

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

FSIS DIRECTIVE

5100.3
Revision 2

10/18/11

ADMINISTRATIVE ENFORCEMENT REPORTING (AER) SYSTEM

I. PURPOSE

The purpose of this directive is to explain the system and procedures used in the Office of Field Operations (OFO) for documenting and maintaining case files supporting administrative enforcement and other actions taken under the authority of the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA).

KEY POINTS:

- *Sets out roles and responsibilities for recommending and documenting administrative enforcement actions, and for maintaining case files supporting administrative enforcement and other actions.*
- *Describes the procedures Enforcement, Investigations and Analysis Officers (EIAOs) and District Case Specialists (DCSs) are to use when creating, updating, and closing AER case files using the Assurance Net application.*

II. CANCELLATIONS

FSIS Directive 5100.3, Revision 1, dated 03/07/06

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to clarify the roles and responsibilities of personnel associated with administrative enforcement actions and AER case files, and to reflect the implementation of the electronic case management system in the Assurance Net application.

IV. REFERENCES

9 CFR Parts 313, 416, 417, 500, 590 and 592
FSIS Directive 5000.1, verifying an Establishment's Food Safety System,
FSIS Directive 5100.2, EIAO Responsibilities Related to Recalls & Consumer Complaints,
FSIS Directive 5420.1, Homeland Security Threat Condition Response,
FSIS Directive 5500.2, Significant Incident Response,
FSIS Directive 6500.2, Incident Investigation Team Reviews,
FSIS Directive 6910.1, District Veterinary Medical Specialist Work Methods,

Distribution: Electronic

OPI: OPPD

FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding & Disposal, FSIS Directive 8080.1, Recall of Meat and Poultry Products, and FSIS Directive 8410.1, Detention and Seizure

V. ACRONYMS AND DEFINITIONS

For the purposes of this directive the following acronyms have these meanings:

AER	Administrative Enforcement Report
DCS	District Case Specialist
DDM	Deputy District Manager
DM	District Manager
DO	District Office
EARO	Executive Associate for Regulatory Operations
EED	Evaluation and Enforcement Division
EIAO	Enforcement, Investigations, & Analysis Officer (see note below)
SEIAO	Supervisory Enforcement Investigations & Analysis Officer
EPIA	Egg Products Inspection Act
FMIA	Federal Meat Inspection Act
FLS	Frontline Supervisor
FSA	Food Safety Assessment
FSIS	Food Safety and Inspection Service
IPP	Inspection Program Personnel
MOI	Memorandum of Interview
NOIE	Notice of Intended Enforcement (see note below)
NOS	Notice of Suspension (see note below)
NR	Noncompliance Record
OFO	Office of Field Operations
OIG	Office of Inspector General
OPHS	Office of Public Health Science
OPPD	Office of Policy and Program Development
OPEER	Office of Program Evaluation, Enforcement and Review
PHV	Public Health Veterinarian
PPIA	Poultry Products Inspection Act
RIMD	Risk Innovations Management Division
RMS	Recall Management Staff
TRECS	Tracking Recall Effectiveness Checks System

NOTE: For the purposes of this Directive, the term EIAO also means EIAO trained Public Health Veterinarian when conducting EIAO activities. In addition, when used in this Directive, the term “enforcement letters” refers to Notice of Suspension, Notice of Intended Enforcement, and Notice of Reinstatement of Suspension letters.

VI. BACKGROUND

A. The AER case management system provides an electronic means for creating, updating, and maintaining documentation collected and produced by the Agency relating to various administrative enforcement actions and other administrative cases. The AER system is designed to ensure that all administrative actions are fully supported and are based on relevant facts, the Acts, and applicable regulations. The AER is an organized means for documenting not only the initial support for the enforcement or other administrative action, but for documenting all the steps in the administrative process associated with each action until the case is considered closed. Although the AER system was primarily established to ensure case files for administrative enforcement actions are properly assembled and maintained, the system is also used for maintaining complete files associated with other activities, such as District level appeals and recall effectiveness checks.

