

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

FSIS DIRECTIVE

5100.1
Rev. 4

5/29/15

ENFORCEMENT, INVESTIGATIONS AND ANALYSIS OFFICER (EIAO) FOOD SAFETY ASSESSMENT (FSA) METHODOLOGY

Implementation of new FSA procedures in PHIS will be 6-10-15. For FSAs scheduled prior to this date, the EIAO is to record his or her FSA reports using Word versions of the modified tools. Updated tools will be available on the EIAO SharePoint site on 6-1-15.

CHAPTER I – GENERAL

I. PURPOSE

The purpose of this directive is to provide instructions to EIAOs on how to conduct FSAs using a new work methodology, so an EIAO can complete the in-plant portion of most FSAs in 5 to 7 production days. This directive also provides instructions on how to document FSAs using the FSA tools that are a series of questionnaires that an EIAO is to use to gather information. The new work methodology is designed to focus the FSAs on public health risk and to increase consistency in how EIAOs conduct FSAs. For the purposes of this directive, the term “EIAO” also refers to EIAO-trained Public Health Veterinarians (PHVs) when they are conducting EIAO activities. The term “District Office (DO)” includes the District Manager (DM); the Deputy District Manager (DDM); the Supervisory Enforcement, Investigations and Analysis Officer (SEIAO); and the District Case Specialist (DCS).

II. CANCELLATION

FSIS Directive 5100.1, Revision 3, Enforcement, Investigation and Analysis (EIAO) Comprehensive Food Safety Assessment Methodology, 8/23/11

III. SIGNIFICANT CHANGES

1. Establishment of a timeline for the completion of most FSAs from 2 to 4 weeks to 5 to 7 production days;
2. FSAs are to be performed after the EIAO derives results from a Public Health Risk Evaluation (PHRE);
3. The EIAO is to focus on certain processes during the FSA based on the PHRE;
4. Any Routine *Listeria monocytogenes* (RLm) sampling is to be conducted before the start of an FSA; and
5. The EIAO is to focus on assessing and analyzing the establishment’s food safety system as a whole and is not to only verify whether individual regulatory requirements are in compliance.

IV. BACKGROUND

- A. The EIAO is to perform a risk-based, targeted review of establishment food safety systems through the FSA.
- B. FSIS has revised the FSA methodology to more effectively utilize resources, so that the in-plant portion of most FSAs can be completed within a 5 to 7 production day timeframe.
- C. As a result of these changes, this new methodology will result in more FSAs being routinely performed at establishments that represent the greatest risk.

CHAPTER II – FSA

I. FSA METHODOLOGY OVERVIEW

- A. FSAs are performed when the DO determines that one is appropriate based on its analysis of the PHRE, described in [FSIS Directive 5100.4, Enforcement Investigations and Analysis Officer \(EIAO\) Public Health Risk Evaluation \(PHRE\) Methodology](#).
- B. The purpose of an FSA is to assess and analyze an establishment's food safety system to verify that the establishment is able to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements.
- C. The EIAO is to use FSA tools (General Tool, Meat Tool, Poultry Tool, Ready-to-Eat (RTE) and Not Ready-to-Eat (NRTE) Tool, and Thermal Processing Tool) within the Public Health Information System (PHIS) (PHIS User Guides are available on the [PHIS Intranet site](#)) to record findings and to determine whether:
 - 1. The HACCP system is designed to prevent, reduce, or eliminate the hazards identified in the hazard analysis;
 - 2. The establishment's decisions in its hazard analysis are appropriately supported, including by the establishment's validation documents; and
 - 3. The establishment's sampling and testing programs are designed appropriately and performed under validated conditions, and that the establishment reacts appropriately to sampling results.
- D. The purpose of the FSA tools (in PHIS) is to provide the EIAO with a structured framework for conducting the FSA. The EIAO is to analyze the answers to the questions in the tools to reach a logical and supportable recommendation that no action is necessary, that the in-plant team is to issue noncompliance records (NRs), that the DO is to issue a Notice of Intended Enforcement (NOIE) with or without NRs, or that the DO is to issue a Notice of Suspension (NOS). The EIAO is to document his or her findings by responding to the questions in the new FSA tools.
- E. In responding to questions in the tools, the EIAO is to focus on documenting vulnerabilities and noncompliance, not making positive editorial findings. In particular, he or she is to summarize the findings that bear most directly on the recommendation that he or she is making at the end of each individual tool with respect to what action, if any, is necessary with respect to the establishment's HACCP system. The EIAO is to use the decision-making analysis section of the general tool to provide an analysis of the background, applicable sample results, and the observations made throughout the FSA to support the recommendation. The EIAO is to provide a recommendation that is supported by FSIS statutory and regulatory requirements (i.e., the Acts and 9 CFR). The EIAO is to summarize the analysis in an Executive Summary.

F. The EIAO Process Overview and FSA workflow diagrams shown below in Figures 1 and 2 provide a visual depiction of the FSA process, including the performance of FSAs that are part of Incident Investigation Team Reviews (IITs), as described in [FSIS Directive 5500.3, Incident Investigation Team Assessment](#). The EIAO is to follow the work method flow diagrams shown below as he or she navigates this directive.

