The Administrative Enforcement Report (AER) Process

OBJECTIVES

After successful completion of this module the trainee will be able to:

1. Explain and/or list the following concepts of critical thinking
    a. What is critical thinking?
    b. The importance of critical thinking to the AER process

2. Explain the role of the PHV in the AER process
    a. In-plant team leader
    b. Ensuring accurate supporting documentation
    c. Ensuring proper lines of communication
    d. Performing verification activities (verification plans)

3. Explain the role of the AER within the FSIS regulatory framework
    a. Statutes and Rules of Practice as a framework of the AER case file
    b. Ensuring that the establishments receive due process

4. List and describe the main supporting components of the AER
    a. Noncompliance Records (NRs)
    b. Memoranda
    c. Memoranda of Interview (MOI)
    d. Signed Statements
    e. Other Agency Letters

5. Accurately document a Memorandum of Interview (MOI)

6. List two "other" sources of information pertinent to the AER process
    a. Consumer Complaint Monitoring System (CCMS)
    b. Recall System

INTRODUCTION

This module covers the agency's "**Administrative Enforcement Report**" (AER) format and thought processes.

This module will also cover:

- The use of critical thinking in developing an enforcement action.
- Different types of official documentation.
- The work methods and general process of building a case.
- The process behind recommending or taking an enforcement action.

- The basics of building a case and assembling an AER case file.
- How an establishment's response is verified by the agency.
- How to assess an establishment's corrective actions.

Overview of the AER Process

Background

Program Investigators prepare enforcement reports for serious violations of the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA). These reports typically include a Predication Statement, Synopsis of Facts, Narrative Summary, Chronology of Events, List of Witnesses, and Evidence Obtained but not Submitted. This format has proven to be useful and necessary for significant criminal and civil cases. However, this format can also be time consuming to complete. Under *9 CFR Part 500 - Rules of Practice*, FSIS is faced with the challenge of providing a report immediately which supports the basis of the action taken.

Administrative proceedings, including the documentation produced as a result of administrative actions, provide FSIS the authority to suspend inspection, with or without notice. They also provide FSIS the authority to stop a plant's right to do business when serious inhumane practice or food safety concerns are raised. Administrative proceedings can immediately affect the plant's right to conduct business and profit financially. FSIS needs this documentation immediately if an appeal by the plant is received, if the plant requests an expedited hearing, if FSIS requests a complaint to withdraw the grant of inspection, or if legal actions are taken such as hearings, injunctions, requests for seizure, etc.

Administrative enforcement actions can be appealed immediately and can result in an expedited hearing before an Administrative Law Judge, or other legal officials such as a District Court Judge. The AER and accompanying exhibits support that the agency has a basis for the action taken. This section describes the role of the PHV in the AER process to ensure that there is accurate supporting documentation when the agency proposes or imposes an enforcement action (e.g., Notice Of Intended Enforcement

(NOIE), withholding the marks of inspection, suspension). The documentation (e.g., NRs, memoranda, other Agency letters, etc.) must demonstrate the link between the enforcement action and the regulations. The regulations will be linked with specific provisions of the FMIA, PPIA, or EPIA later in the AER process. The AER process is used by FSIS to ensure that Agency personnel have analyzed all available information, applied critical thinking when making decisions, and have documented those decisions in a manner that will support the actions taken by the agency. The AER method of documentation demonstrates that FSIS has an effective and efficient means to document and maintain administrative actions taken under the Rules of Practice. The methodology helps to ensure uniformity and consistency.

The AER Report (FSIS Form 5400-9)

The Administrative Enforcement Report (AER), FSIS Form 5400-9, provides an effective and efficient means for FSIS to document and maintain enforcement actions taken under the *Rules of Practice (9 CFR Part 500)*. Some AER documentation is written with statutory and regulatory citations. It is important that both the regulatory and statutory support is properly cited for the instances that the AER case file is needed as an exhibit in court proceedings.

The Rules of Practice include:

- Regulatory control action
- Withholding action or suspension without prior notification
- Withholding action or suspension with prior notification
- Notification, appeals, and actions held in abeyance
- Withdrawal of the grant of inspection
- Refusal to grant inspection
- Procedures for rescinding or refusing approval of marks, labels, and containers

Statutory support includes the Acts:

- Federal Meat Inspection Act (FMIA)
- Poultry Products Inspection Act (PPIA)
- Egg Products Inspection Act (EPIA)

The AER process entails using a critical systems thinking approach to analyzing available information and facts. Once all pertinent and available information has been properly documented and analyzed and the decision leads to a recommended enforcement action, the case file is assembled and maintained by specially trained personnel. After the establishment has responded to the intended or effective enforcement action, the adequacy of the response must be verified by agency personnel. You as the PHV-IIC will play a critical role gathering and documenting facts, as well as in these verification procedures.

The AER process is not necessarily linear. Many of the elements are performed concurrently, in a "back and forth," or circular/spiral manner. For example, if it is decided that more information is needed to make a solid recommendation, and then steps must be taken back to gather this necessary information and then the information must be reanalyzed. It may take several "rounds" of information gathering/documenting and analyses before a recommendation for an enforcement action can or should be made. Under many circumstances, the issue may be resolved by the establishment without the need for such a recommendation.

Critical Thinking

An Overview of Critical Thinking

This section is a brief introduction into "critical thinking." This is an integral part of the AER process and your job as a PHV-IIC and also later in your role as an EIAO. Every field PHV will receive training as an EIAO and will ultimately perform the same duties as "full time" EIAOs, albeit at a lower frequency.

Applying critical thinking and analysis will help ensure that any action taken or recommendation made by you as the PHV, whether it be to recommend or not to recommend enforcement, is *well thought out* and based on a *thorough review* of all pertinent information. It is important to realize that this process is meant to result in a legally defensible case file that will, if necessary, stand up in a court of law. If your analysis is correctly performed and your thought process is well documented, then chances are very good that any resulting enforcement decision will never be taken to court.

Applying critical thinking will help associate any actions taken with the applicable statute or regulation, and also ensure that a solid basis exists for taking further action when warranted. The best laid out thought process is worthless if actions taken are not supported by the statutes or regulations.

Critical Thinking and How It Fit into the AER Process

Richard Paul[1] defines critical thinking as: "The ability to think about one's thinking in such a way as to recognize its strengths and weaknesses and, as a result, to recast the thinking in an improved form."