B. OFO personnel carry out investigations and administrative enforcement actions under the Rules of Practice regulations (9 CFR Part 500) or Egg Products Inspection regulations (9 CFR Part 590) when a Federal establishment is not meeting the provisions of the FMIA, PPIA, or the EPIA (the Acts) or the regulations promulgated under these Acts. When OFO decides to pursue an enforcement action under 9 CFR 500.3, *Withholding or suspension without prior notification*, it issues a Notice of Suspension; or under 9 CFR 500.4, *Withholding action or suspension with prior notification*, it issues a NOIE. In connection with these enforcement actions, OFO prepares an AER case file to include supporting documentation, and evidence collected to support the enforcement action.

C. The AER case management system in the Assurance Net application is used to maintain an electronic record of the AER, including an electronic FSIS Form 5400-9, files representing the exhibits (i.e., evidence) supporting the action, and Agency-generated documentation relevant to the case. As a case progresses, OFO updates the AER to include the new information that it gathers or generates. The system allows authorized users to search and review AER information at all phases of an administrative enforcement or other action and allows users to search and review case files associated with past actions.

D. The roles and responsibilities relating to developing and maintaining AER case files are explained in detail in this Directive. In most but not all cases, EIAOs provide the initial supporting documentation for an administrative case file, and in some cases, may create the AER record in the Assurance Net system. However, it is the DCS who has overall responsibility for all AER case files, whether initiated by an EIAO or by the DCS. The District management team members (DM/DDMs) are responsible for approving enforcement and other actions documented in the AER system. The DVMSs play a role similar to the EIAO in enforcement cases involving humane handling violations. The SEIAOs serve in a backup capacity to the DCSs on AERs.

VII. EIAO RESPONSIBILITIES

The primary roles of the EIAO with respect to the AER system are to collect, examine and copy evidence supporting enforcement actions, to make recommendations that enforcement actions be proposed or taken based on FSA findings or other investigations, and to assist in the activities that follow the enforcement action, as required.

A. Collecting Evidence and Accessing, Examining, and Copying Records

1. The FMIA, PPIA, and EPIA provide FSIS personnel with the authority to examine facilities, inventory, and records at Federal establishments and at warehouses, distribution centers and other in-commerce facilities subject to those statutes (21 U.S.C. 460, 642, 1034, and 1040). FSIS regulations also provide access and examination authority (including 9 CFR 310.25, 320.4, 416, 417, 430.4, 590.200, and 590.220). These statutory and regulatory provisions also provide FSIS personnel authority to copy certain business records.
2. At the entrance meeting before a Food Safety Assessment (FSA) or other investigation, EIAOs or other involved FSIS personnel are to explain to the establishment management the statutory and regulatory authorities that allow them to access to examine and copy records during the course of their duties.
3. EIAOs are to collect evidence, including photographic evidence, and complete the appropriate FSIS forms as set out in FSIS Directive 8010.3, "Procedures for Evidence Collection, Safeguarding and Disposal." EIAOs are to complete Section I and Section II of FSIS Form 8000-17, "Evidence Receipt and Chain of Custody," for all evidentiary items and are to transfer the evidence along with signed hard copy of this form to the DCS, via UPS, in accordance with FSIS Directive 8010.3.
4. For photographic evidence, EIAOs are to send the master CD-R along with each completed FSIS Form 8000-15, "Photographic Log-Sheet" and the corresponding FSIS Form 8000-17 to the DCS, via UPS, as indicated in FSIS Directive 8010.3.
5. It is possible that when an enforcement recommendation is made, it may not be necessary to copy an entire plant record to support a given finding. EIAOs are to use sound professional judgment to only copy those plant records that are needed to support a finding or an enforcement recommendation. The following are examples of cases in which it may not be necessary to copy an entire record.
 - a. If there are only certain aspects associated with a plant's HACCP plan, Sanitation SOP, or prerequisite program records that are inadequate or regulatory noncompliant, then the EIAO is to copy those portions of the record to establish that noncompliance with regulatory requirements has occurred.

