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

# FSIS DIRECTIVE

5100.3
Rev. 4

12/21/20

## ADMINISTRATIVE ENFORCEMENT ACTION DECISION-MAKING AND METHODOLOGY

**DO NOT IMPLEMENT THIS DIRECTIVE UNTIL DECEMBER 28, 2020.**

## CHAPTER I – GENERAL

### I. PURPOSE

A. The Agency is reissuing this directive to incorporate egg products. On October 29, 2020, the Food Safety and Inspection Service (FSIS) issued the Egg Products Inspection Regulations. Under these regulations, egg products plants are now subjected to the requirements of 9 CFR part 500, *Rules of Practice* (ROP). Under 9 CFR 591.1(b), "establishments" also include egg products plants. The Egg Products Inspection Regulations rule has four effective dates. On December 28, 2020, 9 CFR part 500 will become applicable to egg products plants. On October 29, 2021, egg products plants will need to have developed Sanitation Standard Operating Procedures (Sanitation SOPs). On October 31, 2022, egg products plants will need to have developed Hazard Analysis and Critical Control Point (HACCP) plans. On October 30, 2023, the Egg Products Inspection Regulations rule will become effective for freeze-dried egg products and egg substitutes. This directive will be implemented for egg products plants on December 28, 2020, when 9 CFR part 500 becomes applicable to egg products plants.

B. For the purpose of this directive, the term "establishments" will be used to refer to meat and poultry establishments and egg products plants collectively. When the directive is only referring to egg products plants, such as when discussing the implementation of the Egg Products Inspection Regulations rule, then they will still be referred to as egg products plants.

C. This directive explains the enforcement methodology and decision-making thought process that District Office (DO) personnel are to use to ensure that all actions are supportable and properly documented. This directive describes the responsibilities of DO personnel for documenting and maintaining case files to support administrative enforcement and other actions taken under the authority of the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA), and Humane Methods of Slaughter Act (HMSA).

D. In this directive, the term Enforcement, Investigations, and Analysis Officer (EIAO) also means EIAO-trained Public Health Veterinarians (PHV). The term District Manager (DM) includes both the District Manager and the Deputy District Manager. The term DO refers to the DM or the designee. The term District Veterinary Medical Specialist (DVMS) also includes DVMS-trained PHVs.

### III. CANCELLATION

FSIS Directive 5100.3, Revision 3, *Administrative Enforcement Report (AER) System*, 2/16/17

### IV. BACKGROUND

A. The FMIA (21 U.S.C. 603 and 608), PPIA (21 U.S.C. 456), and EPIA (21 U.S.C. 1035) authorize the Secretary to require meat, poultry, and egg products establishments to be maintained and operated in a sanitary manner to prevent adulterated products from entering commerce. The HMSA requires that

humane methods are used for handling and slaughtering livestock.

B. When an official establishment is not meeting the provisions of the FMIA, PPIA, EPIA, or the HMSA (the Acts) or the regulations promulgated under these Acts, Office of Field Operations (OFO) personnel may carry out inquiries and investigations, to support administrative enforcement actions under the ROP (9 CFR part 500). When the DO decides to pursue an enforcement action under 9 CFR 500.3, *Withholding or suspension without prior notification*, it issues a Notice of Suspension (NOS) letter. When the DO decides to pursue an enforcement action under 9 CFR 500.4, *Withholding action or suspension with prior notification,* it issues a Notice of Intended Enforcement (NOIE) letter. In connection with these enforcement actions, the DO prepares an Administrative Enforcement Report (AER) case file to include establishment documentation, FSIS and establishment communications, supporting documents, evidence collected (as described in FSIS Directive 8010.3, *Procedures for Evidence Collection, Safeguarding and Disposal*), and verification plans.

## CHAPTER II – DECISION-MAKING AND ENFORCEMENT METHODOLOGY

### I. ENFORCEMENT ACTIONS

A. Enforcement recommendations can originate from the Frontline Supervisor (FLS), inspection program personnel (IPP), EIAO, DVMS, and other sources. Enforcement actions are taken in accordance with the ROP (9 CFR part 500).

B. Examples of situations when IPP and FLS recommend enforcement actions include when establishments have multiple, recurring noncompliances; implement ineffective corrective actions; receive multiple adulterant positive results from FSIS testing; or ship adulterated product. An example of a situation when an enforcement action is recommended by the EIAO includes when the EIAO identifies that the establishment's HACCP system is inadequate. An example of a situation when an enforcement action is recommended by the DVMS includes egregious humane handling violations.

C. OFO personnel are to be aware that egg products plants are not required to develop and maintain Sanitation SOPs (9 CFR 500.3(a)(3), 9 CFR 500.4(b) and (c), 9 CFR 500.6(c), and 9 CFR 500.7(a)(2)) until October 29, 2021 and are not required to develop or maintain HACCP systems (9 CFR 500.3(a)(2), 9 CFR 500.4(a), 9 CFR 500.6(b), and 9 CFR 500.7(a)(1)) until October 31, 2022. However, some plants may voluntarily choose to meet these requirements sooner. In determining applicable enforcement actions under 9 CFR part 500, IPP are to be knowledgeable concerning whether the establishment is voluntarily operating under HACCP or Sanitation SOP requirements or is required to operate under such requirements. Whether the establishment is required to meet these regulations or has voluntarily opted to do so, they are subjected to applicable enforcement provisions in 9 CFR part 500.

### II. FIELD PERSONNEL RESPONSIBILITIES

A. IPP are to contact the FLS through their chain of command when noncompliance findings may warrant intended enforcement or enforcement. The FLS is to collaborate with the DO to determine next steps.

B. IPP are to review enforcement or enforcement-related letters, including Food Safety Assessment (FSA) findings as applicable.

C. IPP are to verify the implementation of the establishment's corrective actions and preventive measures as described in the verification plan through directed Public Health Information System (PHIS) verification tasks.

D. IPP are to document findings of noncompliance in PHIS from performing verification tasks and share the findings with the FLS.

E. IPP are to maintain copies of enforcement letters, completed and active verification plans, and

supporting documents in the government office.

F. The FLS is to document and share timely findings with the DO that may indicate the establishment is unable or unwilling to perform or implement the corrective actions and preventive measures.

G. The FLS is to share the verification plan findings with the EIAO or DVMS and District Case Specialist (DCS) for review.

## III. EIAO RESPONSIBILITIES

A. Before scheduling or starting each FSA, the EIAO is to evaluate and document the background findings of an establishment's food safety system in a Public Health Risk Evaluation (PHRE), as described in FSIS Directive 5100.4, *Enforcement, Investigations, and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology*.

B. The EIAO is to construct a regulatory rationale and make enforcement recommendations based on the PHRE or FSA findings or other investigations, as described in this directive.

C. The EIAO is to assist in the documentation and verification of activities that follow the enforcement action (Figure 1).

