instructions for entering data related to these activities and how to manage a grant of inspection (GOI) in the Public Health Information System (PHIS).

NOTE: In this directive, the term establishment includes official meat and poultry establishments. Duties can be performed by a designee when appropriate, when the designee has the applicable role in PHIS available, and when approved by the supervisory chain.

Per 6 V.S.A. § 3305 (8), the federal meat inspection regulations and federal poultry inspection regulations of the U.S. Department of Agriculture, Title 9, Code of Federal Regulations, Chapter 3, 9 CFR §§ 300.1 et seq., together with any amendments, supplements, or revisions thereto, are adopted, for the State meat inspection program to operate in an 'equal to' status.

II. CANCELLATION

FSIS PHIS Directive 5220.1, Rev. 1, Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS, 1/30/13

III. RESPONSIBILITIES FOR GRANTING INSPECTION FOR NEW OFFICIAL MEAT AND POULTRY ESTABLISHMENTS

- A. When an applicant requests a new commercial license for meat and poultry products, the Chief of Inspection or designee, is to confirm that inspection is required based on the information provided by the applicant on intended activity. Inspection is required, per <u>6 V.S.A. § 3306, 9 CFR 302.1</u>, <u>381.6, 532.1</u>, and <u>590.20</u>, at establishments that slaughter or prepare meat food products or slaughter or process poultry for human food that is subsequently transported and held for sale in commerce. Examples of preparing meat or poultry products include, but are not limited to, canning, salting, rendering, boning, cutting up, or otherwise manufacturing or processing.
- B. The Chief is to provide applicants interested in voluntary and other reimbursable services instructions on how to request these services, and the Form 5200-6 Request for Voluntary Inspection. This requesting of voluntary or other reimbursable services is a separate procedure from

the application for mandatory State inspection.

- C. If inspection is required, the Chief is to provide the Meat and Poultry Inspection guide to the applicant. Additionally, the following documents are helpful:
- 1. Request for Meat Inspection Services and Meat Handler's License Application
- 2. Sanitation Performance Standards Compliance Guide;
- 3. How to Develop a Meat and Poultry Product Recall Plan;
- 4. FSIS Compliance Guideline HACCP Systems Validation;
- 5. <u>FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock</u> (for livestock slaughter establishments);
- 6. Vermont Humane Handling and Good Commercial Practices; and
- 7. FSIS Food Defense Plan Security Measures for Food Defense.
- 8. Guidebook for the Preparation of HACCP Plans;
- 9. A Sanitation Standard Operating Procedure Model;
- 10. Appropriate <u>HACCP Models</u> based on the HACCP processing categories identified on the application; and
 - 11. The Food Standards and Labeling Policy Book if requested
- D. For all applications for meat and poultry, the Chief or designee is to review the application for accuracy and completeness. The Chief or designee is to return to the applicant any application that is not complete and specify the areas of the form that need attention.
- e. For all new applications, if questions 21, 22 or 23 on the <u>Request for Meat Inspection Services</u> indicate to the Chief or designee a compliance history or concern, the Chief is to request assistance from the Office of the Attorney General.
- F. If there is no basis to refuse inspection, the Chief is to process the application, provided all other requirements are met, which include:
 - 1. Reserve an establishment number and informing the applicant of the reserved establishment number so it can prepare labels;
 - 2. Providing the information to the EIAO for reviews of written plans, reviews of required written plans and procedures, i.e., Hazard Analysis and Critical Control Point (HACCP) plans, Sanitation Standard Operating Procedures (Sanitation SOPs), recall plan or procedures, etc., and
 - 3. Initiate a facility review when the applicant is ready.

NOTE: For a new applicant, the Chief or designee is to reserve an establishment number in the meat

inspection file of establishment numbers. The establishment numbers will be reserved for a period of one year for new applicants and for applicants adding types of inspection i.e., adding poultry to a meat establishment. The reserved establishment number will be cancelled if the applicant does not or has not communicated its intentions during the year. The applicant can always reapply after the reserved number has been cancelled by resubmitting a new application.

IV. PROCESSING APPLICATIONS FOR CHANGES OF OWNERSHIP, LOCATION, OR FOR ALL OTHER UPDATES FOR ESTABLISHMENTS

- A. The <u>6 V.S.A.</u> § <u>3306(b)</u> require that a new application shall be made in cases of a change of ownership or location.
- B. For updates to existing applications, if changes made to questions 21, 22 or 23 indicate to the Chief or designee a compliance history, the Chief is to request assistance from the Office of the Attorney General.
- C. The Chief may contact AAG in any other situation that they believe merits correlation/consultation with AAG, such as applications related to legal cases, consent orders, and establishments or plants where VAAFM previously withdrew or denied a license or inspection.