- b. When multiple records of the same type demonstrate noncompliance, it may not be necessary to copy all records but only to copy a representative sample. In the event that an EIAO has questions about that which should be copied to support an enforcement recommendation, then he or she is to confer with the SEIAO or DCS.
 - c. In lieu of copying records and when it is practical because the information needed is not voluminous, the EIAO may type the information exactly as it appears in the record and include this information in the FSA or other report. When this approach is taken, the EIAO is to specify that the information typed is the exact information as it appeared in the original record reviewed. The EIAO is also include the title of document from which he or he is quoting, the date of the document, the version of the document, if applicable, and any other information that is needed to identify the record.
6. EIAOs are to use assigned digital cameras or assigned scanners to make needed copies. Alternatively, in the event an establishment copy machine is available, the EIAO could request management provide a copy of any records needed or request permission to use the plant copy machine.
7. If management refuses to allow the EIAO to access, examine or copy records, even after the EIAO makes the establishment aware of the relevant statutory and regulatory authorities, EIAOs are to consult with the DO for further guidance. The DO is to determine the next appropriate step, which may include issuing a written request to access, examine, and copy records. The DO also is to confer with the assigned EARO regarding the initiation of procedures to obtain an administrative subpoena for the requested information. When the determination is made that an administrative subpoena will be necessary, the EARO is to contact OPEER EED to request an administrative subpoena.

NOTE: In most cases, establishment management agrees to allow access, especially after EIAO's explanation of FSIS's statutory authority.

8. EIAOs are to provide all evidence to the DCS. In the event that an EIAO's official duty station is at the DO, or if the EIAO is in close proximity to the DO, the EIAO is to hand-deliver to the DCS or to the DDM or DM, any original evidence collected during the course of the FSA, investigation, or other administrative activity. Otherwise, EIAOs are to send all original evidence associated with an enforcement or other recommendation to the DCS via an overnight carrier, and not by regular mail. In the event that an EIAO prepares FSIS Form 8200-1, Property Receipt (see FSIS Directive 8010.3) to account for records temporarily taken away from the establishment or to the government office for review or copying, then the EIAO also is to provide a copy of this form to the DCS to include in the AER.

B. Supporting Enforcement Recommendations and Verification Plans

1. The EIAO is responsible for making recommendations to the District management team regarding the action he/she believes is warranted following the completion of an FSA, investigation, or other administrative enforcement activity. He or she is to document the support for the recommendations in the FSA report, in a MOI, or in a decision memo. These documents become exhibits (i.e., evidence) in the AER case file, should an enforcement action result. If no enforcement action or other case results, there is no AER created.
2. EIAOs are to describe supporting documents for the AER 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 regulations or statutes. EIAOs are to present information in a manner that explains the “who, what, when, where, and how” of the alleged violation in a chronological order of events. For enforcement actions, the documents are to link the alleged violations to FSIS statutory and regulatory requirements (e.g., the Acts, and 9 CFR).
3. If, while conducting an FSA or investigation, an EIAO determines the facts will likely support recommending an enforcement action, it is important that he or she communicate with the SEIAO or DCS as soon as possible, so that the EIAO will know which facts or documents to collect to support an enforcement action and to ensure that the basis for the recommendation is sound.
4. When making enforcement recommendations, the EIAO is to identify the relevant adulteration provisions under 21 USC 602 (m) (1)-(4) of the FMIA, 21 USC 453 (g) (1)-(4) of the PPIA, or 21 USC 1033 (a) (1)-(8) of the EPIA, as well as the findings that support the adulteration determination and the impact from a public health perspective.
5. While conducting FSAs or investigations, EIAOs are to communicate with the SEIAO, FLS and inspection program personnel (IPP) about the findings to make certain they have collected and considered all relevant information. EIAOs are to document information obtained from IPP and the FLS in a MOI and include the MOI in the supporting documentation for the recommended enforcement action.
6. EIAOs are to seek expert advice from officials from RIMD when they need information related to scientific or technical issues before documenting their findings or making an enforcement recommendation. OPPD, RIMD is then responsible for bringing in experts from other program areas, such as OPHS, on a case by case basis. RIMD will place information on the AskFSIS page that answers questions concerning FSAs from EIAOs. If the answers are relevant to the AER case and are relied upon for supporting the case, the EIAOs are to document the information for inclusion in the AER.
7. If during the course of the FSA, investigation, or other administrative activity, any

novel or unusual circumstances emerge that need expedited consideration by Agency experts, the EIAO is to communicate the need for that information to the SEIAO. The SEIAO, through the DM or a DDM, also is to correlate with the corresponding EARO about the matter, and the EARO is to coordinate obtaining input from other Agency experts.