## IV. SUPERVISORY EIAO (SEIAO) RESPONSIBILITIES

A. The primary role of the SEIAO during an administrative enforcement action is to review and respond to findings and enforcement recommendations to determine if the findings support the proposed enforcement recommendation.

B. The SEIAO is to ensure that the EIAO understands and implements the collection, safeguarding, and evidence handling procedures described in FSIS Directive 8010.3.

C. The SEIAO is to facilitate communication among the EIAO, DO, and field personnel, and collaborate with the DCS during the enforcement process (Figure 1).

D. The SEIAO is to ensure that additional PHREs and/or FSAs are not scheduled in lieu of supportable enforcement action.

## V. DCS RESPONSIBILITIES

A. DO support staff, the EIAO, or other designees are to follow the instructions in this section when assisting with DCS responsibilities.

B. The DCS is OFO's designated Evidence Officer, in accordance with FSIS Directive 8010.3, and is to ensure evidence integrity and disposal to support enforcement.

C. The DCS is to review PHRE or FSA findings that lead to enforcement recommendations proposed by the EIAO and the DVMS to the DO management team to ensure enforcement actions are supported under the ROP (9 CFR part 500).

D. The DCS is to assemble, maintain, and safeguard the hardcopy of the case file in the DO in accordance with evidence collection procedures and per the Evidence Officer responsibilities described in FSIS Directive 8010.3. The DCS is to use FSIS Form 8000-17 *Evidence Receipt and Chain of Custody*.

E. The DCS is to upload and manage case files in AssuranceNet (ANet). The DCS is not to accept evidence that does not follow the Chain of Custody procedures described in FSIS Directive 8010.3.

F. The DCS is to communicate with the SEIAO, EIAO, and DVMS about potential enforcement matters and assist the DO management team by providing guidance and direction on enforcement issues.

G. The DCS is to facilitate open communication among the DO, EIAO, DVMS, FLS, and IPP to ensure all parties are involved in the enforcement process.

H. The DCS is to ensure that the basic components and structure of enforcement letters are included in all enforcement letters, including the establishment's appeal and hearing rights and to whom the appeal or hearing request is to be directed.

I. The DCS is to ensure that the enforcement letter is promptly delivered to the establishment.

J. The DCS is to review the establishment's proffered corrective actions and preventive measures to ensure they are meaningful. The DCS is not to accept the establishment's corrective actions until the DM has reviewed all information in accordance with Section X.

K. The DCS is to assist the EIAO, SEIAO, or DVMS in developing the IPP verification plan (Section XI of this chapter). The DCS is to ensure IPP and the establishment have a clear understanding of the noncompliance issues and the specific verification procedures. The DCS is to review all revisions of the verification plan throughout the abeyance/deferral period.

L. The DCS is to ensure proper distribution of the enforcement letters.

M. The DCS is to ensure that all relevant documents after the issuance of the enforcement letter are added to the AER case file in a timely manner.

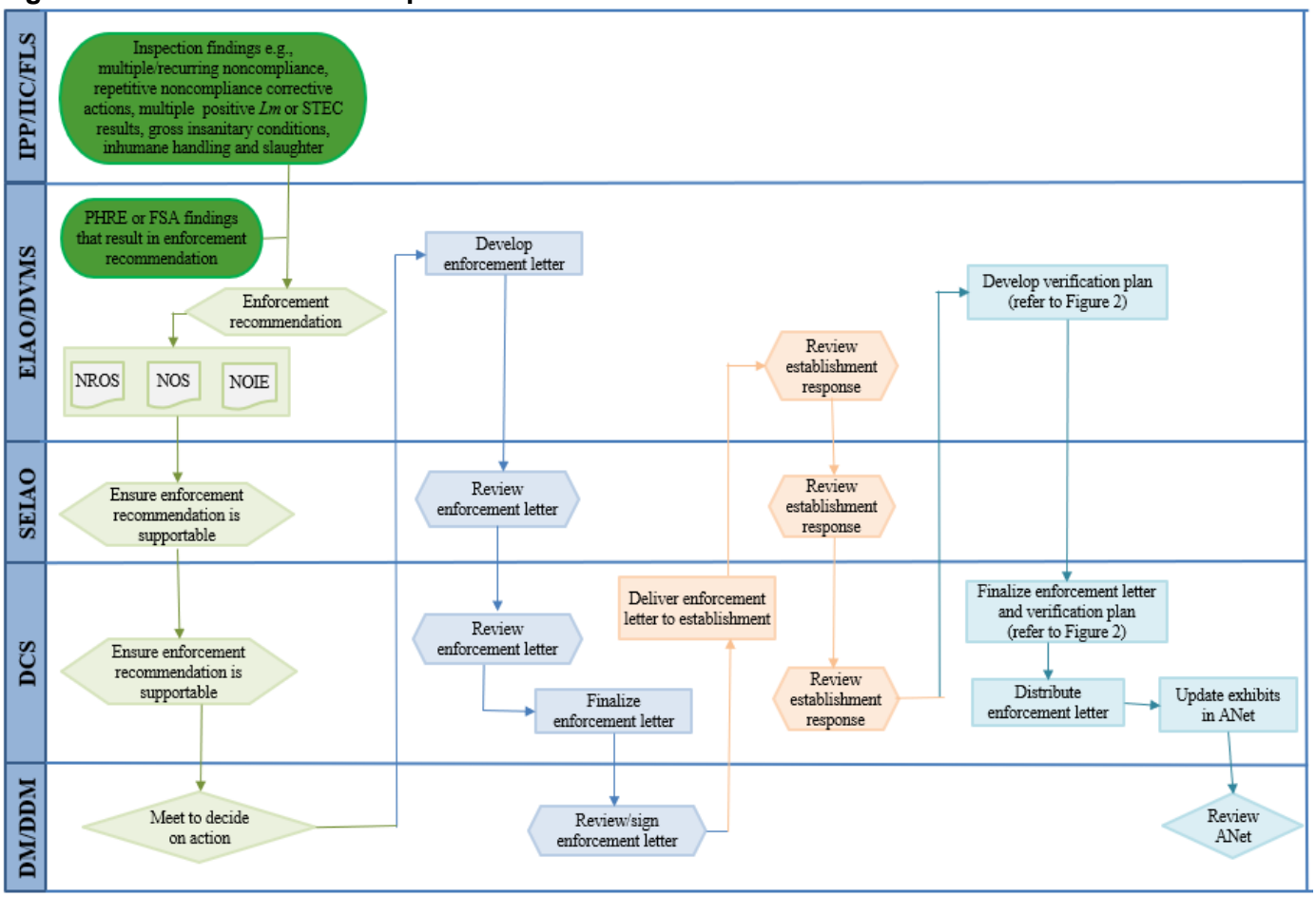
**NOTE:** Evidence is not to be kept in locations outside the DO such as private homes, personal or government cars, hotels, or other locations. All evidence is to be promptly transferred to the DCS in accordance with evidence transfer procedures, set out in FSIS Directive 8010.3, for maintenance in a secure area in the DO.

