FOOD SAFETY ASSESSMENT (FSA) METHODOLOGY

CHAPTER I – GENERAL

I. PURPOSE

This directive provides instructions on how to document Food Safety Assessments (FSA). The 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" refers to any EIAO trained Meat Safety Assurance (MSA) staff member conducting FSA activities. The term "Central Office" (CO) includes the State Establishment Coordinator (SEC) and Assistant State Director.

II. CANCELLATION

MSA Directive 5100.1, Revision 4.1

CHAPTER II – FSA

I. FSA METHODOLOGY OVERVIEW

A. The purpose of a 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 statutory and regulatory requirements.

B. The EIAO is 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, which should include 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.

C. The EIAO is to reach a logical and supportable recommendation for one of the following letters; No Further Action (NFA), a Letter of Concern, Warning Letter, or Notice of Intended Enforcement (NOIE).

D. The EIAO is to document their findings in the final assessment (MSA 20a). The EIAO is to focus on documenting vulnerabilities and noncompliance. In particular, the EIAO is to summarize the findings that bear most directly on the recommended action, if any, regarding the establishment's HACCP system. The EIAO is to use the decision-making analysis to evaluate the food safety system, applicable sample results, and the observations made throughout the FSA to support the recommendation based upon statutory and regulatory requirements (e.g., the Acts and 9 CFR).

II. PREPARATION IN ADVANCE OF THE FSA

A. When an EIAO is preparing to conduct a comprehensive a food safety assessment, he or she should:

1. Contact the Circuit Supervisor 1-2 weeks in advance of the assessment to coordinate contact with the establishment prior to the visit.

2. The EIAO should review all relevant data and determine whether there are patterns or trends that should be investigated when visiting the establishment. The types of data that should be reviewed are:

   - PHIS data
   - Enforcement data
   - Laboratory results

3. Review, if necessary, relevant policy issuances (Federal Register Notices, FSIS Directives and Notices, MSA Directives and Notices) that pertain to the processes associated with the establishment.

B. When the food safety assessment is complete, the EIAO should assess the significance of the pre-visit data as they relate to the overall assessment outcome.

C. As part of preparation for the FSA, the EIAO is to determine whether pathogen sampling Routine *Listeria monocytogenes* (RLm), Intensified Verification Sampling (IVT), or other sampling is to be performed.

1. If an FSA will include RLm the EIAO is to prioritize sampling before the

start of the FSA. The EIAO is to consider the sampling results when determining the FSA outcome. In some limited circumstances (e.g., there are unanticipated sampling delays or presumptive positives), results may delay the completion of the FSA.

2. The EIAO should 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 MSA Directive 10,240.5, the EIAO may collect some samples pre-operationally (pre-op) but should collect most samples during operations. As is also stated in MSA Directive 10,240.5 sampling may be performed over multiple days, especially if the establishment takes two days to produce the sampled lot (e.g., slices the product one day and packages it the next).

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. The EIAO is to identify additional sampling sites when meeting with the Inspector-in-Charge (IIC) and during the establishment tour.

4. The EIAO is to keep in mind that the sampling may 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 IIC and/or may take Regulatory Control Action.

D. Provide the establishment with at least 1 week notice that RLm sampling will occur, and that an FSA will be performed following the RLm sampling.

E. The EIAO is to contact the State Lab and the Sampling Coordinator 2 weeks prior to sampling to schedule a RLm and review the establishment's previous sampling results in SharePoint.

F. 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., at least the last 60-90 production day records, HACCP plan, sampling program, sampling results). Having the documentation available at the start of the FSA will help the EIAO accomplish the in-plant portion of the FSA;

2. Review the most recent MSA-67 and the Sample Tracker to identify

the sampling programs being conducted 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. The EIAO shall conduct an entrance meeting to be attended by the IIC, establishment management, and if possible the CM or designee. Discussion topics during the entrance meeting include but are not limited to:

1. The purpose and scope of the FSA and how it differs from the day-to-day verification activities that are performed by the IIC;

2. The EIAO's intended typical work schedule during the assessment;

3. The EIAO may make observations during all shifts and during pre-operational activities;

4. The EIAO is to inquire whether the establishment has in place any special procedures to access production area(s);

5. The EIAO is to ask where the establishment stores the HACCP and SSOP records (HACCP Systems, SSOP, prerequisite programs, support). Additionally, the EIAO is to request access to examine and copy or scan any records that may be needed to support noncompliance determinations made during the assessment;

NOTE: The EIAO must be given access to the HACCP Systems, SSOP's and all the records associated with them.