8. Given that the administrative enforcement process calls for enforcement to be initiated in a timely manner, EIAOs are also to assist the DO in drafting NOIE and NOS letters or with drafting other documents associated with the enforcement action.
9. At the exit meetings, EIAOs are to provide establishment officials with a copy of the FSA report or investigation report marked "draft." The report is marked "draft" so that the information concerning the exit meeting can be incorporated before finalizing the report. By the time of the exit meeting, the findings and recommendation outlined in the FSA are to be considered final. If an enforcement action results, the DO is to deliver the enforcement letter to establishment within 24 hours of the exit conference. The final copy of the FSA report is to be issued by the DO to the establishment within 48 hours of the exit conference. Note: if only NRs result from an FSA (i.e., no enforcement action is taken), there is not an AER created.
10. When the DO decides to defer enforcement, or to hold a suspension in abeyance, because the establishment has agreed to make corrective and preventative measures acceptable to FSIS, the EIAO is expected to assist the DO in preparing a verification plan designed to verify that those measures are being executed effectively. Once the verification plan is reviewed by the SEIAO and DCS, the EIAO communicates and discusses the plan with both the FLS and the assigned IPP. This discussion is to ensure that there is a clear understanding of the noncompliance issues and of the specific verification procedures FSIS in-plant personnel will perform to verify the effectiveness of the corrective and preventive measures completed by the establishment.
11. In addition, during the deferral or abeyance period, EIAOs are expected to conduct periodic follow-up visits (at 30 day intervals) to the establishment until the AER case is ready to be closed. During these visits, EIAOs are to review documentation generated by the establishment and by IPP to determine whether the corrective and preventive measures completed by the establishment have been effective. EIAOs are also to provide information and recommendations to the DO to help decide when an enforcement matter should be closed, or if additional action is warranted.

VIII. DVMS RESPONSIBILITIES

A. The DVMS has a primary role in the evaluation, documentation, and recommendation of enforcement action and preparation of verification plans when there is an inhumane handling incident or an action based on a history of humane handling violations by the establishment.

B. Based on information provided by IPP or, in some cases, first-hand observational knowledge, or the history of humane handling noncompliance by the establishment, the DVMS makes recommendations on the appropriate enforcement action. The documented recommendation is to specify the regulatory requirements that have not been met and the relevant statutory authorities.

C. As the investigation and other administrative activities are being conducted, the DVMS needs to confirm that the MOI provided by IPP with first-hand observational knowledge of the inhumane incidents clearly and fully provide all relevant information that supports taking the enforcement action. Additionally, all relevant communications concerning the inhumane incidents with or by supervisory personnel (e.g., FLS or Mini-IPPS Supervisory PHV) and establishment personnel need to be documented in a MOI. These documents are to be included as separate exhibits in the AER to provide support for the enforcement actions described (e.g., Notice of Suspension or Notice of Intended Enforcement), and copies are to be provided to establishment management. In the case of a noncompliance history leading to the enforcement action, the DVMS needs to provide the analysis of the trend in noncompliance of inhumane incidents and work with the DCS on the enforcement strategy.

D. If any scientific or technical issues are raised that need further clarification, before making the enforcement recommendation, the DVMS is to seek expert advice directly from the Humane Handling Enforcement Coordinator or officials in OPPD. The DVMS also needs to ensure that he or she documents any guidance received and includes the documentation in the AER.

E. Given that the administrative enforcement process calls for enforcement to be initiated in a timely manner, the DVMS is also expected to assist in drafting the NOIE and NOS letter or other documents, as needed, associated with the enforcement action.

F. When the DO decides to defer enforcement, or to hold a suspension in abeyance, because the establishment agrees to take corrective and preventive measures, the DVMS is expected to assist in preparing the verification plan that will be used to ensure that the corrective and preventive measures proffered by the establishment are effective. The DVMS also 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 IPP are to conduct to verify the effectiveness of the corrective and preventive measures provided by the establishment.