N. The DCS is to ensure that files are uploaded to the AER in the appropriate format (PDF, JPEG, PNG, TIFF, and DOC/DOCX) and documents not directly related to the enforcement action are not included.

O. The DCS is to upload all evidence and documents to the AER record in ANet prior to case referral to Office of the Investigation, Enforcement and Audit (OIEA) - Enforcement Operations Branch (EOB).

P. The DCS is to ensure that custom exempt reviews conducted by OFO are entered into ANet (FSIS Directive 8160.1, *Custom Exempt Review Process*).

**Figure 1. Enforcement Development and Workflow**




## VI. DM RESPONSIBILITIES

A. The DM is to ensure administrative enforcement actions are applied consistent with the instructions in this directive.

B. The DM is to correlate with the SEIAO to ensure that additional FSAs are not performed when it is appropriate for the DO to take timely enforcement action, including in response to PHRE findings.

C. The DM is to sign enforcement letters, as appropriate, described in this directive.

D. The DM is to ensure that due process entitlements, per 9 CFR part 500, are provided to establishments during enforcement.

E. The DM is to correlate with the Executive Associate for Regulatory Operations (EARO) about unusual circumstances raised by the IPP, EIAO, SEIAO, DCS, or DVMS that need expedited consideration and input by other Agency experts (e.g., the Office of Policy and Program Development (OPPD), the OIEA - EOB, the OFO Humane Handling Enforcement Coordinator (HHEC), or the Office of Public Health Science).

F. The DM is to refer the AER or other case documentation to OIEA - EOB, in accordance with FSIS Directive 8010.5, *Case Referral and Disposition,* when it describes violations that require evaluation for administrative enforcement action; seizure of adulterated, misbranded or other violative product in commerce; or administrative subpoena when program employees are denied access to or examination of establishment, facilities, inventory, or records.

G. The DM is to refer the AER or other case documentation to OIEA - Compliance and Investigations Division (CID), in accordance with FSIS Directive 8010.5, when it describes criminal enforcement matters and allegations.

## VII. DVMS RESPONSIBILITIES RELATED TO HUMANE HANDLING ENFORCEMENT

A. The DVMS plays a role similar to the EIAO in enforcement cases that involve humane handling violations. The DVMS roles and responsibilities are described in FSIS Directive 6900.2, *Humane Handling and Slaughter of Livestock,* and FSIS Directive 6910.1, *District Veterinary Medical Specialist (DVMS) Work Methods.*

B. The DVMS is to evaluate, document, and recommend humane handling enforcement action when there is an inhumane handling incident or an action based on a history of establishment humane handling violations. The DVMS is to recommend the appropriate enforcement action under the ROP (9 CFR part 500) based on information from IPP, first-hand observational knowledge, or establishment history of humane handling noncompliance. The documented recommendation is to specify the regulatory requirements and relevant statutory authorities the establishment has not met.

C. The DVMS is to confirm that IPP, FLS, or Supervisory PHV provide a noncompliance record (NR) (as described in FSIS Directive 6900.2) that describes the inhumane incident and fully provides all relevant information that supports the enforcement action. The DVMS is to provide these documents to the DCS for inclusion in the AER.

D. The DVMS is to provide an analysis of the trend in noncompliance of inhumane incidents at the establishment when the DVMS determines that the noncompliance history supports enforcement action. The analysis is to be provided to the DCS for inclusion in the AER as an exhibit in the case file.

E. The DVMS is to correlate with the DCS on the enforcement strategy and the support for enforcement. As a subject matter expert, the DVMS is to assist in drafting the NOIE and NOS letters or other documents associated with the enforcement action, as needed.

F. The DVMS is to assist in the review of the establishment's proposed corrective actions and preventive measures. The DVMS is also to assist in the development and review of the verification plan. The DVMS is to discuss the verification plan with the FLS and IPP to ensure that there is a clear understanding of the noncompliance issues and of the specific verification procedures.

G. The DVMS is to conduct follow-up verification visits to the establishment for a minimum of 90 calendar days at 30-day intervals during the deferral/abeyance period. When a follow-up visit is performed by a DVMS-trained PHV, the DVMS is to communicate with the DVMS-trained PHV regarding any questions or issues that the DVMS-trained PHV identifies during the visit. The DVMS is to document all follow-up visits and provide the documentation to the DCS for inclusion in the AER file as exhibits.

H. The DVMS is to provide recommendations to the DO to help the DO decide when an enforcement action should be reinstated or closed. The DVMS is not to close an inhumane handling suspension action without one or more on-site visits during the abeyance/deferral period.

I. The DVMS is to follow all evidence collection procedures in accordance with FSIS Directive 8010.3 and ensure that all evidence is transferred under chain of custody to the DCS for inclusion in the AER.

## VIII. STATUTORY AUTHORITY TO EXAMINE FACILITIES AND COPY RECORDS

A. The FMIA, PPIA, and EPIA provide FSIS broad authority to conduct inspections and examinations of the premises, facilities, equipment, and operations of inspected establishments, which includes, but is not limited to accessing, examining, or copying records or taking photographs (21 U.S.C. 460, 609, 642, 1034,

and 1040). The statutes require establishments to provide FSIS access to conduct inspections and to examine facilities, inventory, and records. The EIAO and other authorized FSIS personnel are to use photography as a method or technique to conduct inspections and examination to verify that products are safe, wholesome, properly labeled, not adulterated, and that establishments are operating under sanitary conditions.

B. At the entrance meeting before an FSA or other investigation, authorized FSIS employees (specifically EIAOs and compliance investigators) are to make the establishment aware of the relevant statutory and regulatory authorities to access, examine, or copy records, including electronic records, and to take photographs. Authorized FSIS employees are to consult with the DO for further guidance if establishment management refuses to allow authorized FSIS employees to access, examine, or copy records, or take photographs. The DO is to determine the next appropriate step, which may include issuing a written request to access, examine, and copy records; taking appropriate enforcement action to suspend the establishment for interference with inspection; or obtaining an administrative subpoena. Administrative subpoenas are obtained in consultation with OIEA - EOB.

C. Authorized FSIS employees are to collect photographs as part of investigative inspection duties in addition to collecting photographic evidence when necessary to support findings. Authorized FSIS employees are to contact the DO through the supervisory chain of command if the establishment prevents authorized FSIS employees from collecting photographic evidence. When appropriate, the DO is to suspend the assignment of inspection personnel at the establishment for interference with an FSIS employee under 9 CFR 500.3(a)(6) when the authorized FSIS employee is prevented from taking photographs to support the findings and, therefore, prevented from conducting inspections and examination under the FMIA, PPIA, and EPIA.

D. The DO is to confer with the assigned EARO regarding initiating procedures to obtain an administrative subpoena for the requested information, in accordance with FSIS Directive 8010.3. When the determination is made that an administrative subpoena may be necessary, the DM, through the EARO, is to refer to the supporting case documentation to OIEA - EOB, in accordance with FSIS Directive 8010.5.