Studies have also been performed that have looked at people identified as "critical thinkers" and the following common characteristics were identified[2]. Not everyone that is a critical thinker will possess all of these characteristics, but this gives you an idea of some of the qualities that are beneficial to the process:

- People who hone critical thinking as a skill
- Inquisitive people
- People with a keenness of mind
- People with a hunger for reliable information
- People who actively use reason
- Open minded people
- People who are systematic
- Analytically minded people

Some examples of people who use critical thinking in their profession or life include scientists, doctors, trial lawyers, engineers, and good thinkers in general. Critical thinking

[1] Dr. Richard Paul. (1993) Critical Thinking – What Every Person Needs to Survive in a Rapidly Changing World, edited by Jane Willsen and A.J.A. Binker, Foundation for Critical Thinking, Santa Rosa, CA

[2] Steven D. Schaefersman, 1997, Miami University and Peter A. Facione, 1998, Santa Clara University

is a natural part of these professions, and by default your education in veterinary medicine has set you up for a career in "critical thinking."

Critical Thinking Frameworks

As scientists and veterinarians, you are already familiar with several types of critical thinking frameworks:

- The scientific method
- A medical diagnosis
- A systems analysis

You have used the "*scientific method*" in veterinary school and in practice. A medical diagnosis is basically a mixture of the scientific method and a systems analysis. When you make a veterinary diagnosis you use the basic framework of the scientific method, but also include a "*systems analysis*" approach when you assess the symptoms by organ system(s). You must have an understanding of the organ ***systems*** to rule out certain differential diagnoses. When performing an analysis of the effectiveness of an establishment's food safety ***system***, you will use these same basic principles.

You may not be as familiar with the *legal or regulatory analysis* method as with the other methods mentioned. This method is used when assessing an establishment's compliance with regulatory requirements, as they relate to their food safety system and public health.

In reality, you will be using a mixture of the above methods to achieve your goal. You will be analyzing a variety of both scientific and regulatory information that is intertwined in an establishment's food safety system. It will be your job as a PHV-IIC to determine whether the mixture that the establishment has put together is effective and meets basic regulatory requirements. Later, after receiving specialized EIAO training, you will be assessing whether the mixture meets the intent of all of the statutory and regulatory requirements.

Critical Thinking and Public Health

So far, we have been focusing on critical thinking as a component of the AER thought process. Let's look at it from a public health point of view, since ensuring the public's health is the ultimate goal of FSIS. FSIS has long been a public health regulatory agency. The recent emergence of certain foodborne diseases, such as *E. coli O157:H7* has forced FSIS to take a new look at this mission and make changes to the long established system of meat, poultry, and egg inspection.

It is part of any regulatory public health agency's mission to seamlessly integrate scientific principles with a legal framework and public health values[3]. Critical thinking is important in achieving this seamless integration. It was used while making significant organizational and necessary changes at the agency level—it will be as important when you are making public health and related enforcement decisions at the local level.

The Scientific Method as an Example of Critical Thinking

Now that we have covered some of the basics of critical thinking, we will spend some time reviewing the "scientific method" as an example of a critical thinking method. This will help to better understand the connection of scientific critical thinking to the AER process. Later, we will look at the legal analysis methodology as an example of how to assess information from a regulatory aspect.

According to Steven Schafersman[4], the scientific method requires three major prerequisites:

1. Use of empirical evidence
2. Use of logical reasoning
3. Possessing a skeptical attitude

The first prerequisite of the scientific method is the use of empirical evidence, which is using evidence that can be seen, heard, touched, tasted, etc. It is *tangible* evidence that can be experienced and is repeatable. In other words, it is using evidence that can be objectively verified.

[3] Steven D. Schafersman, 1997, Miami University

[4] Steven D. Schafersman, 1997, Miami University

The use of logical reasoning, the second prerequisite of the scientific method, is an *acquired* skill—it must be learned. Logical reasoning forces us to face the true facts and not give in to personal emotions or beliefs. Remember, *emotions* are not empirical evidence they are personal reactions to the facts. Likewise, feelings and subjective beliefs are not empirical facts. *Beliefs* are personal perceptions of the truth—they have a personal or subjective spin on them that is influenced by many things, such as culture, environment, etc. The use of logical reasoning forces us to face reality and be as objective as possible.

The third major prerequisite of the scientific method is the possession of a skeptical attitude. This does not mean that you should be skeptical beyond accepting the truth—but it does mean that you should not accept something as the truth without question. Change and progress would not happen if we did not constantly question our beliefs, examine new evidence, reexamine old evidence, and combat self deception. Just because someone says it is so—does not make it true. A healthy questioning of the perceived "truth" can lead to new insights and to change for the better.

One way of questioning the "truth" is by testing beliefs against objective reality. Remember beliefs are personal, subjective *perceptions* of reality. If the consequences and/or outcomes of an action can be consistently and objectively predicted, regardless of who is performing the action, we are much closer to the *real* truth.

The Steps of the Scientific Method:

Now that we have covered the prerequisites of performing the scientific method, we will review the individual steps to be performed in this methodology. Remember, this is not a new concept for you as a scientist and veterinarian, but it *will be used in an unfamiliar way* in your new position as a PHV.

In the purely scientific world, the steps to perform are as follows:

1. The first step is to identify the problem to study. This is done through an analysis of existing information and facts, as well as through gathering new information and facts. This is often performed through observation or qualitative studies.

2. The second step is to gather information and facts relevant to the identified problem. This will help further define the problem and assist in formulating a hypothesis to be scientifically tested.
3. The third step, once sufficient information has been gathered, is to formulate the hypothesis.
4. The fourth step is to scientifically test the hypothesis. This is generally performed through quantitative studies. The result of this test will be to either prove that your hypothesis is correct—or not.
5. The fifth step, if your hypothesis was not correct is to modify the hypothesis after further study and then test the revised hypothesis. This is repeated until the correct solution is found.
6. The final step is then to construct a theory from the evidence gathered and the proven hypothesis.

In your role as PHV-IIC, you will not be conducting pure scientific studies. You will, however, use the basic concepts of this logical thought process when analyzing the effectiveness of an establishment's food safety system. You will be tasked with identifying problems, such as regulatory noncompliance, gathering and documenting information pertinent to the identified problem, and proposing a regulatory solution if the establishment does not adequately remedy the problem on their own.

By using this type of thought process, you stand less of a chance of letting your emotions or feelings dictate your actions. Your actions will be supportable by the agency, both to the regulated industry and if necessary in a court of law.

Regulatory Analysis as an Example of Critical Thinking

As was mentioned before, you will also be performing a legal or regulatory analysis in your role as PHV-IIC. This section of the module will be an introduction into this thought process. You will receive more in-depth and detailed training on this type of methodology when you receive EIAO training in the near future.

When performing a regulatory (legal) analysis, you will follow a framework that is very similar to the scientific methodology you are acquainted with. There is, however, an important distinction between the two methods: The goal of the scientific method is to

scientifically prove a point, while the goal of the legal analysis is to *legally* prove a point. Another way of looking at it is that the scientific method follows the laws of science, while the legal analysis follows man-made laws, statutes, regulations, etc.