G. In addition, a DVMS or DVMS-trained PHV is expected to conduct periodic follow-up verification visits (e.g., at 30 day intervals) to the establishment during the deferral or

abeyance period. During these visits, the DVMS or DVMS-trained PHV is to evaluate the data and information that has been generated by establishment personnel and the documented verification activities performed by in-plant IPP to determine whether the corrective and preventive measures that were proffered by the establishment have been effective. When a follow-up visit is performed by a DVMS-trained PHV, the DVMS is expected to communicate with the DVMS-trained PHV regarding any questions or issues that the DVMS-trained PHV identifies during the visit where the DVMS's subject matter expertise may be needed. The DVMS is to document all follow-up visits and to provide the documentation to the DCS for inclusion in the AER file.

H. The DVMS is also expected to provide recommendations to the DO to help decide when an enforcement action should be closed, or if additional action is needed. An inhumane handling suspension action is not to be closed without one or more on-site visits by the DVMS during the abeyance period.

I. The DVMS is expected to follow the procedures in this directive pertaining to collecting evidence (e.g., copies of plant records or other records, photographs taken), and he or she is to ensure that the information is submitted to the DCS for inclusion in the AER.

IX. DCS RESPONSIBILITIES

A. The DCS plays a key role in developing the AER case strategy and in ensuring that the AER contains documentation that supports the enforcement or other action taken. The DCS also has primary role in managing, preparing and entering the contents of the AER case into Assurance Net in a timely manner.

B. To ensure that the AER case file contains supporting documentation, the DCS is to communicate with SEIAOs and EIAOs about potential enforcement matters and is to assist the DO management team by providing guidance and direction on enforcement issues. The DCS is to correlate with the SEIAOs, EIAOs, or other personnel about the findings as the AER cases are in progress. The DCS is to bring to the attention of the DDM or DM any issues that may be problematic or need further clarification.

C. In addition to ensuring that the evidence that forms the basis for initiating the enforcement action has been included in the AER, the DCS ensures that all relevant documents after the issuance of the NOIE or NOS letter are added to the AER case file. The relevant documents include the following:

1. Enforcement letters (e.g., NOIE, Notice of Suspension, Letter of Deferral, Letter of Warning) issued by the DO to propose, initiate, defer or put in abeyance, or close an enforcement action;
2. Letters and documentation submitted to the District Office by the establishment or industry officials concerning the enforcement matter, such as responses to a NOIE or to a NOS letter;
3. Written plans or programs or excerpts from these documents, included as part of the establishment response to the enforcement action;

4. Correspondence between the DO and the establishment during the life of the AER; and
5. Verification reports from in-plant inspection personnel and EIAOs or other relevant records collected during a deferral or abeyance period.

D. The DCS is responsible for ensuring that the enforcement letters issued by the DO include a background summary of the facts supporting the enforcement action and the statutory and regulatory authority for proposing or taking the action. The DCS is to ensure that these letters contain appropriate FSIS contact information, including the address and telephone number of the DO, so that the establishment can contact FSIS and provide a written response in a timely manner. In addition, the DCS is to ensure that the letters inform establishment officials of their appeal and hearing rights and to whom the appeal or hearing request should be directed.

E. The DCS has primary responsibility for managing the contents of the AER, ensuring that report information is entered in Assurance Net in a timely manner, and maintaining the AER through the life of the case. The SEIAO serves as backup to the DCS for managing AERs.

F. The DCS has the primary responsibility for starting an AER case file and entering the AER information into Assurance Net. However, in instances in which the SEIAO or EIAO assigned to the matter has the necessary computer equipment and available internet access, then the SEIAO or EIAO may access Assurance Net and initiate the AER and enter and upload the AER information. In other instances, it may be more efficient for the DCS to enter the information in the Assurance Net AER case management system at the DO. The DCS is to work with assigned SEIAO or EIAOs to decide the method they will use to initiate, enter, and maintain the AER case files in Assurance Net.