E. Authorized FSIS employees are to send all evidence and Chain of Custody forms, including FSIS Form 8200-1, *Property Receipt,* associated with an enforcement action or other recommendation to the DCS in accordance with evidence transfer procedures provided in FSIS Directive 8010.3.

F. Authorized FSIS employees are to confer with the DCS if they have questions about what documents are to be copied to support an enforcement recommendation.

G. Authorized FSIS employees are to use government-issued cameras or scanners to make needed copies in accordance with FSIS Directive 8010.3. Alternatively, in the event an establishment copy machine is available, they are to request that management provide a copy of any records needed or are to request permission to use the establishment's copy machine.

## IX. SUPPORTING ENFORCEMENT ACTIONS AND CASE REFERRALS

A. The EIAO and DCS are to analyze the hazard analysis, supporting documentation, HACCP plan, Sanitation SOPs, Sanitation Performance Standards (SPS), and prerequisite program findings to determine if an enforcement action is supported.

B. The DO is to explain the rationale and factual basis for all enforcement actions and describe supporting documents for inclusion in the AER in a manner that would enable a person unfamiliar with the facts or with the establishment's processes, to understand the sequence of events that led to the noncompliance findings and the enforcement action. Enforcement actions should be based upon violations of the FMIA, PPIA, EPIA, or HMSA and supported through descriptions of regulatory noncompliance. For example, a regulatory rationale may state:

1. "The establishment is preparing, packing, and holding product under insanitary conditions whereby it may become contaminated with filth, or whereby it may have been rendered injurious to human health," or

2. The establishment is producing product that is adulterated, which has rendered the product injurious to health."

C. The DO is to identify the relevant adulteration provisions under FMIA (21 U.S.C. 601(m)(1)-(4)), the PPIA (21 U.S.C. 453(g)(1)-(4)), and the EPIA (21 U.S.C. 1033(a)(1)-(8)), and the humane handling and slaughter provisions under the HMSA (7 U.S.C. 1901 *et seq.*), as well as the findings that support the adulteration/humane handling violation determination and the impact from a public health perspective. The DO is to link the alleged violations to FSIS statutory and regulatory requirements (e.g., the Acts and 9 CFR).

D. If the establishment implements corrective and preventive measures during the course of the FSA, investigation, or incident, this action does not negate the recommendation that the DO issue an enforcement action. These deficiencies represent the findings of the FSA, investigation, or incident and it typically requires time for the establishment and FSIS to verify the effectiveness of corrective actions and preventive measures.

E. If the EIAO or DCS finds noncompliance that would warrant an intended enforcement or a suspension recommendation, but there is no information that would suggest that multiple or recurring noncompliances have occurred, the EIAO or DCS is to explain how the findings establish a basis for concern about the safety of product being produced and why these findings support the recommended enforcement action.

F. The DO is not to reference NRs that are not used to support the regulatory rationale or how the conditions have resulted in adulterated product or the creation of insanitary conditions that may cause product to be adulterated in the NOIE, NOS, or Notice of Reinstatement of Suspension (NROS) letter. IPP are to issue these NRs separately as described in FSIS Directive 5100.1, *Enforcement, Investigations, and Analysis Officer (EIAO) Food Safety Assessment (FSA) Methodology*.

G. The DO is to seek expert advice when information related to policy, technical, or scientific issues is needed before documenting findings or making an enforcement recommendation. The DO is to keep the OFO EARO apprised of the request. If the answers are relevant to the AER case and are relied upon for supporting the case, the DO is to document the information for inclusion in the AER.

H. When appropriate, the DO is to refer case files to OIEA - EOB, or OIEA - CID, as described in FSIS Directive 8010.5. The letter referring the case to another program area will close the case (Table 2). The DO is not to include documents issued to the establishment by OIEA - EOB in ANet after the DO refers the case to OIEA - EOB. OIEA - EOB is to document and maintain the case file; however, the DO is to be aware that it may be contacted by OIEA - EOB for assistance once the case file is referred. When the DO is contacted by OIEA - EOB to provide a review or gather documentation, the DO is to submit the documentation to OIEA - EOB and OIEA - EOB will add it to the case file.

I. The DO may take a withholding action or suspend the establishment's use of alternative procedures associated with a waiver of regulatory requirements in accordance with FSIS Directive 5020.1, *Verification Activities for the Use of New Technology in Meat and Poultry Establishments and Egg Product Plants*. The withholding action or suspension can occur with or without prior notification. The enforcement action will remain in effect until the establishment proffers corrective actions that are deemed sufficient by the DO to address the multiple or recurring noncompliance issues that led to the enforcement action. If the establishment has multiple enforcement actions or egregious noncompliance involving the alternative procedures associated with a waiver of regulatory requirements, the DO is to refer the matter to the OPPD for possible revocation of the waiver in accordance with FSIS Directive 5020.1.

## X. VERIFICATION PLAN DESIGN AND EXECUTION

A. The verification plan is a tool designed to verify the effectiveness of the establishment's proposed corrective actions and preventive measures that were proffered and led to the DO decision to defer enforcement or hold a suspension in abeyance. A verification plan is designed to provide detailed instructions to the IPP, the EIAO, and the DVMS for verifying the establishment's proposed corrective actions and preventive measures (Figure 2). Verification plan results are to be recorded in PHIS. PHIS reports are to be used by OFO personnel to view the verification plan results.

B. The DO is to assess whether the establishment's proposed corrective actions and preventive measures that were proffered contain the following elements, as applicable:

1. Procedures or assessment methods the establishment will use to address the cause of the regulatory noncompliance;

2. Specific actions the establishment will use to eliminate and prevent the cause of the regulatory noncompliance;

3. Monitoring activities the establishment will use to ensure that changes are implemented and effective to address the regulatory noncompliance; and

4. Scientific support the establishment provides, for new or modified interventions or processes used to support decisions in the hazard analysis, to support that corrective actions and preventive measures are effective. The scientific support should identify the critical operating parameters necessary for the intervention or process to function as intended and the establishment's current processes should incorporate those parameters as required in 9 CFR 417.4.

C. After determining that the establishment's proposed corrective actions and preventive measures contain the elements described in paragraph B above, the DO is to develop the verification plan and determine whether to issue a deferral or abeyance letter.

D. The DO is to describe the Agency's verification responsibilities in a verification plan that covers a minimum of 90 calendar days when an enforcement action has been deferred or held in abeyance.

E. The DO is to analyze the establishment's previous enforcement history to ensure that the current proffered corrective actions and preventive measures are substantially different and meaningful.

F. The bi-weekly verification plan, at a minimum, is to include:

1. The background that led to an enforcement action and deferral or abeyance of that action;

2. The organized list of the establishment's proposed corrective actions and preventive measures;

3. The documents, processes, products, or programs that are required to be verified;

4. The frequency of the verification in 3 above;

5. The directed PHIS task associated with each verification activity in 3 above;

6. Free text space to record additional information as needed; and

7. A statement to inform the establishment that the DO is to be informed of any changes to corrective actions and preventive measures during the verification period. For example, if an establishment decides to buy an additional piece of equipment or implement an additional monitoring activity after the implementation of the verification plan, the DO is to be informed of these changes and the

verification plan is to be revised before the establishment implements the changes.