Figure 1. EIAO Process Overview

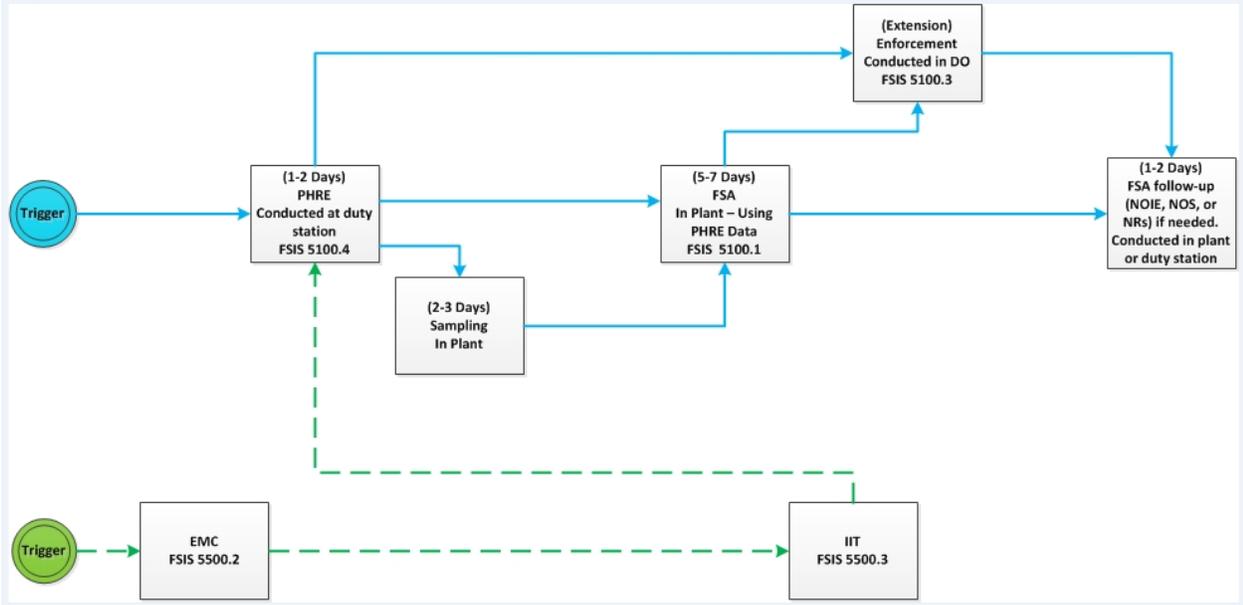
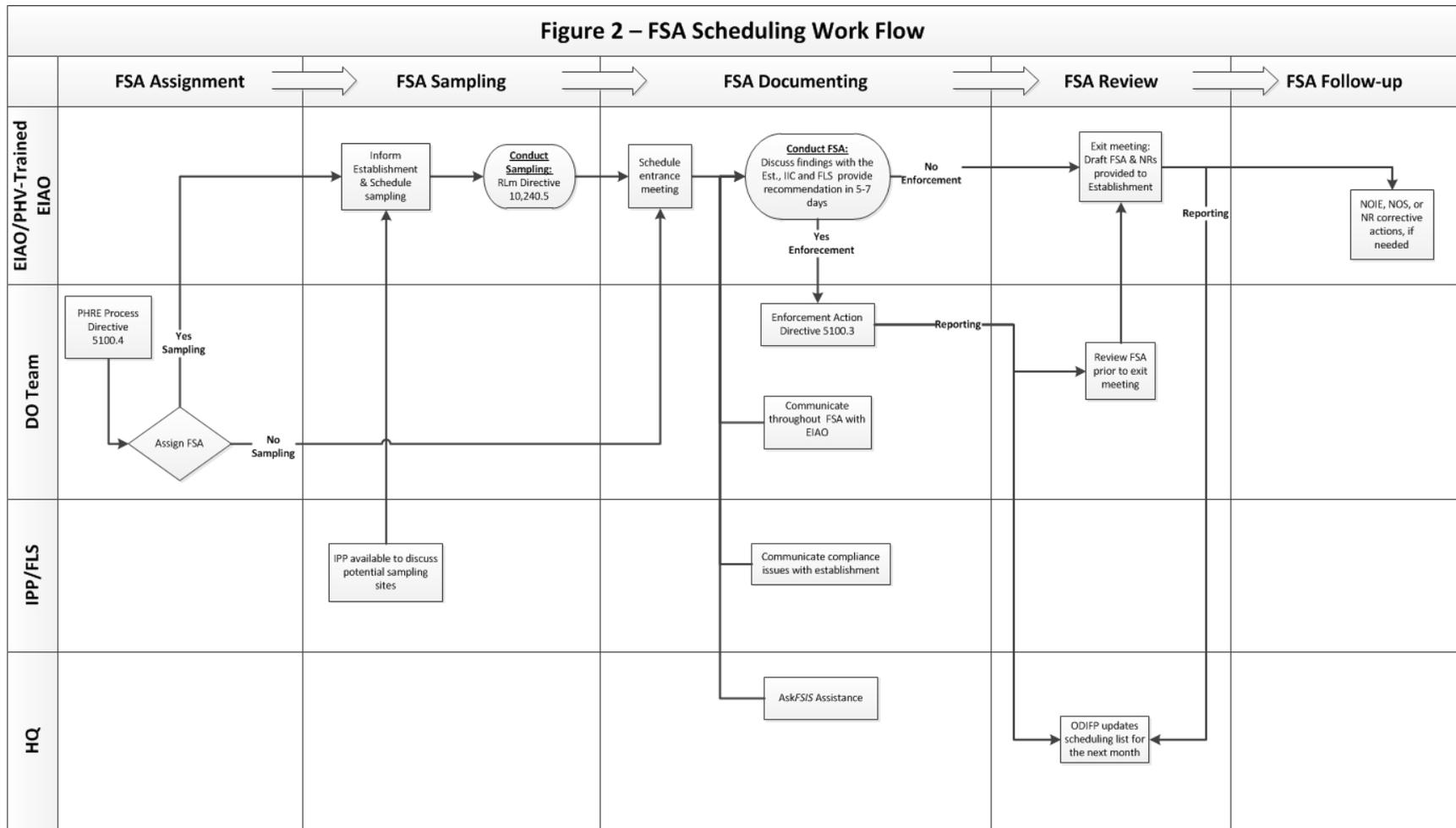


Figure 2 – FSA Scheduling Work Flow



II. PREPARATION IN ADVANCE OF THE FSA

A. When the DO decides that an FSA is necessary based on the PHRE, the EIAO is to define the scope of the FSA and determine which tools will be completed. The EIAO is to identify specific HACCP categories at the establishment based on information gathered in the PHRE. The EIAO is to define the scope of the FSA utilizing the Assessment Plan (as described in [FSIS Directive 5100.4](#)) based on FSIS statutory and regulatory requirements (i.e., the Acts, and 9 CFR).

B. In addition to the selection of the tools, the EIAO is to include in the Assessment Plan the types of observations he or she plans to make and the types of documentation he or she plans to review. Doing so will maximize the amount of time spent in plant and effectively use the establishment's time.