G. For each administrative enforcement action proposed or taken, the AER case file is to be created in Assurance Net within 48 hours of issuance of the NOIE or NOS letter. Basic information about the AER report is entered on electronic form FSIS Form 5400-9 "Administrative Enforcement Report," including the type of enforcement action or other administrative action, date of the report, and other identifying information. As new information is gathered by OFO during the administrative process, this information is to be added to the AER and uploaded in Assurance Net in a timely fashion to make certain that the AER is kept up to date until the matter is closed. Attachment 1 provides guidance on what should be the first exhibit and the final exhibit in each type of case file. Additional guidance is also provided on the various types of documentation to be included as exhibits on the most common case file types.

H. The DCS uploads supporting information and documentation in the AER case management system by using the "Evidence Collected" tab in the AER record in Assurance Net and then describes the evidence using the "Description of Evidence" box. The DCS also describes in more detail, each piece of evidence (i.e., exhibit) using

the “Exhibit Cover Sheet Description” box. This description automatically populates on the “List of Exhibits”, which displays the description of each exhibit in chronological order and numbered by the DCS. The description is to be concise, but complete enough for anyone reviewing the “List of Exhibits” to get sense for the progression of the AER case and the documentation contained in the case file.

I. When evidence collected by an EIAO is received in the DO, the DCS is to complete Section II of FSIS Form 8000-17, Evidence Collection and Chain of Custody, which accompanies the incoming evidence, in accordance with FSIS Directive 8010.3. The DCS is also to update the electronic version of this form in the Assurance Net system to reflect the transfer of evidence. This entry is to state that the evidence was received in the DO, and that the purpose of the change in custody was to transfer custody of the evidence from the EIAO who collected it to the DO.

J. The DCS is to maintain a hard copy of the entire AER case file, including the evidence received from the EIAO, in a secure file cabinet.

K. AERs are automatically assigned report numbers in Assurance Net. The first number is the DO number and the second number is the fiscal year. The lettering and corresponding numbers identify the report type. For example, AER 65-10-N003 indicates the issuance of an NOIE (N) in the Albany DO (65) in fiscal year 2010 (10). The last number (003) indicates that this is the third report of that type (i.e., the third NOIE) that has been created nationally during the fiscal year. Attachment 2 sets out the list of report types with an example of a corresponding report number.

L. For Recall Effectiveness AERs, which involve assistance from multiple Districts, there is one District assigned overall responsibility for completing one Recall Effectiveness AER. The primary District Recall Officer in the recalling District is responsible for ensuring that the AER includes recall effectiveness check information collected by the assisting Districts, as well as the other pertinent documentation.

M. For AER cases that are related (e.g., a situation where in the course of a recall there has been a prohibited act or an NOIE that resulted in a suspension), the DCS is to use the Past/Related AER tab to link the AER case file records in Assurance Net.

N. On occasion, there may be a circumstance that warrants reopening of a closed AER file. For example, an establishment that received an NOIE decided voluntarily to stop operating. Based on this information, the AER for the NOIE was closed. Later, the establishment notifies FSIS that it intends to resume operations. This notification may necessitate re-opening the closed AER, such as the establishment’s request to resume operations and evidence that upon reopening it has satisfactorily addressed the issues that led to the NOIE originally. If there are situations that warrant re-opening a case, the DCS is able to re-open the case in the system.

NOTE: When one case leads to another case, both are maintained in Assurance Net as separate cases. For example, an NOIE that moves to a Suspension will be two AERs and two separate case files in Assurance Net. However, as stated under above, these two separate cases can be linked in Assurance Net.

O. Details regarding the use of the AER case management system in Assurance Net are found in the Assurance Net - OPPS, AER, Delegation of Authority, and Reporting User Guide, dated September 2011.

X. RETENTION AND DISPOSAL OF REPORTS

A. Per FSIS Directive 8010.3, closed AERs 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 AER was closed and then may be destroyed, except as provided below.

B. In instances when an AER 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 OIG directed or other unique type of investigation), the specific AER may need to be held under retention for an extended time period. These AERs are not to be destroyed after the normal 3 year retention period. When these situations arise, the DCS is to consult with the EARO and EED regarding the appropriate amount of time to maintain the report. The DO maintaining a specific AER for an extended time period is to make sure that the specific AER is clearly marked as to the reason for which it is being held longer than the normal retention schedule and therefore has not been destroyed.