V. OFFICE RESPONSIBILITIES

- A. When a prospective meat or poultry establishment notifies the office that it is ready to be reviewed, the Chief is to:
 - 1. Confirm the prospective establishment will be performing slaughtering or processing activities that require inspection, per <u>6 V.S.A. § 3306</u>, 9 CFR 302.1, 381.6 or 532.1. The Chief is to refer the applicant to the <u>Food and Drug Administration</u> and <u>state and local regulatory agencies</u> when the applicant is going to be performing activities that are not under VAAFM jurisdiction.
 - 2. Review the physical establishment and equipment and determine whether these comply with <u>9</u> <u>CFR 416.1</u> through <u>416.5</u>;
 - 3. Determine whether the prospective establishment has developed written sanitation SOPs in accordance with <u>9 CFR 416.11</u> through <u>416.16</u>;
 - 4. Determine whether the prospective establishment has conducted a hazard analysis, or had one conducted for it, for all processes and has developed a HACCP plan covering each product produced by the establishment that according to the hazard analysis includes one or more hazards that are reasonably likely to occur, as described in 9 CFR 417.2(b):
 - 5. Determine whether the prospective establishment has developed written recall procedures in accordance with <u>9 CFR 418.3</u>;
 - 6. Complete all sections of the Circuit Supervisor On Site Check list including the 9 CFR Regulations/Resources by checking "COMPLY," if compliant
 - 7. Establish with the establishment management, hours of operation to ensure core hours are consistent with other establishments on the assignment, if applicable. Complete MI-42 Schedule of Operations; and
 - 8. Save completed and signed forms in the establishment's profile.

B. If the Chief or designee determines the prospective establishment is not compliant, he or she is to inform the establishment of his or her concerns. If the establishment notifies the Chief or designee that all noncompliant observations are corrected, the Chief or designee is to revisit the establishment.

VII. RMA RESPONSIBILITIES

A. If the Chief decides that inspection should be provided to the establishment, he or she is to ensure that the RMA updates PHIS to reflect the GOI status as "Conditional," and the establishment's approved operating hours (see *PHIS Users Guide*).

The Chief also notifies the Business Office that the license can be issued to the Establishment.

- B. During the 90 days following the issuance of the conditional status in PHIS to meat and poultry establishments, in accordance with 9 CFR 304.3(b) and 381.22(b), the Chief or designee is to verify that the establishment has validated its HACCP plans as per FSIS Directive 5000.1, Verifying an Establishments Food Safety System, in accordance with 9 CFR 305.1(c), 381.22(c) and 417.4.

 The Chief is to ensure inspection program personnel(IPP) at meat and poultry establishments have performed a Hazard Analysis Verification (HAV) task as instructed in VT Directive 5000.6, Performance of the Hazard Analysis Verification (HAV) Task and verified that the establishment has validated its HACCP plans as required by 9 CFR 304.3(c), 9 CFR 381.22(c), 9 CFR 590.149(c), and 9 CFR 417.4.
- C. During the 90 days following the issuance of the conditional status in PHIS to meat and poultry establishments, the Public Health Veterinarian (PHV) verifies that livestock are being handled humanely at livestock slaughter establishments and that poultry are being handled in a manner consistent with poultry good commercial practices (GCPs) at poultry slaughter establishments. The PHV is to follow the instructions in FSIS Directive 6910.1, District Veterinary Medical Specialist (DVMS) Work Methods.
- D. For meat and poultry establishments, within 90 days of issuing the conditional status in PHIS, if the Chief determines that the establishment has validated its HACCP system as required by <u>9 CFR 417.4(a)</u> and has met all other applicable requirements, he/she is to ensure the RMA updates PHIS to reflect the establishment's grant status as "Granted."
- E. For most meat and poultry establishments, an initial 90-day validation period corresponds to approximately 60 working days of records for review. Some small and very small establishments may operate less than 5 days per week. However, at least 13 production days of records need to be available for review by the Agency to determine whether an establishment operating less than 5 days per week has validated its HACCP system adequately. To allow such small and very small establishments the time necessary to gather data to validate their HACCP systems, the Chief may allow an additional 30 calendar days under the conditional status for an establishment to complete validation of its HACCP system.
- F. If at the end of the 90-day conditional period or 120- day period if an additional 30 days has been granted to the establishment or plant for validation, the Chief determines that the establishment has not validated its HACCP system in accordance with <u>9 CFR 417.4</u>, the Chief may take an appropriate action in accordance with the 6 V.S.A Chapter 204.
- G. The Chief is to ensure the official file is maintained of electronic copies of the application, the recommendation, the grant, and any related documents. In addition, the Chief is to ensure that PHIS is updated to accurately reflect the status of the establishment.
- H. If an official establishment or official plant is inactive for more than 120 days, the Chief is to follow the instructions in <u>VT Directive 5220.3</u>, *Issuance of a Ten-Day Letter for Inactive Operations*.