C. The following tools are available for selection:

If an establishment produces....	Products considered to fall under the following HACCP Processing Categories...	Then the EIAO Is to Select the Following Tool in Addition to the General Tool...
Raw Poultry Products	Slaughter Raw – Intact (Raw Not Ground) Raw – Non Intact (Raw Ground)	Poultry Tool
Raw Meat Products	Slaughter Raw – Intact (Raw Not Ground) Raw – Non Intact (Raw Ground)	Meat Tool
NRTE Meat or Poultry Products	Heat treated, shelf stable; Not heat treated, shelf stable; Secondary inhibitors, not shelf stable; Heat treated, not fully cooked, not shelf stable	RTE/NRTE Products Tools
RTE Meat or Poultry Products	Heat treated, shelf stable; Not heat treated, shelf stable; Fully Cooked, not shelf stable Secondary inhibitors, not shelf stable;	RTE/NRTE Products Tools
Thermally Processed	Thermally Processed Commercially	Thermally Processed,

If an establishment produces....	Products considered to fall under the following HACCP Processing Categories...	Then the EIAO Is to Select the Following Tool in Addition to the General Tool...
Meat or Poultry Products	Sterile	Commercially Sterile Tool

D. The EIAO is to complete the general tool for every FSA. Chapter V, Section VIII, D and E describe the information the EIAO is to document in the General Tool. The EIAO is to determine the other tool or tools to choose based on areas of concern. For the majority of the FSAs, the EIAO is only to complete the General Tool and one other tool (e. g., Meat Tool if Shiga toxin-producing *Escherichia coli* (STEC) positives, or RTE/NRTE Processed Products Tool for *Listeria monocytogenes* (Lm) positives or RLM sampling). The following are situations where the EIAO could complete more than 2 tools:

1. In new establishments coming under a permanent grant of inspection, all tools covering the HACCP categories for products the establishment produces are to be selected. The EIAO is to focus on initial validation. Chapter VI, Section VII provides instructions for verifying establishment’s scientific support and in-plant validation data;
2. Criteria in [FSIS Directive 5100.4](#) span multiple HACCP categories (e.g., STEC positive in raw non-intact and Lm positive in RTE product); and
3. During the PHRE or FSA the EIAO identifies concerns involving processes in other tools.

E. As part of scoping the FSA, the EIAO is to determine whether pathogen sampling RLM, Intensified Verification Sampling (IVT), IIT sampling, or other sampling is to be performed.

1. If an FSA will include RLM sampling according to [FSIS Directive 10,240.5](#), *Verification Activities for the Listeria monocytogenes Regulation and the Ready-To-Eat (RTE) Sampling Program*, the EIAO is to prioritize sampling before the start of the FSA. RLM sampling can span up to 3 days. The time for sampling is not included in the 5 to 7 in-plant production day FSA. The EIAO is to take into account the sampling results when determining the FSA outcome. In some limited circumstances (e.g., there are unanticipated sampling delays or presumptive positives), results may not be available within the 5 to 7 in-plant production day FSA time period.
2. The EIAO is to arrive at the establishment the day (day 1) before sampling to perform the walk-through, meet with the establishment management, and stage his or her supplies for sampling. As stated in [FSIS Directive 10,240.5](#), the EIAO is to collect some samples pre-operationally (pre-op) but collect most samples during operations. As is also stated in [FSIS Directive 10,240.5](#), sampling may be performed over two days (days 2 and 3) if the establishment takes two days to produce the sampled lot (i.e., peels the product on one day and slices it the next day).
3. In identifying sampling sites, the EIAO is to refer to the table of food contact surface sites that have previously tested positive during RLM or IVT sampling (Attachment 1). The EIAO or PHV is to identify additional sampling sites when meeting with inspection program personnel (IPP) and during the establishment tour.

4. The EIAO is to keep in mind that the sampling will occur before the start of the FSA. However, if he or she observes insanitary conditions or product adulteration at the establishment during the sampling, the EIAO is to immediately inform the IPP.

F. When an EIAO is preparing to conduct an FSA, he or she is to:

1. Provide the establishment 1-2 weeks advance notice of the visit; and
2. Provide the FLS and IPP 1-2 weeks advance notification of the establishment visit.

NOTE: An exception to the 1 – 2 week advance notice would be for a for-cause FSA (see Table 1 in [FSIS Directive 5100.4](#) for a list of for-cause FSAs).

G. Provide the establishment with at least 1 week notice that RLM sampling will occur, and that an FSA will be performed the week after the RLM sampling.

H. The DO is to manage the FSA timeline and, when necessary, utilize more than one EIAO or cross utilize EIAOs from different districts.

I. Before the EIAO starts the FSA, he or she is to:

1. Communicate with establishment management the types of documentation that need to be made available for review (e.g., last 60 production day records for the EIAO to randomly select 13, HACCP plan, sampling program, sampling results). Having the documentation available at the start of the FSA will help the EIAO to accomplish the in-plant portion of the FSA within the 5 to 7 day timeframe;
2. Review the Tool questions he or she is to complete and, using the findings from the PHRE, identify the areas of focus (all Tool question will be answered during the FSA); and
3. Review the laboratory sampling results obtained from the PHRE PHIS report to identify the sampling programs being generated by PHIS at the establishment.

CHAPTER III - ESTABLISHMENT ARRIVAL, ENTRANCE MEETING, and ON-GOING COMMUNICATION

I. ACTIVITIES AN EIAO PERFORMS UPON ARRIVAL AT THE ESTABLISHMENT AND DURING THE ENTRANCE MEETING

A. Prior to meeting with establishment management, the EIAO is to hold a pre-entrance meeting with the IPP at the establishment to discuss the FSA process and answer any questions.

B. The EIAO is to conduct an entrance meeting that is to be attended by the IPP, the FLS if possible, and establishment management. During the entrance meeting, the EIAO is to explain the reason for the FSA and answer questions about the overall process. The topics that the EIAO is to discuss during the entrance meeting include but are not limited to:

1. What an FSA is, how the scope was determined using the PHRE, and how it differs from the day-to-day verification activities that are performed by IPP;

2. The EIAO's intended typical work schedule during the assessment;
3. That the EIAO may make observations during all shifts and during pre-operational activities;
4. How the EIAO will access the production floor. The EIAO is to inquire whether the establishment has in place any special procedures;
5. Where the EIAO will conduct her or his work. The EIAO is to ask where the establishment stores its records and ask that he or she be given access to examine and copy or scan any records that may be needed to support noncompliance determinations made during the course of the review;
6. That the EIAO will communicate with the in-plant inspection team and establishment management about findings as the assessment progresses;
7. Whom the EIAO is to contact with questions. The plant designates various people for different processes and should identify either a telephone extension, an e-mail address, or some other way to communicate with management personnel to get assistance;
8. When to confer with establishment management in order to meet all intended parties' needs;
9. That, depending on any noncompliance, the impact on food safety will determine whether NRs are given to the establishment immediately or at the exit meeting;
10. The possible FSA outcomes;
11. That, at the conclusion of the FSA, an exit conference will be held with establishment management;
12. That once the in-plant portion of the FSA is complete, the establishment will be provided a final copy of the FSA report once the FSA is complete; and
13. The EIAO is to provide contact information to establishment and IPP so that they can contact him or her, if necessary.