6. 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 to meet all intended parties' needs;

9. The possible FSA outcomes; which will include a letter with one of the four possible outcomes, as well as a copy of the MSA 20a.

10. At the conclusion of the FSA, an exit meeting with establishment management will be held to discuss the in-plant portion of the FSA;

11. The EIAO's contact information so the establishment may contact him or her, if necessary.

B. The EIAO is to use the MSA 20a to document the entrance meeting. The EIAO is to include the date and participants in the documentation of the conference.

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 discovering them as possible. The EIAO is to describe to establishment management, in clear terms, the noncompliances and the vulnerabilities that he or she identifies as the assessment progresses. During 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. If the EIAO recommends an enforcement action, the EIAO is to document relevant noncompliances in the Notice of Intended Enforcement (NOIE).

C. The EIAO is to discuss his or her findings and recommendations with the CO 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 IIC and CM throughout the assessment and to describe any noncompliances or vulnerabilities that he or she has identified.

1. The EIAO, the IIC, and the CM are to work collaboratively to ensure that all noncompliances are communicated to establishment management and documented for issuance either during the exit

meeting or immediately following. The EIAO is to notify the CM and IIC 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.

2. During the assessment process, the EIAO is to provide frequent updates to the IIC and CM to inform them of the EIAO's findings and of any recommendations that the EIAO is planning to make.

3. The CO 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, 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, not demand, information and be able to explain to establishment officials MSA's statutory authority under the Texas Meat and Poultry Inspection Act (TMPIA) to examine facilities and to copy records. If the EIAO encounters uncooperativeness or unwillingness of establishment officials to provide information, the EIAO is to communicate with the CO to develop a strategy for gaining access to necessary information.

CHAPTER IV – OVERVIEW OF PERFORMING THE FSA

I. TIME TO COMPLETE FSAs

A. The EIAO is to complete the in-plant portion of the FSA in a timely manner. The FSA may be extended if additional time is necessary to develop the recommendation for an enforcement action (NOIE or suspension).

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 CO.

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 as opposed to focusing solely on the verification of 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), sanitation performance standards (SPS) throughout the establishment and grounds outside the establishment, humane handling, as well as sampling when possible (at a minimum the sampling records should be reviewed); and

2. Reviewing a random selection of at least 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 documents to evaluate the establishment's HACCP system. The EIAO is to be aware that guidance represents best practice recommendations by FSIS/MSA and does not represent requirements that must be met. Establishments may choose to adopt different procedures than those outlined in a guideline, but they 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 product flow and to plan for future observations. This chapter describes the types of observations the EIAO is to make during 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. After reviewing 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 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 by verifying the hazard analysis, using scientific knowledge, knowledge of Regulations, Agency Policies and issuances, and professional expertise. The EIAO is to assess whether the establishment has addressed hazards commonly associated with a process (9 CFR 417.2(a)(1)), 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 shall submit questions to the CO as soon as possible to allow time for the CO to research and formulate 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)

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 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. The establishment maintains records that demonstrate that the program is being implemented as written (i.e., monitoring of the critical

operational parameters);

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 renders the hazard not reasonably likely to occur.

If one or more above characteristics are not met (e.g., monitoring of the critical operational parameters is not performed), the EIAO may determine that a prerequisite program is not effective, resulting in a hazard being reasonably likely to occur because the hazard is not accounted for in the hazard analysis. If the prerequisite program were ineffective there would be noncompliance with 9 CFR 417.5(a)(1) and 417.2(a). The establishment would need to reassess its hazard analysis, as indicated in 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, as indicated in 9 CFR 417.6, and may result in the EIAO recommending an Enforcement Action be issued by the CO and possibly recommending a Regulatory Control Action (RCA) by the inspection staff. In some cases of an inadequate system a recall may be justified.