IX. PROCESSING REQUESTS FOR CHANGE IN APPROVED WORK SCHEDULES BY AN OFFICIAL ESTABLISHMENT OR OFFICIAL PLANT

An official establishment or official plant that wishes to alter its approved hours of operation, including a request for an additional shift or the elimination of a shift, will submit a request to the Chief or designee. The Chief is to consider the request for change in hours of operation, or shifts, as set out in <u>9 CFR 307.4</u> and <u>381.37</u>. If the Chief approves the request, the MI-42 *Schedule of Operations* will be revised and sent to the administrative assistant, along with a request to update the schedule. A request to update PHIS is sent to the RMA.

X. OFFICIAL ESTABLISHMENT VOLUNTARY SUSPENSION OR WITHDRAWAL OF INSPECTION

Voluntary Suspensions

- A. A voluntary suspension of inspection occurs when an establishment submits a written (i.e., fax, electronic, paper) request to the office for a temporary suspension of operations (e.g., for purposes of sale, major structural changes, or remodeling). A voluntary suspension of inspection is temporary and normally does not exceed 120 calendar days. Upon receipt of such requests, the Chief or designee is to issue a letter confirming the Voluntary Suspension or Voluntary Withdrawal of Inspection Service.
- B. After 120 calendar days under voluntary suspension, the Chief is to follow the instructions found in VT Directive 5220.3, Issuance of a Ten-Day Letter for Inactive Operations.
- C. An establishment or plant under a voluntary suspension of inspection may need to remain under voluntary suspension more than 120 days due to circumstances that are beyond its control, i.e., inability to obtain equipment on schedule, inability to complete major structural changes because of weather conditions, etc. In such cases, the Chief may extend the 120-day voluntary suspension period but may need to assign another review of the establishment prior to resuming inspected operations.
- D. If an establishment's license is suspended by VAAFM, effective corrective actions must be proffered by the establishment to bring the establishment into voluntary compliance. A voluntary suspension by the establishment would not negate the ability of VAAFM to proceed with an enforcement action such as a suspension.
- E. The Chief or designee may grant establishments that operate on a seasonal basis a voluntary suspension of inspection of more than 120 days based on the effective and efficient use of VAAFM personnel.
- F. When an establishment submits a written (e.g., electronic, paper) request for reinstatement of inspection to the Chief or designee after a voluntary suspension, the Chief or designee is to:
 - 1. Instruct the IIC to visit the establishment, if necessary, to determine whether its written plans, facilities and equipment warrant the reinstatement of inspection;
- G. If reinstatement of inspection is warranted, the Chief is to ensure that the data in PHIS is updated to reflect the establishment's current "active" status.

Voluntary Withdrawals

A voluntary withdrawal or closing of a license occurs when an establishment submits a written request to cease operations. Upon receipt of such requests, the Chief or designee notifies the business office, and

issues a letter confirming a voluntary withdrawal of inspection. The license closure is permanent, and establishments wishing to relicense and reinstate inspection must reapply.

XII. REFUSAL OR WITHDRAWAL OF INSPECTION

A. The Chief is to notify the Director of FSCP and the AAG when there is regulatory support for inspection to be refused or withdrawn (other than voluntary withdrawal) from an licensed recipient of inspection.

B. The Chief is responsible for initiating inquiries, assembling documentation, and maintaining contact with AAG, regarding the refusal or withdrawal of inspection. In those instances when the Chief has a basis, under the 6 V.S.A Chapter 204, to refuse to provide inspection services, or to initiate action for the withdrawal of a license, the Chief is to refer the matter to AAG for review and appropriate. The Chief is to provide pertinent information (e.g., information regarding withdrawal of inspection for failure to maintain sanitary conditions, HACCP violations; inhumane slaughter or handling) to AAG to support the refusal or withdrawal of inspection.

XIII. QUESTIONS

Asst. Director FSCP Meat Inspection Section

VT Agency of Agriculture, Food and Markets

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