C. In the instances in which an EARO determines that an AER case is considered to be novel or precedent setting in nature (e.g., reports related to high visibility recalls, illnesses outbreaks, or investigations), even if there are no administrative or legal proceedings involved, the DO may be directed to hold the AER case file longer than three years. The DO management staff and DCSs are to exercise care not to destroy cases of this nature and are to consult with the EARO regarding the appropriate amount of time to maintain such reports.

D. Furthermore, in instances when EARO has determined that an AER case file should be maintained for a prolonged period of time, it may be necessary to ship the report to the National Archives and Records Administration Center for retention and storage. When this occurs, the DCS is to consult the FSIS Records Management Staff about the necessary shipping and storage procedures.

E. Disposal procedures for Administrative Enforcement Reports, including all exhibits, are as follows:

1. All case files, including all copies of documentary evidence are to be destroyed by shredding or incineration; and

2. Disposal of evidence is to be documented in Section III of the "Evidence Receipt and Chain of Custody" form in accordance to the retention schedule listed in FSIS Directive 8010.3.

XI. DM/DDM RESPONSIBILITIES

A. The DM and DDM are to ensure that the procedures addressed in this directive are being carried out in the DO. The DM and DDM are expected to carefully consider the findings and the enforcement recommendations made by EIAO, DCS or DVMS, and should ensure that they have a full understanding of the facts before an enforcement decision is reached. The DM and DDM are to communicate with the DCS, SEIAO and EIAOs or, in inhumane handling cases, the DVMS, regarding case strategy or regarding any potential issues that need their involvement.

B. The DM or a DDM signs NOIE or NOS or other enforcement related letters. Before signing such a letter, the DM or DDM is to carefully review the letter, the supporting documents and the facts discussed to make certain that the facts are correctly set out and fully support the action. The DM or designated DDM is to be available to discuss enforcement issues with plant officials or with their representatives if the DO is contacted. The DM or DDM is to ensure that due process entitlements are provided when enforcement or other types of administrative actions are taken.

C. If during the course of the FSA, investigation, or other administrative activity, any novel or unusual circumstances are raised by the EIAO or DCS that need expedited consideration by other Agency experts, the DM or DDM is to correlate with the EARO about the matter and coordinate obtaining input from other Agency experts.

Refer questions through supervisory channels.



Assistant Administrator
Office of Policy and Program Development

ATTACHMENT 1

Guidelines for Exhibits in Typical AER Case Files

The following shows the document that will serve as the first exhibit and last exhibit for each AER type listed below.

<u>AER Type</u>	<u>Initial Exhibit</u>
NOIE	NOIE Letter
Suspension	Notice of Suspension Letter
Reinstatement	Notice of the Reinstatement of Suspension Letter
Appeal to DM	Incoming Appeal Letter to the DM
Withholding of Labels	Letter Withholding Labels
Withdrawal Custom Exempt	Referral Memo to EED
Recall Effectiveness Check	Recall Initiation Letter from RMS
Prohibited Act	Letter of Prohibited Activity
Withdrawal of Inspection	Referral Memo to EED
Complaint for Suspension	Referral Memo to EED
Traceback Methodology	To Be Determined
Full Traceback Methodology	To Be Determined
Detention	Voluntary Destruction, Personal Use, Relabeling or Referral Memo to EED Requesting Seizure

<u>AER Type</u>	<u>Closure Exhibit</u>
NOIE	Letter of Warning
Suspension	Letter of Warning
Reinstatement	Letter of Warning
Appeal to DM	Letter Granting or Denying Appeal
Withholding of Labels	Letter Reinstating Labels
Request to Withdrawal Custom	EED Decision Letter/Memo
Recall Effectiveness Check	RMS Recall Close Out Letter
Prohibited Act	(Varies – case by case)
Withdrawal of Inspection	EED Decision Letter/Memo
Complaint for Suspension	EED Decision Letter/Memo
Traceback Methodology	To Be Determined
Full Traceback Methodology	To Be Determined
Detention	Voluntary Destruction, Personal Use, Relabeling or Referral Letter to EED Requesting Seizure

NOTE: In all enforcement cases the first exhibit will be the NOIE or Notice of Suspension Letter to Establishment advising establishment management of the enforcement action, and the last exhibit will be the documentation, such as a Letter of Warning, issued to the establishment or other information to reflect why the case is closed. However, if the NOIE leads to a suspension, the closing document in the NOIE AER is the Letter of Suspension. If a Reinstatement of Suspension letter is issued, this

letter will close out the Suspension AER case file, and a new AER is to be created for the Reinstatement of Suspension action.