The steps to perform are as follows:

1. Gather the facts
2. Evaluate the evidence
3. Identify the regulatory (legal) elements
4. Develop the rationale
5. Draw the conclusion

The first step is basically the same as in the scientific methods—gather the facts or information needed to determine what the problem is. You will ask yourself such questions as:

- Who are the persons involved?
- What event has happened?
- What is the location that is involved?
- Why did the event happen?

It is important that the information gathered is pertinent and based on *objective facts*—not subjective opinions. All of the gathered evidence should be properly documented.

After the facts have been gathered, then the evidence must be evaluated. In doing this, the significance of the gathered information is weighed and assessed to determine if there is an indication of a problem. In other words, does the evidence point to a potential statutory or regulatory noncompliance? If not, do we need more evidence? Or, does the evidence indicate that there is no problem at all?

If it is determined that there is evidence of a potential noncompliance, then the next step is to identify the statutory and regulatory elements involved. This, of course, *requires a basic understanding and good working knowledge* of the most commonly used statutes, regulations, and current policies (i.e. directives, notices).

To identify the applicable elements, you can ask yourself:

- What are the applicable provisions of the statute?
- What are the applicable regulations?
- What are the applicable policies?

It is not expected of you that you will be an expert in *all* of the statutory and regulatory language. You may also need an interpretation of the most current policies, since these are frequently updated to meet changing conditions. If you need technical assistance with unfamiliar statutes, regulations, or current policies, then you can contact your supervisor, mentor, or the Technical Service Center.

After you have identified the regulatory elements, the next step is to develop the rationale. This is putting the pieces of the puzzle together to see the *big picture*.

- In doing so, you evaluate and explain the *relationship* of all of the pertinent events and actions. For example, you could create a "timeline" of the events by time, place, person, etc.
- Once you have identified the relationships of the events and actions, you will need to explain the *cause and effect* of the relationships. In other words, you need to be able to explain why the events took place in the manner that they did.
- Finally, you will explain the *consequences*, or outcomes, of the action or actions, given the relationships identified.

The final step of the regulatory analysis is using a process of deduction to draw a conclusion. When drawing your conclusion, it is once again vital that you limit yourself to the known *facts*. In legal language, the facts are stated in a "premise," which includes the reasons for the action, the pertinent facts, and the gathered evidence. Relying on certainty that is based on the logical connection of premises will result in an accurate and defensible conclusion that has been proven as true.

As you can see, the general principles are very similar to the scientific methods; the difference is that this method is more focused on whether a law, statute, or regulation has been violated rather than whether a scientific principle has been met.

In recommending actions, you will need an explanation of your conclusion. In doing so, you will state the results of your thought process—of your reasoning. You will then ***justify*** your reasoning and base this justification on the facts and credible evidence. Finally you will present your explanation in the form of a compelling argument. Being able to accurately state results, justify procedures, and effectively present arguments, both orally and in writing, are essential skills in accomplishing this goal.

Examples of how a justification can be presented include:

- Constructing a chart that organizes the findings
- Citing the standards and contextual factors used to judge the quality or interpretation of a text
- Appealing an established criteria as a way of showing the reasonableness of a given judgment

As a PHV-IIC you will mainly be documenting your thought process on NRs and in memoranda. There are also other occasions that will require you to justify your reasoning, such as in responses to an establishment's appeals to actions, when answering inspector's grievances, and many others.

Self regulation is not as much an individual step in critical thinking as it is a common thread throughout the process. When performing any of the five steps mentioned above, you should *constantly* be evaluating and correcting your interpretation as more or better information becomes available. You should consequently examine and correct any inferences that have been drawn and that are affected by the change in interpretation. You should then review and reformulate any explanations you have completed that are based on the corrected inferences. This requires skills in self examination and self correction.

As an example, you may possibly need to change your conclusion in view of the realization that you have misjudged the importance of certain information. This realization could come about after you have received additional credible and pertinent evidence that was not immediately available during your first analysis of the information.

As a PHV-IIC, you will find this to often be the case, such as when an establishment appeals a decision made by yourself or a CSI. If the establishment can provide you with new, credible, and pertinent information, you may need to revise your conclusion and possibly sustain the appeal. It is important to be open to new information and not let your emotions or beliefs be your guide.

One of the inherent problems with any assessment of information is that there might be holes in the information. Another problem is that the information may be presented in such a way that the person assessing the information is missing something—even though all of the information is there. In other words, they are not seeing the forest for the trees.

Information Sources Used in the AER Process

The critical thinking process is all about looking at information - and there are many sources of information available. The following section is a brief overview of some the more common sources of information used in the AER process.

Sources of documented information from “within” the plant include:

- Noncompliance Records (NRs)
- Memoranda of interview, discussions, meetings, agreements, and similar documents
- Other agency letters

These methods of documentation will be discussed in more detail later in the module. There are other sources of information that are located outside of the plant. These include:

- The Consumer Complaint Monitoring System (CCMS)
- The Recall System

The following is only a very brief introduction to these systems. You will receive more in-depth training in your EIAO training.

Other Administrative Activities

OFO personnel also carry out other administrative activities for which an FSIS Form 5000-9 is started, and all supporting documentation will be attached exhibits. Such administrative activities include:

1. Reviews of the sanitary conditions at custom exempt operations, and, when necessary, the preparation of written recommendations along with evidence to the Office of Program Evaluation, Enforcement, and Review (OPEER).
2. Detention of product as set out in FSIS Directive 8410.1
3. Recall Effectiveness Checks as set out in FSIS Directive 8080.1, Revision 4, Recall of Meat and Poultry Products, and FSIS Directive 5100.2, Enforcement, Investigations, and Analysis Officers (EIAO) Responsibilities Related to Recalls and Consumer Complaints,
4. Investigations of prohibited activities as set out in the FMIA, section 10, the PPIA, section 9 and 10, and the EPIA section 8, such as adulterated product deliberately distributed into commerce,
5. Investigating illness outbreaks such as illness outbreak related to recall
   NOTE: Illness outbreak investigations related to the Consumer Complaint Monitoring System are documented under the CCMS system, not the AER system.
6. Non-routine incident investigations addressed in FSIS Directive 6500.1, Emergency Management Committee, and FSIS Directive 6500.2, Incident Investigations Teams.

The Consumer Complaint Monitoring System, or CCMS, can be described as follows:

- FSIS receives, tracks, and uses consumer complaints to *help identify* unsafe meat, poultry, and egg products that are available to consumers in commerce
- It is important to remember that complaints are *alleged* by the consumer until they have been verified by the agency
- It is however not possible to verify all complaints

FSIS receives consumer complaints through a wide variety of sources:

- USDA Meat and Poultry Hotline
- Office of Field Operations (OFO) District Offices/Headquarters, FSIS

- Office of Program Enforcement Evaluation and Review (OPEER), FSIS
- Office of Public Health Science (OPHS), FSIS
- Labeling and Consumer Protection, FSIS
- State or Local Health Departments
- Other Federal Agencies

Once the complaint is received, it is entered into an electronic database that is used to record, triage, coordinate, and track all consumer complaints that are reported to the agency. Personnel in the District Office review the database daily for open and new cases and dispatch an EIAO when necessary to investigate.