III. SANITATION SOPs

The Sanitation SOP is required by regulation (9 CFR 416.12). The EIAO is to analyze and document how noncompliance 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 Sanitation SOP findings on the MSA 20a.

IV. SANITATION PERFORMANCE STANDARDS (SPS)

Sanitation Performance Standards (SPS) are required by regulation (9 CFR 416.1 – 9 CFR 416.6). The EIAO is to verify compliance with the SPS regulatory requirements by directly observing the conditions in the establishment and observing establishment employees. The EIAO is to document SPS findings on the MSA 20a.

V. HUMANE HANDLING

Humane Handling is required by 9 CFR 313. The EIAO is the verify compliance with the regulatory requirement by directly observing the conditions in the establishment and observing establishment employees. The EIAO should be

familiar with *MSA Directive 6900.2 Rev 2, Humane Handling and Slaughter of Livestock* prior to performing an FSA in a Slaughter Establishment. The EIAO is to document humane handling findings on the MSA 20a.

VI. 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 FSA, the EIAO is to observe the establishment collecting samples according to its supporting documentation and document any noncompliance.

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 60-90 days; and

2. Review corrective actions taken in response to positive sample results (including re-assessment when required) and evaluate whether the corrective actions were effective.

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

1. MSA Directive 10,010.3, *Traceback Methodology for Escherichia coli (E. coli) O157:H7 in Raw Ground Beef Products and Bench Trim*;

2. MSA Directive 10,240.4, *Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program;* and

3. MSA Directive 5000.2, *Review of Establishment Data by Inspection Personnel*.

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

i. *Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory*;

ii. *FSIS Compliance Guideline: Controlling Listeria monocytogenes in post- lethality exposed Ready-to-eat Meat and Poultry Products;*

iii. *FSIS Compliance Guideline for Controlling Salmonella and Campylobacter in Poultry*; and

iv. *FSIS Compliance Guideline for Controlling Salmonella in Market Hogs*

b. If, after reviewing these documents, the EIAO still has a question regarding the sampling program, he or she is to submit a question to the CO.

VII. DIRECT OBSERVATIONS OF ESTABLISHMENT ACTIVITIES

A. The EIAO is to make observations of the establishment's activities across all shifts. 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 MSA statutory and regulatory requirements. The EIAO is to make the following direct observations:

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 may observe the IIC performing pre-operational sanitation SOP verification. The EIAO must observe establishment pre-operational sanitation activities.

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/antimicrobial 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 a slaughter establishment employs in its food safety systems, considering the factors and questions presented in MSA Directive 6410.3, *Verifying Sanitary Dressing and Process Control Procedures by Off-line Inspection Program Personnel (IPP) in Poultry Slaughter Operations,* and MSA Directive 6410.1, *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age.*

5. The EIAO is to make direct observations if the establishment is sampling (e.g., *Lm* sampling for RTE establishments under Alternative 2b and 3, Shiga toxin-producing *Escherichia coli* (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 also to make direct observations of the establishment's in-house laboratory, if applicable.

VIII. RECORDS REVIEW

A. During the FSA the EIAO is to review HACCP system components, including intended use, flow chart, hazard analysis, HACCP plan, supporting documentation, prerequisite programs, decision making documents, 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 evaluate whether the establishment is

maintaining an adequate food safety system.

B. 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., different concentrations of antimicrobials or different thermal processing temperatures).

C. The EIAO is to randomly select 13 or more production days from the preceding 60 days and review data from those production days. This limited review will provide the EIAO with knowledge of how the HACCP system is implemented, and whether it is designed effectively to meet regulatory requirements, while allowing the EIAO to manage time.

D. 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 or more of data.

E. The EIAO is to assess the design and implementation of the establishment's recordkeeping system, to comply with HACCP recordkeeping requirements. When assessing the design of the recordkeeping 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)); IIC 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 CM and document the findings on the MSA 20.