G. The Inspector In-Charge (IIC) is to ensure scheduling of the corresponding directed tasks in PHIS for the verification tasks and frequencies listed in the verification plan. IPP are to use the justification "*Verification Plan for Enforcement Actions*" to justify the scheduling of the directed task.

H. The FLS is to review the PHIS report for completed verification activities (e.g., Task Summary and List for an establishment) at least on a bi-weekly basis and provide recommendations to the DO regarding the establishment's implementation and performance of corrective actions and preventive measures.

I. During the 30-, 60-, and 90-day visits, the EIAO is to review the PHIS report for verification activity results (e.g., Task Summary and List for an establishment) and assess whether corrective actions are effective and make recommendations to the DO (FSIS Directive 5100.1, Chapter VI, Section III.C).

J. FSIS personnel are to document findings during the follow-up verification visits. FSIS personnel are to describe in detail the establishment's progress in implementing the corrective and preventive actions and any additional information as appropriate.

K. The DO is to seek policy guidance, as needed, if there are questions during the review of proposed corrective actions prior to the DO acceptance of the corrective actions. For example, if the DCS is not able to determine if the scientific support is valid, then the DO is to submit a question and seek guidance through askFSIS (Chapter V).

## XI. VERIFICATION PLAN DOCUMENTATION AND WORKFLOW

A. Specific instructions regarding the use of ANet are in the ANet User Guide. Instructions for using ANet and documenting the AER are available on the ANet website.

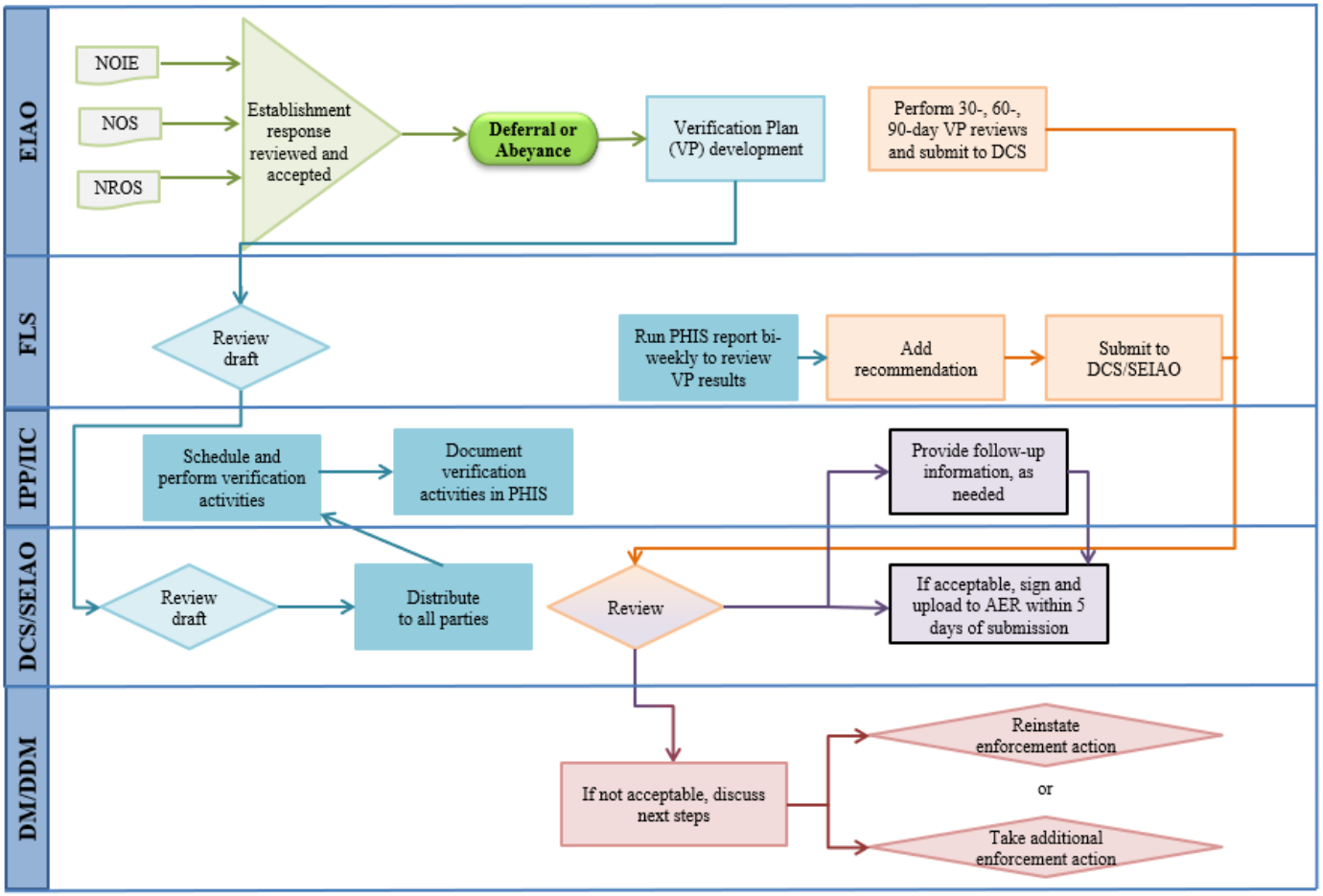
B. As described in Figure 2, the appropriate DO personnel develops verification plans (after the DO reviews), obtains necessary clarifications, assesses whether the establishment's proffered corrective actions and preventive measures contain the elements described in Section X. B of this chapter and accepts the establishment's proposed corrective actions and preventive measures. The EIAO and DCS have the primary responsibility for drafting verification plans. The DVMS is to draft verification plans related to humane handling enforcement actions.

C. DO personnel are to assist in developing the verification plan for Consent Orders in consultation with OIEA - EOB.

D. The DCS is to send the verification plan with the Letter of Deferral (LOD) / Notice of Suspension Held in Abeyance (NOSA) to the Quarterly Enforcement Report mailbox when issued. The address is in Outlook at *FSIS – FO/Quarterly Enforcement Report*. Final verification reports are not to be sent to the Quarterly Enforcement Report.

E. The DCS is to upload all verification plan reports into ANet. Verification plans are to be uploaded to the AER within 5 days after the submission deadline to the DCS (bi-weekly for IPP, 30-day intervals for EIAO/DVMS) unless the DCS determines follow-up is needed.

**Figure 2. Verification Plan Development and Workflow**




## CHAPTER III – ENFORCEMENT ACTIONS AND LETTERS

### I. THE RULES OF PRACTICE (ROP)

A. The ROP (9 CFR part 500) regulations identify the conditions under which the Agency can take enforcement actions and include the criteria for when those actions are warranted. These regulations were issued to ensure that all establishments are afforded due process.