C. The EIAO is to use the General Tool to document the entrance conference. The EIAO is to include the date and participants in the documentation of the conference. The EIAO is not to document discussion of the meeting.

II. COMMUNICATING WITH INTERESTED PARTIES DURING AN FSA

A. The EIAO is to communicate with the establishment throughout the course of the assessment and to inform establishment management about any findings of regulatory noncompliance as soon after finding them as possible. The EIAO is to describe to establishment management, in clear terms, the noncompliance and the vulnerabilities that he or she identifies as the assessment progresses. During the course of the assessment, the EIAO is not to predict possible outcomes of the FSA.

B. An establishment's attempt to bring itself into compliance upon being notified of a noncompliance finding during the FSA does not negate the noncompliance finding. The EIAO is to document descriptions of noncompliance in the FSA. IPP are to document noncompliance in NRs. If the EIAO recommends an enforcement action, the EIAO is to document relevant noncompliances in the NOIE or suspension letter.

C. The EIAO is to discuss his or her findings and recommendations with the DO to ensure that all scientific, technical, and policy issues in the EIAO's report have been resolved.

D. The EIAO is to communicate with the IPP and frontline supervisor (FLS) throughout the course of the assessment and to describe any noncompliances or vulnerabilities that he or she has identified.

1. The EIAO, the IPP, and the FLS are to work collaboratively to ensure that all noncompliances are communicated to establishment management and documented for issuance either during the FSA or at the exit meeting. The EIAO is to notify the FLS and IPP immediately when a noncompliance that has an immediate impact on food safety is observed. Noncompliance such as design, support, or recordkeeping issues should be presented at the exit meeting. All noncompliance identified by the EIAO, while performing the FSA are to be documented in the relevant tools, irrespective of whether the NRs were provided to the establishment at the exit meeting or earlier.
2. During the assessment process, the EIAO is to provide frequent updates to the IPP and FLS to inform them of the EIAO's findings and of any recommendations that the EIAO is planning to make.
3. The DO may request additional information from the EIAO or may provide additional resources as a result of this communication process.

III. IMPORTANCE OF PROPER COMMUNICATION

A. The EIAO is to carry out his or her duties in a fair, firm, professional, and courteous manner; treat in-plant and establishment personnel with respect; and keep them informed as to his or her actions by maintaining open lines of communication.

B. The EIAO is to request information, not demand it, and to be able to explain to establishment officials FSIS's statutory authority under the Acts to examine facilities and to copy records. In the event that the EIAO encounters uncooperativeness or unwillingness of establishment officials to provide information, the EIAO is to communicate with the SEIAO or with the DO to develop a strategy for gaining access to necessary information. The DM is to contact the Executive Associate for Regulatory Operations (EARO) to coordinate the involvement of the Office of Investigation, Enforcement, and Audit (OIEA) and the issuance of an administrative subpoena to obtain such records, if necessary, because of continued establishment uncooperativeness.

CHAPTER IV – OVERVIEW OF PERFORMING THE FSA

I. TIME TO COMPLETE FSAs

A. As stated in [FSIS Directive 5100.4](#), the EIAO is to complete the in-plant portion of the FSA within 5 - 7 production days. “Production days” are the days the establishment is producing the product relevant to the FSA. The FSA may be extended if additional time is necessary to develop the recommendation for an enforcement action (NOIE or suspension), or if 3 or more tools are selected for completion during the FSA (e.g., at a new establishment coming under a permanent grant of inspection).

B. The EIAO is to be present at the establishment making observations throughout the FSA.

C. Once the in-plant portion of an FSA begins, the EIAO is to continue the FSA, except in extenuating circumstances as directed by the DO.

II. GENERAL METHODOLOGY TO USE WHEN CONDUCTING THE FSA

A. The EIAO is to evaluate the HACCP system as a whole. The HACCP system includes the hazard analysis, any supporting documentation including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records. Therefore, the EIAO is to consider all supporting documentation that affects decisions in the hazard analysis when developing a recommendation.

B. The EIAO is to focus on assessing and analyzing the establishment’s food safety system as a whole and is not to only verify whether individual regulatory requirements are in compliance. The EIAO is to focus on the vulnerabilities or noncompliances that affect the food safety system and the establishment’s ability to produce safe and wholesome meat or poultry products in accordance with statutory and regulatory requirements.

C. In general, the EIAO is to conduct the assessment by:

1. Direct observation of establishment implementation as described in Chapter V of this directive. At a minimum, the EIAO is to observe the establishment carrying out its HACCP verification procedures, Sanitation standard operating procedures (Sanitation SOPs), and sampling; and
2. Reviewing a random selection of 13 days of records and documentation specific to the HACCP plan targeted (see Chapter V).

D. The EIAO is to use this directive along with the directives and [Compliance Guidelines](#) referenced in Chapter V and any other relevant FSIS documents to evaluate the establishment’s HACCP system. The EIAO is to be aware that guidance represents best practice recommendations by FSIS and does not represent requirements that must be met. Establishments may choose to adopt different procedures than those outlined in a guideline, but they would need to support why those procedures are effective.

CHAPTER V - SPECIFIC ACTIVITIES AN EIAO IS TO PERFORM DURING THE FSA

I. INITIAL STEPS

A. The EIAO is to take a tour of the establishment on the first day of the FSA to understand the establishment's process and flow and to strategize for future observations. See Section V. of this chapter regarding the types of observations the EIAO is to make during the course of the FSA. As stated above, in an establishment where RLM sampling is performed, the EIAO is to perform the establishment tour before RLM samples are collected.

B. To best use his or her time during the establishment tour and the FSA, the EIAO is to:

1. Prepare for the establishment tour by reviewing the flow chart and HACCP plan immediately on the first day of the FSA. After review of the flow chart and HACCP plan, the EIAO can formulate a plan to observe critical control points (CCPs), pathogen intervention applications, and possibly sampling;
2. Ask questions of the establishment during the tour in order to ensure he or she has a basic understanding of the establishment's process and flow; and
3. Identify the parts of the establishment where raw and RTE products are produced if performing a FSA at a RTE establishment, as well as how raw and RTE areas are separated (e.g., by time, space, or separation as well as through other means such as different colored uniforms).