Similarly, if FSIS becomes aware of a presumptive positive laboratory sample result for a foodborne public health hazard and the establishment has shipped the affected product, a recall of that product will be issued. In this instance, the District Office will once again dispatch an EIAO to investigate.

In both cases, you as the PHV-IIC at the affected establishment will be working closely with the EIAO in the investigation and, if necessary, in building the case for the AER.

Supporting Documentation in the AER Process

Proper and well thought out documentation is the key to supporting any conclusions or decisions made. Documentation is the rock foundation of the AER process. Like any foundation, if it is built of solid rock it can support a lot of weight. If, on the other hand, it is built of sand, it will not adequately support any structure.

In your role as a PHV-IIC, it will be your duty to ensure that all documentation generated by you and your inspection team is complete, accurate, well thought out, and well supported

The following section is a brief overview of some of the documentation that is used in the AER process. These documents are then attached to an AER as support.

The most common types of documentation encountered in the AER process include:

- Noncompliance Records (NRs)
- Memoranda
- Memoranda of Interview (MOIs)
- Signed Statements
- Decision Memos
- Other Agency Letters

Now let's take a closer look at some of these types of documents.

The Noncompliance Record (NR)

The Noncompliance Record, or NR, will be the format that you will use most frequently in the plant environment. This is an electronic form that is used to document regulatory noncompliance and build a history through linking non-compliances with common causes.

As was discussed in the FSRE portion of your PHV training, it is important to ensure that the *proper regulatory citation* is included on the form when documenting any noncompliance. If an improper regulation is cited, then the document will not stand up to the appeals process or in a court of law. If you are not sure about the regulatory citation, then ask your supervisor or contact the Technical Service Center for assistance.

The documentation on an NR should be *complete* and accurately depict the circumstances and relevant facts. The description should focus on the big picture—on the systems-level problem. If you concentrate on minor non-compliances then chances are you will miss larger systems problems. Again, you should focus on the forest, not the trees—the trees should help describe the forest.

Memoranda

Memoranda are important documents in establishing a history. These are documents that can be on agency letterhead or on a blank piece of paper. They can be in any number of formats, including letter style, memo style, or other. Regardless of style, the memorandum should be *signed and dated*.

The content of a memorandum can include matters that are not a regulatory noncompliance, but are pieces of information that "round out" or complete the picture. This includes information provided to the plant, documentation of group discussions, or minutes of meetings. It is important to keep a copy of any memorandum provided to the establishment in the agency files.

Memoranda of Interview (MOI)

Memoranda of Interview (MOI) are a special form of memorandum that documents a formal or informal interview with agency personnel. An interview is conducted if the pertinent facts are unclear or if there is additional relevant information that is otherwise not documented. These are important pieces of documentation in establishing a history Such memoranda are to: 1) identify all participants present at the meeting; 2) explain all facts that provide the basis for the meeting; 3) fully describe the meeting and 3) be written in a concise and clear manner.

MOIs are used to document information pertaining to a specific set of facts and summarize key points of this information as it is gathered in an interview with a person with ***direct***, not second-hand, knowledge of relevant information.

When documenting the information, it is important to accurately depict the relevant ***facts*** as they have been revealed in the interview. Do not document opinions or speculation. Like any other memorandum, the interviewer documents the information and is the one who signs and dates the document.

Signed Statement

A signed statement is very similar to an MOI, but is a more formal record of an interview that is taken by specially trained personnel. In this case, the person being interviewed is asked to sign and date the document after they have reviewed for accuracy. You will not be taking signed statements until further training is received.

Decision Memo

Decision memos are an integral part of the AER documentation process. In the discussion of critical thinking and cognitive skills, we illustrated the importance of explaining, or justifying, one's reasoning based on credible evidence.

A decision memo does just that; it explains the reasoning behind a decision or recommendation for an enforcement action.

Decision memos are vital pieces of documentation in the AER case file. They *synthesize* the available information and supporting documents into a single document. They relay to the reader the *critical thought process* used in analyzing the information and how a conclusion was reached. The decision memo relates the information not only back to regulatory requirements, but also back to the statutory authority of the agency. This is an important aspect of the AER documentation process, since the AER case file is a legal document.

As a PHV-IIC, you may be documenting decision memos pertaining to the recommendation of enforcement action related to noncompliance or inhumane handling.

30-Day Letter

A 30-Day Letter is a letter issued to a plant requesting additional information or requesting that it reassess its HACCP plan in 30-days. These letters are issued for very limited reasons. They are *never used to document regulatory noncompliance* or as a substitute for an NR or NOIE. If the determination has been made that regulatory noncompliance exists and there are concerns regarding food safety, then it is not appropriate to issue a 30-day letter.

It is appropriate to issue such a letter to the plant when there are concerns regarding the scientific validity associated with the design of an establishment's HACCP plan and *when additional information is needed* to determine if regulatory noncompliance exists. The 30-Day letter provides the establishment 30 days to:

- Gather information to support the HACCP plan and hazard analysis
- Reassess the HACCP plan to comply with regulatory requirements

Also, concerns regarding design flaws from other food safety systems, such as the plant's SOP, or *E. coli* testing program, may be included in a 30-Day letter.

Since 30-Day letters are *not enforcement actions*, they can be written by any program employee, including you as a PHV-IIC. Questions pertaining to 30-Day letters can be directed towards your supervisor or an EIAO.

Official Agency Letters

There are a number of official agency letters that are issued to establishments by the District Office. These letters officially inform an establishment, in writing, of an intended enforcement action or one in effect. These are *enforcement letters* and are not issued by PHV-IICs. They are listed here for informational purposes only.

- Notice of Intended Enforcement (NOIE)
- Notice of Deferral
- Notice of Suspension
- Notice of Suspension Held in Abeyance
- Letter of Information (LOI)
- Letter of Warning (LOW)

BUILDING A CASE

Up to now, we have focused on the building blocks of the AER process. These are:

- How to critically process information and reach a defensible and logical conclusion
- How to properly document the information and justify your conclusion

We are now going to look at how to put these building blocks together and build the case for enforcement.

The first step in building a case for enforcement is determining the "enforcement stage" that the establishment is currently in. The enforcement stages are based on the *Rules of Practice (ROP)*, which are found in *9 CFR Part 500*. The ROP were covered in the FSRE portion of your training.