B. 9 CFR 500.3 gives FSIS the authority to take a withholding action or impose a suspension without providing the establishment prior notification.

C. 9 CFR 500.4 gives FSIS the authority to take a withholding action or suspension with prior notification (an NOIE).

D. 9 CFR 500.6 and 9 CFR 500.7, respectively, gives the FSIS Administrator the authority to file a complaint to withdraw a grant of Federal inspection in accordance with the Uniform Rules of Practice (7 CFR subtitle A, part 1, subpart H) and to refuse to grant Federal inspection to an applicant.

E. The DO is to follow the instructions in FSIS Directive 8010.5 to refer the AER or other case documentation to OIEA - EOB when the DO determines violations require evaluation for formal administrative enforcement action. If the DO needs additional information to determine if a referral to OIEA - EOB is appropriate, the DO is to contact the OIEA - EOB Chief to discuss further.

F. The DO is to refer custom exempt review cases to OIEA - EOB or CID, when appropriate. FSIS Directive 8160.1 provides instructions for the review of custom exempt facilities, including referral of repeated or serious noncompliance.

## II. BASIC STRUCTURE AND COMPONENTS OF ENFORCEMENT LETTERS

A. The DO is to present information in enforcement letters to explain the findings in a manner that encompasses all defining aspects of the alleged violation in chronological order (earlier to most recent).

B. The DO is to ensure the findings link the alleged violations to FSIS statutory and regulatory requirements and that enforcement letters describe who is involved, what happened, when it occurred, where noncompliance was found in the establishment's food safety system, and why the Agency is taking action. The DO is to ensure the findings support the adulteration determination and a description of the public health impact is included.

C. The DO is to ensure the enforcement letter describes the facts in a manner that makes clear any past noncompliance and how previous noncompliance relates to present noncompliance. When applicable, the DO is to describe whether the establishment's previously proposed corrective actions and preventive measures were ineffective to address the noncompliance.

D. The DO is to ensure suspension letters (NOS, NROS) contain hearing rights as defined under 9 CFR 500.5(d). The DO is to inform the establishment in the enforcement letter that it may request a hearing pursuant to the Uniform Rules of Practice (7 CFR subtitle A, part 1, subpart H) and include the name, title, and contact information of the Chief of OIEA - EOB, to request such hearing. Any enforcement action taken in accordance with the ROP may be appealed.

**NOTE:** The DO is to use the third person when writing enforcement letters and EIAOs are to use first person when writing FSA and PHRE reports.

E. The DO is to schedule and hold a conference call with the establishment to discuss the contents of the enforcement letter when appropriate. If the enforcement action is preceded by an FSA, the EIAO is to provide the enforcement letter and the draft FSA to the establishment at the exit conference in accordance with FSIS Directive 5100.1.

F. The DO is to promptly deliver enforcement letters to the establishment after finalization. Methods to deliver enforcement letters include e-mail delivery of a scanned, signed PDF file; hand delivery of a hardcopy by FSIS personnel as assigned by the DO; or overnight delivery of a hardcopy by a carrier. A means to ensure delivery confirmation should accompany any delivery method.

## III. NOIE LETTER

A. The DO is to document an intended enforcement action in an NOIE letter. An intended enforcement action, as described in 9 CFR 500.4, provides an establishment with prior notification that FSIS may take a withholding action or impose a suspension of the assignment of inspectors at the establishment and provides the establishment an opportunity to demonstrate or achieve compliance.

B. The DO is to ensure the NOIE letter includes all information as required by 9 CFR 500.5(b), including:

1. FSIS's authority under the Acts;

2. An explanation of the findings and basis for action in a chronological order of events;

3. Findings linked to the FSIS statutes (e.g., the Acts) and regulatory requirements (9 CFR) and a description of how the findings relate to the establishment's ability to produce safe, wholesome, and unadulterated products, including the impact on public health;

4. The establishment's previous enforcement history and how the history relates to the effectiveness of the establishment's food safety system;

5. The establishment's processes or products that are affected by the action;

6. The expected format for the establishment's response and a three (3) business day timeframe for the establishment to respond to the DO; and

7. The DO contact information.

## IV. LETTER OF DEFERRAL

A. The DO is to issue an LOD after it decides to defer the decision to take an enforcement action and allow the establishment the opportunity to implement the proposed corrective actions and preventive measures. The DO is to ensure the issuance of the LOD is accompanied by a verification plan (Chapter II, Section XI).

B. During deferral, the DCS is to review any changes to the establishment's corrective actions and preventive measures and ensure that the DO concurs prior to implementation of the changes. After the DO concurrence with changes to the establishment's corrective actions and preventive measures, the DCS is to update the verification plan accordingly.

C. An LOD is to contain:

1. A brief explanation of the findings and basis for action that led the DO to issue the NOIE, including the dates of issuance of the NOIE letter;

2. The establishment's processes or products that are affected by the NOIE action;

3. Findings from the DO review and acceptance of the establishment's proposed corrective actions and preventive measures;

4. DO contact information; and

5. Reminder that FSIS has the authority to take a suspension or withholding action if the establishment fails to implement its proposed corrective actions and preventive measures or if the corrective actions and preventive measures are not effective.

D. The DO is to take further enforcement action, such as suspension of the assignment of inspectors, in accordance with 9 CFR part 500, if the establishment is unable or unwilling to perform or implement the corrective actions and preventive measures.

## V. NOTICE OF SUSPENSION LETTER

A. 9 CFR 500.3 outlines conditions under which FSIS may take a withholding action or impose a suspension of the assignment of inspectors at the establishment without prior notification.

B. A suspension may be issued to an establishment following an NOIE letter because the establishment failed to provide corrective actions and preventive measures, or those corrective actions and preventive measures were ineffective or not adequately implemented. DO personnel are to document a suspension in an NOS letter that provides the establishment with an explanation of the findings that led to the DO's decision to take enforcement action.

C. A NOS letter is to include all information as required by 9 CFR 500.5(a), including:

1. FSIS's authority under the Acts;

2. An explanation of the findings and basis for action in a chronological order of events;

3. Findings linked to the FSIS statutes (the Acts) and regulatory requirements (9 CFR) and a description of how the findings relate to the establishment's ability to produce safe, wholesome, and unadulterated products, including the impact on public health;

4. The establishment's previous enforcement history and how the history relates to the effectiveness of the establishment's food safety system;

5. The establishment's processes or products that are affected by the action;

6. Expected format for the establishment's response to the DO;

7. DO contact information; and

8. Appeal rights and hearing rights.

## VI. NOTICE OF REINSTATEMENT OF SUSPENSION

A. A suspension may be reinstated during the abeyance period. The DO is to document a reinstatement of suspension in an NROS letter that provides the establishment with an explanation of the findings that led to the District's decision to reinstate the suspension.