C. The EIAO is to start his or her review of the HACCP system, using his or her scientific knowledge, knowledge of Agency issuances, and professional expertise, by verifying the hazard analysis. The EIAO is to assess whether the establishment has addressed hazards commonly associated with a process (9 CFR 417.5(a)(2)), and whether it can adequately support the decisions it made regarding those hazards (9 CFR 417.5(a)(1)). If there are technical questions about the supporting documentation, the EIAO is to submit an askFSIS question to the Risk, Innovations and Management Staff (RIMS), as soon as possible to allow time for RIMS to research the response.

D. For each hazard that the establishment has determined is reasonably likely to occur, the EIAO is to verify that the HACCP plan includes one or more CCPs to control it, and that the establishment has adequate documentation to support the design of the CCPs, critical limits, and monitoring and verification procedures as required by 9 CFR 417.5(a)(2).

E. The EIAO is to gather information carefully on prerequisite programs used to support decisions in the establishment's hazard analysis (e.g., to support that potential hazards are not reasonably likely to occur because they are prevented by a prerequisite program) and is to assess whether the prerequisite programs support decisions made in the hazard analysis, and to determine whether there is compliance with 9 CFR 417.5(a)(1) and 9 CFR 417.2(a).

NOTE: Establishments may have unique names for various prerequisite programs without incorporating "prerequisite" in the title. Temperature control programs, allergen control

programs, *Listeria* sanitation control programs, and purchase specification programs are some examples.

II. PREREQUISITE PROGRAMS

A. The EIAO is to focus on prerequisite programs designed to support a decision in the hazard analysis because these programs are considered to be part of the HACCP system. Examples of prerequisite programs that may be used to support decisions in the hazard analysis include the Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, and programs related to purchase specifications and antimicrobial interventions. Prerequisite programs provide a foundation for the HACCP plan to operate effectively. In order for the establishment to support its decision that a hazard is not reasonably likely to occur on an ongoing basis it needs to ensure the prerequisite programs are designed and implemented effectively.

B. To verify whether prerequisite programs designed to support a decision in the hazard analysis are designed and implemented effectively, the EIAO is to review the features of the prerequisite program and is to evaluate whether the program meets the following characteristics:

1. The program is written and describes procedures (including the critical operational parameters) that the establishment will implement to show that the hazard is not reasonably likely to occur;
2. The program is designed to prevent the hazard from being likely to occur, and the establishment maintains supporting documentation that the program has been validated (i.e., scientific or technical support and in-plant validation data). See Section VII. of this chapter for a discussion of how to review establishment validation;
3. The establishment maintains records that demonstrate that the program is being implemented as written (i.e., monitoring of the critical operational parameters);
4. The establishment maintains records to demonstrate the program effectively prevents the hazard (i.e., on-going verification of the decision that the hazard is not reasonably likely to occur);
5. The program describes actions that the establishment will take when it fails to implement the program, or when it finds that the program has failed to prevent the hazard (i.e., corrective actions in response to an unforeseen hazard per 9 CFR 417.3(b)); and
6. The EIAO may determine that a prerequisite program is effective at preventing the hazard when the program is not written, provided that the program meets the other characteristics described above. When the other characteristics are not met (e.g., monitoring of the critical operational parameters is not performed), the EIAO may determine that the prerequisite program is ineffective resulting in a hazard being reasonably likely to occur because the hazard is not accounted for in the hazard analysis. Since the prerequisite program is ineffective and not preventing the hazard, there is noncompliance with 9 CFR 417.5(a)(1) and 417.2(a). The establishment would need to reassess its hazard analysis, 9 CFR 417.4, to determine whether any modifications to the hazard analysis are necessary and make those changes to address

the hazard. In addition, the HACCP system may be inadequate, 9 CFR 417.6, and result in the EIAO recommending an NOIE be issued by the DO.

III. SANITATION SOPs

The Sanitation SOP is required by regulation (9 CFR 416.12). The EIAO is to analyze and document how problems in complying with Sanitation SOP requirements affect the establishment's ability to support decisions in its hazard analysis or to implement its HACCP plan effectively. The EIAO is to document his or her findings of Sanitation SOP compliance in the General Tool.

IV. REVIEW SAMPLING PROGRAM DESIGN AND RESULT RECORDS

A. If sampling and testing are part of the establishment's HACCP system (e.g., as ongoing verification for a CCP or prerequisite program), the EIAO is to evaluate the design of the establishment's written sampling procedures and the testing methods used. If the establishment conducts sampling during the course of the FSA, the EIAO is to observe the establishment collecting samples according to its supporting documentation and document any noncompliance within the relevant tool (e.g. Meat Tool).

B. In addition to reviewing the design of the establishment's written procedures and the methods used, the EIAO is to:

1. Review results of the program and analyze the results to identify trends and determine whether the process is in control. The EIAO is to review establishment sampling results from the previous 60 days in establishments when using the Poultry and Meat Tool, and from the previous 6 months when using the RTE/NRTE Processed Products Tool;
2. Review corrective actions taken in response to positive sample results (including re-assessment when required) and evaluate whether the corrective actions were effective and meaningful; and
3. If the EIAO is conducting an FSA at a beef slaughter/fabrication establishment that has a written High Event Period (HEP) program, the EIAO is to review the program and evaluate the criteria the establishment uses to define an HEP, and how it supports the criteria it developed, in addition to the above.

C. The EIAO is to reference relevant FSIS Directives that address verification of establishment sampling and testing including:

1. [FSIS Directive 10,010.3](#), *Traceback Methodology for Escherichia coli (E. coli) O157:H7 in Raw Ground Beef Products and Bench Trim*;
2. [FSIS Directive 10,240.4](#), *Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program*; and
3. [FSIS Directive 5000.2](#), *Review of Establishment Data by Inspection Personnel*.

D. The EIAO is to also reference relevant compliance guidelines that address recommendations for establishment sampling and testing including:

1. [Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory](#);
2. [FSIS Compliance Guideline: Controlling Listeria monocytogenes in post-lethality exposed Ready-to-eat Meat and Poultry Products](#);
3. [Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-producing Escherichia coli \(STEC\) Organisms or Virulence Markers](#);
4. [FSIS Compliance Guideline for Controlling Salmonella and Campylobacter in Poultry](#);
and
5. [FSIS Compliance Guideline for Controlling Salmonella in Market Hogs](#).

E. The EIAO is also to review the [Foodborne Pathogen Test Kits Validated by Independent Organizations](#) database to determine whether the method used by the establishment is fit for purpose and performed under validated conditions.

F. If, after reviewing these documents, the EIAO still has a question regarding the sampling program, he or she is to submit a question through [askFSIS](#).