The enforcement stages include:

- Pre-Enforcement Stage

- Enforcement Stage
- Deferral or Abeyance Stage
- Legal Stage

These stages require different actions in your role as PHV-IIC, which will be covered later in this module. For now, let's take a brief look at each of the stages.

Pre-Enforcement Stage

In the Pre-Enforcement Stage, the establishment is not currently under any type of active enforcement action—either NOIE, suspension, or withdrawal.

Possible regulatory actions that are taken under the ROP in this stage are:

- Regulatory Control Action (RCA)
- Withholding the Marks of Inspection

This is the stage that most establishments operate under and is the stage where the professional judgment and critical thinking abilities of the in-plant inspection team are extremely important and most frequently used. In this stage, you as the PHV-IIC will ensure proper documentation of regulatory non-compliances on NRs and appropriate linkages of recurring problems. How to do this is discussed in the FSRE portion of your training. You will also ensure proper documentation of other issues and concerns on memoranda, as was discussed earlier in this module in the "Documentation" section. This is a vital part of the AER process for two reasons. First, you are building a history of any recurring problems while taking the establishment's entire food safety system into account. Second, you are ensuring that the establishment's due process rights are not violated by providing them with the feedback they need to comply with the regulatory and statutory requirements of the agency.

Under normal circumstances the establishment will not leave this stage. If however, you determine through your critical thinking process that the establishment's food safety system is not effective and that there is a public health food safety concern, you are required to act. In doing so, you will follow the ROP:

- If there is an *immediate* concern, you will take immediate action and ensure that there is no threat to the public's health. You will then contact your supervisor for further guidance.
- If there is *no immediate* concern, you will recommend an enforcement action to your supervisor. At this point, an EIAO may or may not be dispatched to the establishment to perform a comprehensive food safety assessment. This will depend on the specifics of the case and whether the specific type of detailed information gathered through this type of methodology is necessary for the analysis or not.
- In both instances, your documentation of the information and the justification you provide regarding your conclusion is an integral part of the continuation of the process.

Enforcement Stage

The establishment is in the Enforcement Stage if it has been issued an NOIE or placed immediately under a suspension. According to the ROP, these constitute two types of suspensions:

Suspension of inspection personnel ***with*** prior notification: In this case, the establishment will receive an NOIE prior to the suspension going into effect. This gives the establishment an opportunity to respond to the agency's concerns before the suspension goes into effect and provides them due process.

Suspension of inspection personnel ***without*** prior notification: Here, the establishment is placed immediately under a suspension; the suspension is in effect, because of an immediate threat to the public's health.

At the point the establishment receives an NOIE, or when the suspension goes into effect without prior notification, is when the establishment is in the enforcement stage. As a PHV-IIC, you and your in-plant inspection team will be actively engaged in the evaluation process of the establishment's response to the suspension while the establishment is in this stage.

Deferral or Abeyance Stage

The Deferral or Abeyance Stage is technically a sub-set of the enforcement stage. An establishment is in this stage when:

- An NOIE has been issued and the plant has adequately responded to FSIS. The suspension then temporarily does not go into effect, allowing the plant to operate and demonstrate to FSIS the effectiveness of their response. You as the PHV-IIC, together with your in-plant inspection team, will verify this effectiveness through a verification plan. If your verification results lead to the conclusion that the response is not effective, the suspension then goes into effect. So the decision to place the suspension in effect is deferred while the effectiveness of the establishment's response is verified.
- An establishment has been placed under a suspension in effect and has adequately responded to FSIS' concerns. The suspension is then temporarily lifted, or held in abeyance, while the establishment demonstrates the effectiveness of their response. As above, you as the PHV-IIC and your in-plant inspection team will verify this effectiveness through a verification plan. If your verification results lead to the conclusion that the response is not effective the suspension is reinstated.

Legal Stage

The Legal Stage is a special type of enforcement stage. In this stage the agency has filed a legal complaint for withdrawal of inspection. This means that the establishment's Grant of Inspection, which allows them to operate under federal inspection, is permanently revoked. The agency will petition the court for withdrawing inspection from an establishment if there are acts of *criminal* intent or if multiple *enforcement* actions against the establishment have been necessary.

If the establishment has been placed in the legal stage, then many layers of the agency will be involved in the case, including legal council. You, as the PHV-IIC may be requested to provide information or to testify under these circumstances. This only once again illustrates the importance of properly thinking through and documenting your decisions and conclusions.

Recommending or Taking an Enforcement Action

As you have seen, the decision to place an establishment under an enforcement action is a multi-layered process and should not be taken lightly. It must be well thought out and supported. The following is a synopsis of the elements involved in making a recommendation for an enforcement action or for taking one.

First, remember that recommending or taking enforcement actions is based on a conclusion reached through a critical analysis of the pertinent and credible information. Ultimately, portions of the analysis will be performed by various members of the District inspection team, such as EIAOs, FLSs, and DMs. But, under normal circumstances, the in-plant inspection team will be the driving force that initiates the process. This recommendation will or will not be supportable based on the strength of their documented case history and the objectivity and logic of the justification. It is your responsibility as a PHV-IIC to ensure that all "in-plant" pieces of the process are well thought out, properly documented, and supportable.

The action that you recommend will depend on several factors that you must take into account during your critical thinking process:

- The enforcement stage the plant is in—as a PHV-IIC, you will most commonly be recommending an action revolving around a suspension.
- The egregiousness of the issue(s)—depending on the severity of the issue you will recommend a suspension either with or without prior notification, or under extreme situations a complaint for withdrawal of inspection may be recommended. The Rules of Practice (9 CFR 500) are the regulations used for making these decisions.
- Prior actions taken—the regulatory and enforcement history of the establishment will play an important role in your recommendation. As such, an establishment that repeatedly cannot, or will not, comply with the regulatory and statutory requirements will be considered for regulatory enforcement based on the repetitive noncompliance. FSIS documentation of the plant's failures is critical in this case.

It cannot be stressed enough that the recommended or implemented action must be adequately *supported and justified*. The documented history found in the relevant NRs, memoranda, and other agency letters, build the foundation for the critical thought process leading to the recommendation. The synopsis of the entire thought process and the justification for the recommendation is then documented in the decision memo and attached to the AER file. Once again, it is your responsibility as a PHV-IIC to ensure that all "in-plant" pieces of the AER process are well thought out, properly documented, and supportable.

Assembling an AER Case File

At the point that a recommendation is made to take an enforcement action against an establishment, an AER case file is initiated. This section is a short introduction into how such a case file is assembled. In your EIAO training, you will receive a more thorough introduction into the management of these AER case files.