B. 9 CFR part 500 outlines the conditions under which FSIS may impose a reinstatement of suspension. FSIS may reinstate a withholding action or reinstate a suspension without or with prior notification.

C. An NROS letter is to include all information required by 9 CFR 500.5(a), including:

1. FSIS's authority under the Acts;

2. An explanation of the findings and basis for action in a chronological order of events, including the findings from the previous suspension action;

3. Findings linked to the FSIS statutes (e.g., the Acts) and regulatory requirements (9 CFR) and a description of how the findings relate to the establishment's ability to produce safe, wholesome, and unadulterated products, including the impact on public health;

4. The establishment's previous enforcement history, including the previous suspension action, and how the history relates to the effectiveness of the establishment's food safety system;

5. The establishment's processes or products that are affected by the action;

6. Expected format for the establishment's response to the DO;

7. DO contact information; and

8. Appeal rights and hearing rights.

## VII. NOTICE OF SUSPENSION HELD IN ABEYANCE AND NOTICE OF REINSTATEMENT OF SUSPENSION HELD IN ABEYANCE

A. The DO is to issue an NOSA or Notice of Reinstatement of Suspension Held in Abeyance (NROSA), after the establishment responds to the DO with acceptable corrective actions and preventive measures, to permit the establishment the opportunity to implement the proposed corrective actions and preventive measures. Issuance of the NOSA/NROSA is also to be accompanied by a verification plan.

B. An NOSA/NROSA letter is to contain:

1. A brief explanation of the findings and basis for action that led the DO to issue the NOSA or NROSA including the dates of issuance of the enforcement letter;

2. The establishment's processes or products that are affected by the enforcement action;

3. The findings from the DO review and acceptance of the establishment's proposed corrective actions and preventive measures;

4. The DO contact information; and

5. A reminder that FSIS has the authority to reinstate the suspension or withholding action if the establishment fails to implement its proposed corrective actions and preventive measures or if the corrective actions and preventive measures are not effective.

## VIII. OTHER LETTERS ISSUED BY THE DISTRICT OFFICE

A. The DO is to issue the following letters to an establishment, as appropriate. The DO is to be aware that these letters are not enforcement letters. However, these letters can be used to correspond in writing with the establishment or to describe the impact of noncompliance to an establishment's food safety system.

B. **Letter of Warning**: The DO is to issue a Letter of Warning (LOW) to an establishment to close an enforcement action after the completion of the verification period or upon notification of a noncompliance with custom exempt requirements. The DO is to issue an LOW to close an enforcement action only when the establishment has been able to demonstrate that the corrective actions and preventive measures have been successfully implemented and corrected the noncompliance described in the enforcement letter and related documents for a minimum of 90 calendar days. When the DO issues an LOW for noncompliance with custom exempt requirements, the LOW is to state that failure to take prompt and appropriate corrective action may result in a recommendation to pursue additional administrative, civil or criminal sanctions.

C. **Letter of Concern**: The DO is to issue a Letter of Concern (LOC), in accordance with FSIS Directive 6100.3, *Ante-Mortem and Post-Mortem Poultry Inspection*, to describe Good Commercial Practices (GCPs) at poultry establishments where GCPs are not followed. An LOC is not an enforcement letter and is not enforcement-related. The DO is not to issue an LOC to establishments to describe enforcement actions, close out enforcement actions, or to request additional information from establishments.

D. **Voluntary Withdrawal of Inspection Letter**: The DO is to issue a Voluntary Withdrawal of Inspection Letter according to information in FSIS Directive 5220.1, *Granting or Refusing Inspection, Voluntary Suspending or Withdrawing Inspection, and Reinstating Inspection under PHIS.* This letter may be used as the final exhibit to close an enforcement action. Before inspection activities can be reinstated, the DO is to address any relevant food safety issues that formed the basis for the enforcement action issued prior to the voluntary withdrawal.

**NOTE:** When a case is referred to OIEA - EOB and the establishment decides to withdraw, the DO is to prepare the Voluntary Withdrawal of Inspection Letter in consultation with OIEA - EOB.

E. **Ten-Day Letter**: The DO is to issue a Ten-Day Letter when an establishment is inactive for more than 120 days and does not communicate its intentions to resume operations as described in FSIS Directive 5220.3, *Issuance of a Ten-Day Letter for Inactive Operations*.

F. **Letter Requesting Access or Examination**: The DO may issue a letter requesting access or examination if management refuses to allow FSIS personnel to access, examine, or copy records, including electronic records, even after FSIS personnel make the establishment aware of the relevant statutory and regulatory authorities.

G. **Official Correspondence Letter**: The DO is to issue this letter when it wishes to correspond with the establishment in writing for issues that are not clearly defined above.

## IX. NO OBJECTION LETTERS

The No Objection Letter (NOL) is not a letter to be issued by a district office. Rather, OPPD is to issue the NOL when an establishment's request to use a New Technology is granted according to FSIS Directive 5020.1. DO personnel are to be aware that an NOL is not an enforcement letter nor is it enforcement-related. The DO is ***not*** to issue an NOL to establishments to warn establishments of possible future enforcement actions or to inform establishments that the DO does not have an objection to a particular product, process, or corrective action.

# CHAPTER IV – USING ASSURANCENET

## I. CASE FILES

A. ANet is an organized, electronic means the DO uses to document case files, including the initial support for the enforcement or other administrative action and all the steps in the administrative process associated with each action (Table 1). The hardcopy case file securely stored at the DO contains the properly documented evidence. ANet assists the DO to ensure case files for administrative enforcement actions are properly assembled and maintained electronically. The system also is used for maintaining complete electronic files associated with other activities, such as district level NR appeals, recall effectiveness checks (REC), and other non-AER activities as described in FSIS Directive 8000.1, *Ensuring Integrity of Data in the AssuranceNet/In-Commerce System*.

B. Specific instructions regarding the use of ANet are in the ANet User Guide. Instructions for using ANet and documenting AERs are available on the ANet website.

C. The AER module in ANet is used to maintain an electronic record of the enforcement action, including an electronic FSIS Form 5400-9, *Administrative Enforcement Report*, files representing the exhibits supporting the action, establishment responses and submitted documents, and Agency-generated documentation relevant to the case (e.g., requests to the establishment for clarification, verification plans). As the case progresses, the DCS is to provide timely updates to the AER in ANet to include the new information gathered or generated.

D. Table 1 lists AER report types with an example of the corresponding report number. (Example: 80-16-N003, District Number 80-Year 2016-NOIE number **003** in the nationwide series)

**Table 1. AER REPORT TYPES AND REPORT NUMBERS IN ANET**

| AER Type | Case File Number Example in ANet |
|---|---|
| NOIE **(N)** | 80-16-**N**003 |
| Suspension **(S)** | 80-16-**S**001 |
| Reinstatement **(R)** | 80-16-**R**001 |
| Appeal to DM **(A)** | 80-16-**A**010 |
| Withholding of Labels **(WL)** | 80-16-**WL**001 |
| Recall Effectiveness Check **(REC)** | 80-16-**REC**001 |
| Prohibited Act **(PA)** | 80-16-**PA**001 |
| Detention **(D)** | 80-16-**D**001 |
| Other **(O)** | 80-16-**O**001 |

| | |
|---|---|
| Traceback **(T)** | 80-16-**T**001 |

E. The DO is to frequently update ANet with exhibits to provide timely updates to all ANet users.

F. In all enforcement cases, the first exhibit in the case file will be the NOIE, NOS, or NROS letters issued to the establishment advising establishment management of the enforcement action (Table 2).