V. DIRECT OBSERVATIONS OF ESTABLISHMENT ACTIVITIES

A. The EIAO is to make observations of the establishment's activities across all shifts while paying particular attention to areas of concern identified during the PHRE. Observations provide valuable information to help the EIAO determine whether the establishment is able to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements. The EIAO is to make the following direct observations and document in the relevant tools:

1. The EIAO's primary role is to verify whether the design and implementation of the establishment's Sanitation SOP is adequate. The purpose of observing implementation is to verify that the establishment conducts the procedures in the Sanitation SOP as written, and that the Sanitation SOP is designed effectively to prevent contamination of food contact surfaces or adulteration of products prior to operations. The EIAO is to spend a limited amount of time observing pre-operational sanitation activities, as inspectors routinely verify that the establishment meets all Sanitation SOP regulatory requirements (monitoring, recordkeeping, maintenance, corrective action). The EIAO is to focus his or her observations to evaluate whether the establishment's pre-operational procedures adequately prevent cross-contamination and the development of insanitary conditions.
2. The EIAO is not to observe IPP perform pre-operational sanitation SOP verification. The EIAO is to observe establishment pre-operational sanitation activities if information reviewed when conducting the PHRE indicated potential issues.
3. The EIAO is to observe the establishment's implementation of food safety measures (e.g., CCPs, prerequisite programs, or other programs) that support decisions in the hazard analysis including antimicrobial interventions, lethality treatments, stabilization treatments, and post-lethality treatment/anti-microbial agent or process.

4. During FSAs performed at slaughter establishments, the EIAO is to make direct observations of the slaughter process and sanitary dressing over multiple days, across all shifts, with a focus on the establishment's sanitary dressing procedures and its ability to maintain process control. The EIAO is to assess the sanitary dressing and process controls slaughter establishments employ in its food safety systems, considering the factors and questions presented in [FSIS Directive 6410.3](#), *Verifying Sanitary Dressing and Process Control Procedures by Off-line Inspection Program Personnel (IPP) in Poultry Slaughter Operations*, and [FSIS Directive 6410.1](#), *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age - Revision 1*.
5. The EIAO is to make direct observations of any establishment sampling (e.g., Lm sampling for RTE establishments under Alternative 2b and 3, STEC sampling for establishments producing raw non-intact products and components of raw non-intact products, and sampling at poultry slaughter establishments in accordance with the requirements in 9 CFR 381.65(g)) to ensure the establishment is following the procedures in its written program. The EIAO is to also make direct observations of the establishment's in-house laboratory, if applicable.
6. The EIAO is to evaluate whether the in-plant team is receiving the appropriate sampling tasks through PHIS based on the products the establishment produces and a review of the laboratory sampling results obtained from the PHRE PHIS report. If the EIAO identifies that the appropriate sampling tasks are not being assigned to the in-plant team, he or she is to contact the FLS.
7. To determine sampling program eligibility the EIAO is to review the following issuances:
 - a. [FSIS Directive 10,010.1](#), *Sampling Verification Activities for Shiga Toxin-producing Escherichia coli (STEC) in Raw Beef Products*;
 - b. [FSIS Directive 10,240.4](#), *Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program*;
 - c. [FSIS Directive 10,250.1](#), *Salmonella and Campylobacter Verification Program for Raw Meat and Poultry Products*;
 - d. [FSIS Directive 10,800.1](#), *Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products*; and
 - e. [Current FSIS sampling Notices](#).

VI. RECORDS REVIEW

A. During the course of the FSA the EIAO is to review HACCP system components, including intended use, flow chart, hazard analysis, HACCP plan, supporting documentation, prerequisite programs, and ongoing verification records. The EIAO is to prioritize records directly relevant to sanitary dressing, prerequisite programs, establishment interventions, lethality and stabilization procedures, establishment sampling results, effectiveness of corrective actions, and other records necessary to answer questions in the FSA tools and to evaluate whether the establishment is maintaining an adequate food safety system.

B. The EIAO is to randomly select 13 production days from the preceding 60 days and to review data from those 13 days. The EIAO is not to review each day's records from the preceding 60 days. This limited review will provide the EIAO with knowledge of how the HACCP system design is implemented, and whether it is designed effectively to meet regulatory requirements, while allowing the EIAO to manage time in order to complete the FSA in the 5 to 7 in-plant production day period.

C. If an establishment has operated for less than 13 days in the preceding 60 days, the EIAO is to review data that goes back further than 60 days, until he or she has reviewed 13 days of data.

D. The EIAO is to assess the design of the record-keeping system, and whether the establishment implements it to meet HACCP record-keeping requirements. When assessing the design of the record-keeping system, the EIAO is to evaluate whether the results of the monitoring and on-going verification procedures are recorded appropriately to reflect the implementation of the establishment's HACCP system.

NOTE: The EIAO is not to focus on compliance with basic recordkeeping requirements (e.g., signature and dating requirements in 9 CFR 417.2(d)). IPP verify the compliance of individual records to such requirements. If there is a systemic problem with basic recordkeeping requirements, the EIAO is to notify the FLS.

E. The EIAO is also to review the records to determine whether there were any deviations from the establishment's critical limits that were not detected by the establishment monitoring procedure or by IPP verification activities.

F. The EIAO may review more than 13 days worth of records if the results of his or her record review indicate a larger food safety concern (e.g., numerous deviations are identified that were not identified by the establishment or IPP).

VII. REVIEW OF ESTABLISHMENT VALIDATION DOCUMENTS INCLUDING SCIENTIFIC SUPPORT AND IN-PLANT VALIDATION DATA

A. The EIAO is to review the two types of supporting documentation required under 9 CFR 417.4(a)(1) to determine whether the HACCP system is validated: the scientific or technical support for the HACCP system design (design) and the in-plant validation data (execution). However, establishments have until January 4, 2016 (large establishments) or April 4, 2016 (small and very small establishments) to gather the in-plant validation data.

B. The EIAO is to evaluate whether the establishment has adequate scientific support for the design of its HACCP system (e.g., CCP, prerequisite program, or other program design), and whether the in-plant validation data demonstrates that it can implement its system as designed.

C. If the EIAO determines the establishment has inadequate support, he or she is to document noncompliance. Until January 4, 2016 (large establishments) or April 4, 2016 (small and very small establishments), if the EIAO finds the in-plant validation data inadequate, the EIAO is to note this fact in the FSA but is not to use the lack of in-plant validation data as the only reason for a finding of noncompliance or an enforcement action.

D. The EIAO is to review the [HACCP Systems Validation Guidance](#) that includes recommendations for meeting the validation requirements.