The AER case file is commonly compared to a book that is comprised of multiple chapters. The entire case file is the "book" which is assembled in multiple sections that are the "chapters," called *Administrative Enforcement Reports* (AER). Each AER corresponds to an enforcement action or stage—from beginning to end. The AER is a special FSIS form that is filled out by specially trained personnel, such as EIAO.

For example, a chapter would begin with the issuance of an NOIE and would end, either:

- When the case is closed after a deferral and the establishment's response was verified as effective, or
- When the suspension goes into effect due to an inadequate response.

All supporting documentation, including the decision memo, is then attached to the AER form for future reference. Each "chapter" (AER) is assembled in the same manner and receives a special AER number that is assigned to it by the DO. While each AER is an independent piece of the file, or "story," they build on one another to complete the "story" that is told by the "book."

There are special rules for assembling and maintaining the AER case files and you will receive specialized training for this purpose in your EIAO training. Until you have received this specialized training, you will not be expected to complete an AER form and/or assemble or maintain an AER case file. You will, however, still be a vital part of the AER *process*.

See chart at the end of this module on pages 34 & 35

Verifying an Establishment's Response to an Enforcement Action

Earlier in this module, we discussed verifying the adequacy or effectiveness of an establishment's response to an enforcement action. FSIS verifies this response through the development and implementation of a "verification plan." You have already covered verification plans in the FSRE portion of your training, so this section will serve as a short review. This is an extremely important part of the AER process.

The verification plan provides a systematic means for FSIS to ensure that a plant is effectively carrying out its corrective actions regarding an NOIE or suspension. Its main purpose is to ensure that <u>all</u> aspects of the establishment's response are appropriately verified.

The verification plan is designed to:

- Verify that an establishment has *fully* implemented revisions to its SSOP and HACCP system
- Verify that an establishment has *fully* implemented all corrective actions
- Verify that the revisions and corrective actions are *effective* in assuring regulatory compliance

The verification plan also assists the plant in understanding the nature and importance of FSIS' verification activities. This is an important factor in the establishment's due process rights.

A verification plan should be developed whenever:

- A decision is made to ***defer enforcement*** (suspension) following the issuance of a NOIE

- A decision is made to hold a ***suspension in abeyance*** following the suspension of the assignment of inspectors
- In both instances, the establishment will provide FSIS with a response to agency concerns. This response must then be verified.

Under normal circumstances, the assigned EIAO has the primary responsibility for preparing the written verification plan. If an EIAO was not involved in the development of the case, then this responsibility will be with the FLS and the in-plant inspection team. In any case, development of the plan should be based on input from the FLS, the assigned EIAO, and the in-plant inspection team, since these are the individuals with the best knowledge of the establishment and the conditions under which it operates.

As the plan is being developed, the FLS should correlate with the PHV-IIC and the EIAO to assure the verification plan:

- Covers pertinent issues
- Is comprehensive
- Accurately reflects verification activities to be carried out by the inspection team

It is important that the plan be correctly developed containing all critical details. This requires objective input from all agency parties involved. The establishment is not a part of this process.

The Role of the PHV in the AER Process

Now that you are familiar with all of the components of the AER process, we will recap your role as a PHV-IIC in the process. Your primary role as a PHV-IIC is to be the *in-plant team leader* in the development of enforcement actions. Once you receive EIAO training, you will also be called upon to perform AER functions specific to that methodology. This will include more detailed assessments of the design of an establishment's food safety system, writing decision memos, and more.

Pre-Enforcement Stage

Depending on the enforcement stage that the establishment is in, you as a PHV-IIC will perform varying functions related to the AER process. In the Pre-Enforcement Stage you

will ensure that NRs are properly documented for regulatory non-compliances by the in-plant inspection team. Remember, NRs are not only a vital document for the AER case file, they also are an important vehicle in ensuring that the establishment's due process rights are not violated.

In the pre-enforcement stage, you will ensure that timely information on the conditions in the establishment is provided to your FLS, and when necessary, you will consult with your FLS for guidance on how to proceed, as well as your approach to an enforcement action or recommendation. You will also ensure constant communication with plant management to provide and obtain relevant information related to pertinent issues. As the PHV-IIC, you will ensure that these discussions are documented in memoranda and placed in the agency's files for future reference.

Enforcement Stage

In the Enforcement Stage, you will ensure important information regarding any action to be taken is communicated to plant management. You will further work with your FLS, any assigned EIAO, and your in-plant inspection team to provide accurate and pertinent information and/or content to the DO for inclusion in the NOIE or suspension letter.

In the enforcement stage, you will remain in communication with your FLS to provide him or her with timely information and updates on the current and continuing conditions in the establishment. You will also continue your role as the in-plant team leader and provide your in-plant inspection team with leadership and support, and you will ensure that the team remains on track and is focused on the task at hand. Tempers can rise during an enforcement action. You will ensure that your in-plant team remains objective and professional, as well as ensure that they are not subjected to intimidation or harassment from the establishment's employees.

Deferral or Abeyance Stage

In the Deferral or Abeyance Stage, you will provide information to your FLS as it applies to the review of the establishment's proposed corrective actions. When necessary, you will communicate with plant management to obtain additional clarifying information to facilitate the review. You will also work with your FLS and any assigned EIAO to ensure that the verification plan is complete and comprehensive. In doing so, you will discuss

the verification plan with the FLS and the in-plant inspection personnel, prior to the establishment implementing its corrective actions. As the in-plant team leader, you will provide guidance to and coach your in-plant inspection team on the appropriate execution of the verification work methods necessary for the proper implementation of the verification plan.

In the Deferral or Abeyance Stage, you will continue to conduct weekly meetings with the establishment with an emphasis on discussing issues that emerge during the deferral or abeyance period. You will conduct special work unit meetings with your in-plant inspection team to correlate on verification activities and discuss any problems, questions, or concerns. When necessary, you will request clarification from your FLS, who is the overall team leader in this effort. You will provide information to and collaborate with any EIAO assigned to the case to summarize the verification activities.

Finally, you will provide timely information to your FLS to recommend a decision on whether to close out, continue, or reinstate a suspension of inspection at the establishment.

Legal Stage

While it is a relatively rare occurrence, the District Office may recommend that the agency file a complaint for withdrawal of inspection from the establishment. As the PHV-IIC, you will also have a role in this Legal Stage of the AER process.