The following information sets out the typical exhibits, in no specific order, that are to be a part of the identified AER case file type. Note that the lists are not all inclusive, and that this guidance is provided only for the most common types of AER case files.

A. Enforcement Actions (NOIE, NOS, NROS)

For enforcement actions pursuant to 9 CFR Part 500 and 590.160, common exhibits include:

1. The NOIE, NOS or NROS letters.
2. Food Safety Assessment reports that serve as the basis for taking enforcement;
3. Copies of HACCP/Sanitation SOP and pre-requisite records, plant testing data and laboratory methodology, scientific or technical information, documentation supporting the action;
4. Memoranda of Interview;
5. Information documenting advice provided by AskFSIS, and other information from the Office of Policy, and Program Development; or Office of Public Health Science;
6. Any relevant laboratory results;
7. Any relevant photographs of product conditions or plant conditions;
8. The establishment response to the enforcement action including documentation demonstrating corrective actions implementation;
9. Communications regarding deferral action and the establishment responses, if applicable;
10. Communications regarding withholding or suspension action and the establishment responses;
11. Communications regarding an abeyance action and the establishment responses, if applicable;
12. Communications regarding the withholding of labels; and
13. Any other information that supports the action taken or the decisions being made during the administrative enforcement process.

14. The 30, 60 and 90 day verification reports;
15. MOIs concerning the weekly plant meetings;
16. Biweekly verification reports; and
17. Final closure letter.

B. Recall Effectiveness Checks

Per 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," the exhibits may include but are not limited to:

1. Recall worksheets;
2. Memorandum of Interview with producing establishment management;
3. Conversation records with inspection program personnel over critical issues;
4. Decision memorandum to request voluntary recall;
5. Laboratory reports (internal and external);
6. CCMS or consumer documentation;
7. Notification by recalling firm of consignees;
8. Company press release;
9. USDA press release;
10. Recall notification report;
11. Official notification by establishment of intent to voluntarily recall and the name of the coordinators;
12. FSIS Form 8400-4, Report of Recall Effectiveness;
13. TRECS Recall Reports;
14. RMS initiating and closing notification letters; and
15. Recall close out letter from the firm.

C. Appeal to DM

1. Establishment's appeal to DM;
2. Program employee decision(e.g., NR) being appealed ;
3. Establishment's 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's appeal to the EARO/AA;
8. EARO/AA letter granting or denying the appeal;
9. Establishment's appeal to Administrator; and
10. Administrator letter granting or denying the appeal.

D. Prohibited Activities

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

1. Memorandum of Interview with responsible officials;
2. Photographic evidence;
3. FSIS decision memorandum;
4. Information of how the product was shipped or received; and
5. Copy of PA Letter issued to the firm.

Attachment 2

The following sets out the list of AER report types with an example of the corresponding report number.

<u>AER Report Type</u>	<u>Report Number</u>
NOIE (N)	65-10- N003
Suspension (S)	65-10- S001
Reinstatement (R)	65-10- R001
Appeal to DM (A)	65-10- A010
Withholding of Labels (WL)	65-10- WL001
Request to Withdraw Custom Exemption (C)	65-10- C001
Recall Effectiveness Check (REC)	65-10- REC001
Prohibited Act (PA)	65-10- PA001
Withdrawal of Inspection (W)	65-10- W001
Complaint for Suspension (CS)	65-10- CS001
Traceback Methodology (T)	65-10- T001
Full Traceback Methodology (F)	65-10- F001
Detention (D)	65-10- D001
Other (O)	65-10-- O001