E. To determine whether the establishment maintains adequate scientific support for the design of its CCP, prerequisite program, or other program, the EIAO is to evaluate whether:

1. The establishment maintains the scientific and technical support for the design of its HACCP system on-file;
2. The scientific support is complete and contains the methodology and results;
3. The methodology is appropriate for the purpose;
4. The results demonstrate that the establishment's process prevents, reduces, or eliminates the hazard to acceptable levels;
5. The scientific and technical support closely relates to the establishment's actual process, product, and hazard identified in the hazard analysis. If it does not closely relate, the EIAO is to evaluate whether the establishment has support or justification (science-based rationale) for why the scientific support should still apply to its process; and
6. The establishment incorporates the same critical operating parameters for the process control measure or intervention described in the scientific and technical support into its CCPs, prerequisite programs, and other programs. If it does not, the EIAO is to evaluate whether the establishment provides additional support or justification (science-based rationale) for the adequacy of the process control measures or interventions that *do not* incorporate the same parameters in the scientific or technical references (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures).

F. To determine whether the establishment maintains adequate in-plant validation data demonstrating that it can implement its CCP, prerequisite program, or other programs, the EIAO is to evaluate whether:

1. The establishment collected in-plant validation data for at least one product from each HACCP processing category;
2. The in-plant validation data consists of data demonstrating that the critical operational parameters of the process are being met. The EIAO is to evaluate whether the in-plant validation data also consists of microbiological data when the establishment does not have adequate scientific or technical support, or when it is not following the parameters in the scientific or technical support. If the establishment has adequate scientific or technical support and is following the parameters in the scientific or technical support, then in-plant microbiological data is not needed to comply with the initial validation requirements;
3. The establishment collected in-plant validation data from 90 calendar days. For large establishments, 90 calendar days equates to approximately 60 production days. For small and very small establishments, 90 calendar days equates to a minimum level of records from 13 production days;

4. The data reflects the process as currently designed, or that changes have been made over time; and
5. The establishment analyzed the in-plant validation data (e.g., reviewed records) during the initial validation period to determine whether it supports that the system can be implemented as designed.

VIII. ANSWERING FSA TOOL QUESTIONS

A. The EIAO is to document all relevant noncompliance and vulnerability findings in the FSA tools.

B. The EIAO is to limit answers in the FSA tool to the question being asked and any vulnerabilities or noncompliance identified. A vulnerability is an identified weakness in the establishment's process that does not rise to the level of noncompliance but that could contribute to the establishment's ability to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements (i.e., the Acts and 9 CFR). Limiting responses will help ensure that the EIAO meets the timeframe and uses his or her time towards building a supportable recommendation.

C. When responding to the questions in the tool, the EIAO is to keep in mind that several questions could have similar responses, depending on the issues at the establishment. In these situations the EIAO does not need to "cut and paste" multiple times. Instead, he or she is to reference the original response. The EIAO is not to spend time rewriting the same information multiple times within the same tool.

D. The EIAO is to complete the General Tool for all FSAs. The General Tool contains establishment demographics, the FSA recommendation, Executive Summary, Decision Making Analysis, and General questions that apply to all of the different HACCP processing categories. Chapter VI of this directive will describe in detail how to respond to the FSA recommendation, Executive Summary, and Decision Making Analysis questions as these sections are to be completed after all other questions are answered.

E. The EIAO is to limit responses in the General Tool to information related to the HACCP category or categories being evaluated within the selected tool (i.e., Meat, Poultry, RTE/NRTE Processed Products Tool; Thermal Processing/Commercially Sterile) and is not to include information from other HACCP processing categories unless the information has a bearing on the category being evaluated as part of the focused FSA.

F. If an FSA is being performed as part of an IIT, the EIAO is also to complete the IIT Tool in PHIS according to [FSIS Directive 5500.3](#).

CHAPTER VI - RECOMMENDATIONS, EXECUTIVE SUMMARY, NONCOMPLIANCE, AND REVIEW PROCESS

I. ANALYZING FINDINGS

A. The EIAO is to use the summary question at the end of each tool to focus on the most significant noncompliances or vulnerabilities that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (generally 3 – 5 key findings). The answer to the summary question will be used to construct the Executive Summary.

B. The EIAO is to use the Decision Making Analysis section of the General Tool to provide the support for the recommendation. In addition, the EIAO is to use the results from RLM, IVT, or IIT sampling to support the decisions he or she makes. The support for the recommendation is derived from the sampling results, PHRE, in-plant observations, and the HACCP system design and implementation documented in the tools. The EIAO is to discuss and interpret his or her major findings and how that the findings impact the establishment's ability to produce safe, wholesome, and unadulterated product. This Decision Making Analysis section is important to provide context and support for recommendation.

II. WRITING THE EXECUTIVE SUMMARY

A. The Executive Summary (document in the General Tool) is a brief overview of the FSA report designed to give readers a quick overview of its recommendations and support. The EIAO is to write it when she or he has finished the Decision Making Analysis section of the General Tool and made a recommendation. The purpose of the summary is to concisely lay out the principal findings of the FSA report in relation to the focus and execution of the Assessment Plan developed under [FSIS Directive 5100.4](#). After reading the executive summary, the reader should understand the main regulatory findings that support the conclusion that the establishment is not meeting specific sections of the Acts.

B. The purpose of the executive summary is to provide an overview of the FSA report. A good executive summary contains the following:

1. A sentence or two that describes the establishment and its processes, including the major types of products it produces;
2. A sentence or two that describes the establishment's compliance history;
3. A sentence that describes the sampling results, if applicable;
4. A couple of sentences that describe the major findings leading to the recommendation; and
5. A couple of sentences that discuss the EIAO's analysis of the significance of those findings under the regulations that result in not meeting the requirements of the Acts, and what they show about the establishment's ability to produce safe products.

C. The executive summary is to emphasize the EIAO's recommendation and include only the essential or most significant information to support that recommendation. The EIAO is to use the Decision Making Analysis section for additional information.

D. The EIAO is to make the summary concise and to ensure that it shows how he or she has arrived at the recommendation. The EIAO is not to duplicate the Decision Making Analysis Section. The EIAO is to use the summary question from each tool to construct the executive summary.

E. The EIAO is not to introduce into the Executive Summary any information that is not contained in the FSA report.

NOTE: A simple rule-of-thumb is to imagine that the Executive Summary is the only part of the FSA report that anyone can see and then ask the question: Does this summary adequately explain and support the recommendation?

III. FSA RECOMMENDATIONS

A. The EIAO is to recommend one of the following outcomes for the FSA: No Further Action, NRs, NOIE (with or without NRs), or NOS.