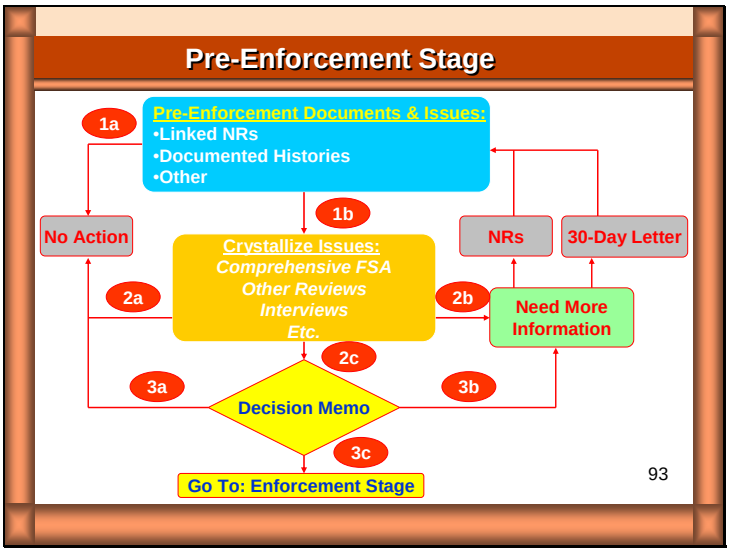
In the Legal Stage, you may be asked to:

- *Collaborate* with the FLS, assigned EIAO, and/or DDM to prepare the recommendation for withdrawal.
- Prepare or assist in the preparation of a *declaration* to be submitted to the court.
- *Testify* at a hearing regarding the conditions in the establishment.
- Provide *timely information* to the FLS, DO, and/or Office of General Council regarding current conditions in the establishment.

A Systematic Review of Enforcement Actions

Now that you have a basic understanding of the components of, and your role in, the AER process, let's look at the flow of the enforcement process from beginning to end. The following pages are flowcharts that depict the options of enforcement actions possible, as they are determined by the critical thought process.

The Pre-Enforcement Stage



The pre-enforcement stage begins with a documented history of noncompliances and issues. Based on the in-plant inspection team's assessment of the information, which is led by the PHV-IIC, there are two courses of action:

1a) The available information does not support any action at this time.

1b) The available information supports further review.

If the consensus is that a further review is warranted (1b), depending on the types of noncompliance an EIAO may or may not become involved in the process at this point. There are three options at this point, depending on the conclusion of the review:

2a) The available information does not support any action at this time.

2b) There is insufficient information to draw a proper conclusion, or the available information is inadequately documented to support an action.

2c) There is sufficient information to start a formalized process. This is the most common option at this point if an EIAO is involved; this is in order to have complete records of their review.

If the option of a formalized review (2c) is chosen, then a decision memo is documented with a formal recommendation. There are three possible recommendations:

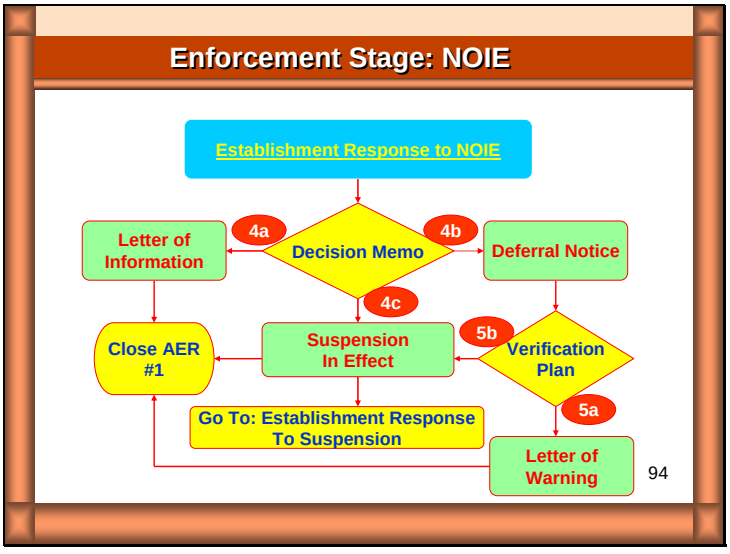
3a) No action is warranted.

3b) There is insufficient or inadequate information at this time to make a recommendation.

3c) There is sufficient evidence to recommend a suspension, either with or without prior notification.

It should be pointed out that there is *no specific, minimum, or maximum timeframe* attached to this process—the process should be timely and the ultimate timeframe will depend on the specific circumstances.

The Enforcement (NOIE) and Deferral Stage



The Enforcement Stage begins when an NOIE has been issued to the establishment. Based on the District inspection team's assessment of the response, which is led by the FLS, there are three courses of action:

4a) The establishment's response reveals that the agency's conclusion is wrong and a suspension is not warranted. The case is closed out with a Letter of Information—this should be an extremely rare occurrence if the assessment is properly performed and supported.

4b) The establishment's response is adequate and the suspension is placed in deferral. (Note: At this point in time the establishment is in the *deferral stage*, which is also depicted on this slide.)

4c) The establishment's response is inadequate and the suspension is placed in effect.

If the decision to suspend is deferred (4b), then a verification plan is developed and implemented. Based on the results of the agency's verification, there are two options:

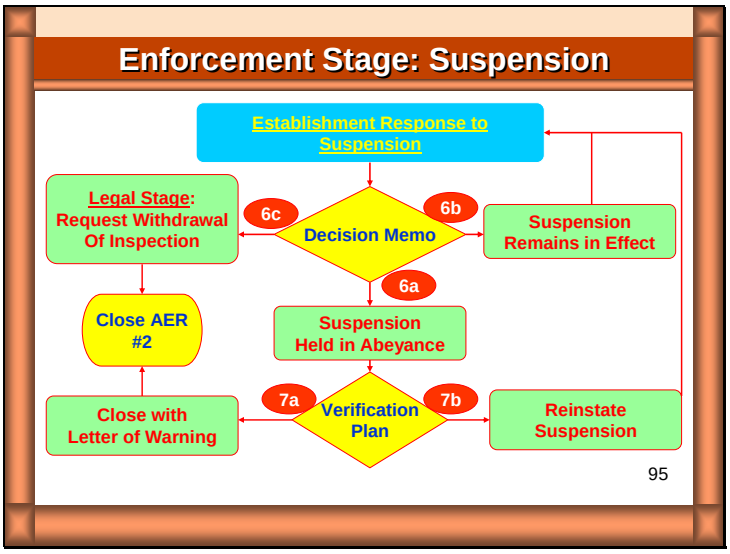
5a) The establishment has adequately and effectively demonstrated compliance and the case are closed with a Letter of Warning. This also closes out the AER and the case file.

5b) The establishment cannot adequately and effectively demonstrate compliance and the case the suspension is placed in effect.

If the suspension is placed in effect (4c or 5b), then the AER for this stage is closed and a new AER for the suspension stage is opened. The case file remains open.

It should be pointed out that, as above, there is also ***no*** *specific timeframe* attached to this process.

The Enforcement (Suspension) and Abeyance Stage



The enforcement stage for a suspension begins when a suspension goes into effect. Based on the District inspection team's assessment of the response, which is led by the FLS, there are three courses of action:

6a) The establishment's response is adequate and the suspension is held in abeyance. (Note: At this point in time the establishment is in the abeyance stage, which is also depicted on this slide.)