G. The DO is to describe exhibits in ANet in a manner that will enable someone unfamiliar with the facts to understand the sequence of events and the basis for the determination that there has been a violation of the statutes or regulations. The reader will be able to discern how the exhibit supports the enforcement action.

H. The DO is to enter enforcement letters into the case file within 48 hours from the time of enforcement letter issuance.

I. The DO is to enter FSAs that result in enforcement action into the ANet case file within 48 hours of the exit conference.

J. The DCS is to ensure that all pertinent documents related to the enforcement action are entered in ANet within 5 business days of the issuance of the enforcement letter. The DCS is to review enforcement actions that are closed out in ANet and send to the DM for review in ANet within 5 business days of the issuance of the LOW (Table 2).

K. The DCS, as Evidence Officer, has overall responsibility for all AER case files, whether initiated by an EIAO, DVMS, or by the DCS.

**Table 2. TYPES OF AER CASE FILES AND ASSOCIATED INITIAL AND CLOSURE EXHIBITS**

| AER Type | Initial Exhibit in AER | Final Exhibit in AER may be One of the Following: |
|---|---|---|
| NOIE | NOIE Letter | LOW, NOS, Voluntary 120-day Suspension; Referral Letter, or Voluntary Withdrawal of Inspection Letter |
| Suspension | NOS Letter | LOW, NROS, Referral Letter, or Voluntary Withdrawal of Inspection Letter |
| Reinstatement | NROS Letter | LOW, Referral Letter, or Voluntary Withdrawal of Inspection Letter |
| Appeal to DM | Incoming Appeal Letter to the DM | Letter Granting, Denying, or Modifying Appeal |
| Withholding of Labels | Letter Withholding Labels | Letter Reinstating Labels |
| Recall Effectiveness Check | RMTAS Recall Initiation Letter | RMTAD Recall Close Out Letter |
| Prohibited Act | Letter of Prohibited Activity | Varies on a case-by-case basis |
| Detention | Voluntary Destruction, Personal Use, Relabeling, or Referral Letter to OIEA - EOB Requesting Seizure | Voluntary Destruction, Personal Use, Relabeling, or Referral Letter to OIEA - EOB Requesting Seizure |
| Traceback | Sample Results | Report documenting the written analysis that provides a summary of the findings and any recommendations for further action |

## II. RECALLS AND RECALL EFFECTIVENESS CHECKS

A. ANet also is the electronic system used to store documents related to recalls and recall effectiveness checks.

B. Exhibits for recall case files may include, but are not limited to, recall worksheets, memorandum of information (MOI), decision memorandums, laboratory reports, consumer complaints, list of consignees, company press release, USDA press release, recall notification report, FSIS Form 8400-4, *Report of Recall Effectiveness*; Tracking Recall Effectiveness Checks System (TRECS) Recall Reports, Recall Management and Technical Analysis Division (RMTAD) initiating notification letters; recalling district close-out letter; and RMTAD recall close-out letter.

C. The DO is to refer to FSIS Directive 8080.1, *Recall of Meat and Poultry Products*, and FSIS Directive 5100.2, *Enforcement, Investigations, and Analysis Officer (EIAO) Responsibilities Related to Recalls and Consumer Complaints,* for additional information regarding recalls and recall case file documentation.

## III. APPEAL TO DISTRICT MANAGER

A. Appeal to DM case files are to be created in ANet within 5 days of the establishment's initial appeal to the DM.

B. ANet exhibits for appeals may include, but are not limited to these documents:

1. Establishment appeal to DM;
2. Program employee decision (e.g., NR) being appealed;
3. Establishment appeal to IIC or FLS;
4. IIC or FLS letter of denial;
5. Any other information that supports the appeal decision;
6. DO letter granting or denying the appeal;
7. Establishment appeal to the EARO or Assistant Administrator (AA);
8. EARO or AA letter granting or denying the appeal;
9. Establishment appeal to Administrator; and
10. Administrator letter granting or denying the appeal.

## IV. PROHIBITED ACTIVITIES

A. Prohibited activities case files are to be created in ANet within 48 hours of issuance of the prohibited activities letter to the establishment.

B. For prohibited activities (e.g., adulterated product deliberately distributed into commerce), the exhibits may include:

1. MOI with responsible officials;
2. Photographic evidence;

3. FSIS decision memorandum;

4. Information of how the product was shipped or received; and

5. Copy of the prohibited activities letter issued to the establishment.

## V. TRACEBACK

A. Traceback case files are to be created in ANet promptly.

B. The exhibits may include:

1. Positive sample results from FSIS or another Federal or State agency's testing of ground beef or bench trim;

2. Supplier and source material information collected by IPP at the time of sample collection;

3. Evidence that shows product is in commerce;

4. Any pertinent PHIS reports or data;

5. Communications with RMTAD; and

6. Report documenting traceback investigation that includes a written analysis of findings and any additional recommendations for action (FSIS Directive 10,010.3, *Traceback Methodology for* Escherichia coli *(*E. coli*) O157:H7 in Raw Ground Beef Products and Bench Trim*).

## VI. RETENTION AND DISPOSAL OF ADMINISTRATIVE ENFORECEMENT REPORTS

A. Per FSIS Directive 8010.3, closed administrative enforcement case files are to be retained at the DO for a period of three (3) years after the end of that fiscal year in which the specific case file was closed.

B. After the retention period has been met, case files, including the AERs and all documentary evidence, may be destroyed by shredding or incineration, except:

1. When a case has involved an administrative or other legal proceeding (e.g., request for a hearing before an Administrative Law Judge, complaint to withdraw inspection, Tort claim, injunction, Bivens complaint, an Office of Inspector General-directed or other unique type of investigation). The DO retaining a specific case file for an extended time period is to make sure that the specific case file is clearly marked with the reason for which it is being held longer than the normal retention schedule; or

2. When an EARO determines that a case file is considered to be novel or precedent setting (e.g., reports related to high visibility recalls, illness outbreaks, or investigations).

C. The record retention and disposal guidelines in this directive do not apply to AER records, including, documentary, photographic, investigative samples, or other evidence that was created in, entered or uploaded into, or maintained in ANet. ANet is an official electronic information system and has a separate record retention and disposal schedule from what is covered in this directive for AERs, documentary evidence, and related records. The disposal of AER records, including evidence, in ANet is to be handled by an Agency-level process in accordance with an approved record schedule for ANet.

## CHAPTER V – QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development