B. Recommending No Further Action

For this recommendation, the EIAO needs to clearly describe the facts gathered that demonstrate that the establishment meets the applicable regulatory requirements, and that no food safety concerns exist.

C. Recommending the issuance of NRs by IPP

1. The DO is to ensure that EIAOs are providing information for NRs consistent with [FSIS Directive 5000.1](#), *Verifying an Establishment's Food Safety System*. The FLS is to ensure that NRs are documented appropriately (including the appropriate PHIS task) and issued at the exit meeting by IPP.
2. The EIAO is to work with the FLS to determine whether there are public health-related or complex HACCP system design, including sampling program, noncompliances that require a follow-up once the establishment has provided corrective actions. The EIAO is to be available to the FLS if the FLS has questions about the NR or the establishment's response to the NR. The EIAO is to state in the General Tool whether follow up is necessary and is to contact the FLS within 30 days of the exit meeting to determine the status of the NR. Ensuring that an establishment has adequately addressed any noncompliances can reduce the likelihood of repetitive noncompliance in the future that could lead to public health events and additional FSAs.

NOTE: When documenting all the NRs associated with the FSA in PHIS (including any imminent food safety concern NRs that were issued before the exit meeting), IPP are to indicate that the NR was completed as part of an FSA by checking the designated box in PHIS. IPP are also to include in the description that the NR was observed as part of an FSA.

D. Recommending that an enforcement action, NOS, or NOIE be issued by the DO.

1. If the establishment is shipping or producing adulterated product, operating without a HACCP plan, or engaging in any other type of noncompliance that supports taking a withholding or suspension action without prior notification (9 CFR 500.3), the first obligation of the EIAO is to stop the wrongful practice. Then the EIAO is to contact the DO to determine whether enforcement action is needed.
2. For an EIAO to recommend that the DO issue a NOIE, he or she needs to have information in his or her report that the conditions in the establishment, or the actions of establishment personnel, constitute a situation that would justify the action under 9 CFR 500.4, and that such conditions have resulted in adulterated product or create insanitary conditions that could cause product to be adulterated.

3. The EIAO is to collect, safeguard, and transfer evidence for an NOIE as described in [FSIS Directive 8010.3](#), *Procedures for Evidence Collection, Safeguarding and Disposal*. The EIAO is to transfer evidence to the DCS and preserve the chain of custody with appropriate documentation.
4. In certain cases, the EIAO may also collaborate with the DCS in creating and maintaining case files in Assurance Net. The EIAO is to follow the DCS instructions in [FSIS Directive 5100.3](#), *Administrative Enforcement Reporting (AER) System*, to ensure that the electronic AER case file contains the appropriate evidence, chain of custody, and other related enforcement documents.

IV. EIAO and DO FINALIZATION OF THE FSA

The DO is to manage the review process for FSAs. FSAs that result in a recommendation of enforcement are to be reviewed by the DCS. The DO is not expected to review all questions within the FSAs. The DO is to use his or her discretion to focus his or her time in accordance with public health risk.

CHAPTER VII - EXIT CONFERENCE

I. SCHEDULING AND CONDUCTING THE EXIT CONFERENCE

A. The EIAO is to schedule the exit conference with establishment management on the last production day of the FSA after review by the DO. The exit conference is to take place within the 5 to 7 in-plant production day timeline. Although it is strongly encouraged that the IPP and the FLS also attend the exit conference, the exit conference is not to be delayed to provide for his or her attendance. The EIAO is to document the date he or she held the exit conference and the attendees in the FSA report using the General Tool.

B. When the EIAO conducts the exit conference with establishment management and any FSIS personnel who attend, the EIAO is to:

1. Thank the establishment for its cooperation;
2. Describe the FSA findings to the establishment, including any recommendations that the EIAO has made to the DO;
3. Describe the basis for all NRs being issued at the exit conference as well as any enforcement recommendations that the EIAO has made to the DO. If there is an enforcement action, the NOIE or NOS are to be given to the establishment at the exit conference;
4. Provide a draft or final copy of the FSA to the establishment management. If a draft is provided during the exit meeting, a final copy of the FSA is to be sent once the exit meeting information has been added; and
5. Answer any questions from the establishment.

C. The EIAO is to direct the small and very small establishments to FSIS [compliance assistance](#) resources to meet the Agency's obligation related to the Small Business Regulatory Enforcement and Fairness Act (SBREFA).

CHAPTER VIII - DATA ANALYSIS AND QUESTIONS

I. DATA ANALYSIS

A year after this directive issues, the Data Analysis and Integration Staff (DAIS) within the Office of Data Integration and Food Protection (ODIFP) is to perform an analysis of the duration of FSAs. This analysis will be used to determine whether the new tools and new instructions were effective in achieving the new 5 to 7 in-plant production day timeframe for most FSAs. FSA data will be analyzed at the national and district levels to examine whether trends in FSA lengths exist. ODIFP is to examine trends of FSA duration by establishment type and establishment size. FSIS will use the results from these analyses to inform improvements to the FSA tools, training, and policy and program development.

II. QUESTIONS

Refer questions regarding this directive RIMS through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the information in the fields provided below. To facilitate a timely response, the EIAO is to indicate what day they are on of the FSA. For example, in the subject line indicate "day 2 of 5 day FSA".

Subject Field: Enter **Directive 5100.1 (including which day of the FSA)**
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select **EIAO Methodology** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



Assistant Administrator
Office of Policy and Program Development

Attachment 1. SUGGESTED FOOD CONTACT SURFACE SITES

Purpose: This document is designed to assist the EIAO in choosing a food contact sampling site for RLM and IVT sampling.

Historical positive results from RLM and IVT testing conducted by FSIS have been used to summarize the most common Food Contact Surface (FCS) positive sites. The EIAO is to use the following list as a foundation for planning RLM sampling prior to beginning an FSA. The final sampling plan should additionally reflect historical areas of concern at the establishment and areas of concern identified by the IPP and FLS.

Most Common Food Contact Surface Positive Sites from Historical RLM and IVT Sampling *
Table
Blade or Knife
Slicer
Conveyor or Conveyer Belt
Glove
Scale
Rack
Cutting Board
Tray or Pan
Chute
Scoop
Mixer

* Additional discussion of FCS sites can be found in the FSIS Compliance Guideline: Controlling *Listeria monocytogenes* (Lm) in Post-lethality Exposed Ready-to-Eat (RTE) Meat and Poultry Products, available at: www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index