6b) The establishment's response is inadequate and the suspension remains in effect.

6c) Circumstances warrant that the agency file a complaint for withdrawal of inspection. This closes out this AER and opens a new AER for the legal stage. The case file remains open.

If the suspension is held in abeyance (6a), then a verification plan is developed and implemented. Based on the results of the agency's verification, there are two options:

7a) The establishment has adequately and effectively demonstrated compliance and the case are closed with a Letter of Warning. This also closes out the AER and the case file.

7b) The establishment cannot adequately and effectively demonstrate compliance and the suspension is reinstated. As above, there is *no specific timeframe* attached to this process.

SUMMARY

Using the AER process is an important part of your job as a PHV. The process entails using your critical thinking skills to assess information and take or recommend actions based on those assessments. The assessment will only be as good as the quality and completeness of the information that is analyzed. Likewise the accuracy of the conclusion will be heavily dependent on the objectivity of your assessment.

As an in-plant PHV-IIC, another of your main functions in the AER process will be to ensure accurate, relevant, and complete documentation of all information related to a problem or concern. Your in-plant inspection team plays a vital role in identifying problems and collecting information. If this is not properly documented, then the information will not be available as support for a potential future case. Proper documentation also means that the appropriate regulation and/or statute is cited.

Remember, your team's documentation and assessments are the foundations of the AER case files. It is your responsibility as the in-plant team leader to ensure that that foundation is rock solid.

A numbering system has been devised to facilitate using the AER for multiple types of cases.

To number the AER:

- The first number is the DO number.
- The second number is the fiscal year.
- The lettering identifies the report type.
- The last numbers enable FSIS to determine how many reports of this nature have been completed in a given District.

For *example*, AER 65-05-N003, the:

- 65 is for the Albany DO.
- 05 is for the fiscal year 2005.
- N indicates an NOIE.
- 003 means the NOIE is the 3rd NOIE issued in Albany in the fiscal year.

The table on the following page contains all of the types of reports that may be completed under the AER system and the abbreviations for each type.

AER Report Type	**Report Number Example**
NOIE (**N**)	65-05-**N**003
Suspension (**S**)	65-05-**S**001
Reinstatement (**R**)	65-05-**R**001
Appeal to DM (**A**)	65-05-**A**010
Withholding of Labels (**WL**)	65-05-**WL**001
Custom (**C**)(Request to withdraw the custom exemption)	65-05-**C**001
Recall Effectiveness Check (**REC**) NOTE: When completed for recall effectiveness checks, insert in block 11 of the FSIS 5400-9, the FSIS Recall Number, (e.g., FSIS-REC-XXX-200X).	65-05-**REC**001
Detention (**D**)	65-05-**D**002
Prohibited Act (**PA**)	65-05-**PA**001
Outbreak of Illnesses Investigation (**OI**)	65-05-**OI**001
Non-routine incident report (**NRI**)	65-05-**NRI**001
Withdrawal of Inspection (**W**) NOTE: This would be specified under OTHER in block 11.	65-05-**W**001
Complaint for Suspension (**CS**) NOTE: This would be specified under OTHER in block 11.	65-05-**CS**001
Other (**O**)	65-05-**O**001

WORKSHOPS

Workshop I

1. The role of the PHV in the AER process is to:
    a. Act as the in-plant team leader
    b. Ensure accurate supporting documentation
    c. Ensure proper lines of communication
    d. Perform verification activities
    e. All of the above

2. Which of the following are supporting components of the AER:
    a. NRs
    b. Memoranda
    c. MOIs
    d. NOIEs
    e. All of the above

3. A Memorandum of Interview is signed by the person performing the interview.

    TRUE FALSE

4. Which of the following are sources of information pertinent to the AER process?
    a. Documented plant history (NRs, memoranda, etc.)
    b. Consumer Complaint Monitoring System (CCMS)
    c. Recall System
    d. All of the above

5. A recommendation for an enforcement action should be based on subjective opinions.

    TRUE FALSE

6. A 30-Day Letter can be issued to an establishment by a PHV for a regulatory noncompliance.

    TRUE FALSE

7. When completing an NR, it is important that it be (choose the best answer):
    a. Short and concise
    b. Long and very descriptive
    c. Accurate and complete
    d. Written in technical terms

8. All noncompliance reports should be accurate, well thought out, and properly supported by an appropriate regulatory citation.

    TRUE FALSE

Workshop II (one hour)

Assignment:

You are the PHV assigned to a large establishment that slaughters swine and processes miscellaneous pork cuts and cooked sausages. Over the last three months, you and inspection personnel have issued NRs for multiple and recurring noncompliances identified for failure of the SSOP to prevent direct product contamination and failure to maintain sanitary conditions as required in the SPS and linked them appropriately. You issue two more NRs this week for heavily beaded condensation found in multiple non-production areas. You review the following NRs:

1 The original NR was written on rodent activity.

#2 A NR issued for condensation leading to direct product contamination.

#3 A NR issued for condensation leading to direct product contamination.

#4 A NR issued for holes in walls around pipes behind the smokehouse.

#5 A NR issued for a door with gaps leading to the outside and a hole in the processing room wall leading to the outside.

#6 A NR issued for rodent droppings in the boiler room.

#7 A NR issued for insanitary conditions due to rodents and contamination of product by insanitary conditions.

#8 A NR issued for condensation in a production area without direct product contamination.

#9 A NR issued for condensation in a non-production area without direct product contamination.

#10 A NR issued for condensation in a non-production area without direct product contamination.

#11 A NR issued for condensation in a non-production area without direct product contamination

A) Is this a SPS or SSOP issue? What is the root cause(s) of the noncompliances?

The establishment responses indicate that corrective actions and preventive measures have been identified and implemented for each noncompliance. FSIS verification and documentation shows that these actions were either not implemented or not effective.

You have kept your Frontline Supervisor informed of the recurring nature of the situation. You have discussed this with plant management during the weekly meetings, and documented these discussions in a memorandum of interview.

B) What is your recommendation, if any?

You first contact your Frontline Supervisor and make him aware of your recommendation. You then contact the District Office and provide data to support your recommendation.

C) From the NRs listed above which ones support your recommendation?

D) What would be your role during this deferral stage?

The District Manager will make a decision on the adequacy of the preventive action as soon as sufficient information becomes available. The DM will use the information to determine the adequacy of the establishment's proposed corrective action, and will notify the establishment in writing of the final decision.

Workshop III (45 Minutes)

Assignment:

- Pair up with your neighbor
- Interview you partner.
- You are interested in the specifics of his/her veterinary education and career
- Write a short Memorandum of Interview (MOI) documenting the facts you have learned

Be prepared to present your MOI to the class.