F. 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 IIC verification activities.

G. The EIAO may review more than 13 days 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 IIC).

IX. 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 and 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.

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 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 demonstrate that the critical operational parameters of the process are being met. The EIAO is to evaluate whether the in-plant validation data also consist 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 are 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 reflect 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 they support that the system can be implemented as currently designed.

CHAPTER VI – Completing MSA Form 20a, Comprehensive Assessment of the Execution and Design of an Establishment's Food Safety Systems Report

Complete MSA Form 20a in accordance with MSA Directive 5100.12, FSA Scoring Methodology.

CHAPTER VII – Documenting Recommendations

EIAOs are to utilize MSA Directive 5100.12 for determining the FSA outcome and determining recommended actions as a result of the FSA. Any additional recommendations should be detailed in the letter generated and provided to the

establishment during the FSA exit .

CHAPTER VIII – Verification Plans

I. Verification Plan Design

A. A verification plan (VP), also know as MSA 20b, is to be developed by the EIAO anytime a recommendation other than "no further action" is made, including when the CO decides to defer enforcement following the issuance of a NOIE or to hold a suspension in abeyance following the suspension of the assignment of inspection personnel. The VP provides a systematic means for inspection program personnel to verify that an establishment is effectively implementing the corrective measures that were proffered to the CO. The EIAO has the primary responsibility for preparing the written verification plan. However, the EIAO may correlate with the IIC, CM, State Establishment Coordinator (SEC), and other MSA Central Office staff in the development of the VP.

B. The EIAO prepares the final report and has primary responsibility for communicating the final verification plan to the IIC and CM. Any follow-up discussion of the verification plan should be accomplished in conjunction with the EIAO, CO, IIC, CM, and the SEC. If a new IIC is assigned to the facility at any time during the deferral or abeyance period (e.g., due to a scheduled rotation), the CM should ensure that the new IIC understands how to implement the verification plan.

C. The EIAO is to verify all corrective measures associated with the establishment's verification plan and document the completion or inadequate measures taken by the establishment.

D. The EIAO will normally visit the establishment to verify acceptable corrective measures when the establishment was issued a LOC, LOW, NOIE, or Withholding/Suspension. If the EIAO has issues with corrective measures, they may return later to verify acceptable implementation. Recommendations made by the EIAO may include continuing to hold the action in abeyance, closing the action, or initiating further enforcement if the establishment's corrective and preventive actions are found not to be effective.

E. The EIAO shall review the completed VP (MSA 20b) for accuracy and content. The EIAO shall upload the VP to the MSA SharePoint. The EIAO will submit the completed and closed verification plan into the appropriate EIAO tracking database.

CHAPTER IX - EXIT CONFERENCE

I. SCHEDULING AND CONDUCTING THE EXIT CONFERENCE

A. A pre-exit conference with the IIC, and the CM or their designee may be conducted and is strongly encouraged. If issues arise about the findings during the pre-exit conference, the EIAO should postpone the exit conference until those issues have been resolved.

B. The EIAO is to schedule the exit conference with establishment management on the last production day of the FSA. The EIAO is to document the date he or she held the exit conference and the attendees in the FSA report.

C. When the EIAO conducts the exit conference with establishment management, 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 CO;

3. Describe all noncompliances at the exit conference as well as any enforcement recommendations that the EIAO has made to the CO. The No Further Action Letter, the LOC, the LOW or NOIE are to be given to the establishment at the exit conference;

4. Provide a Comprehensive Assessment of the FSA and the Letter (e.g., LOC, LOW, NOIE Letter) to the establishment management. If the letter is not available at the time of the exit meeting the EIAO may schedule an exit meeting later to provide the establishment with this letter.

5. Answer any questions from the establishment.

CHAPTER X - APPEALS

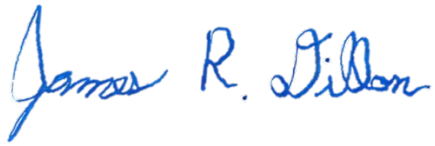
A. The Inspection Staff/Circuit Manager may appeal through the EIAO chain of command. Inspection staff/Circuit Manager should submit appeals prior to the exit meeting to the extent possible.
    a. EIAO

b. EIAO Manager
c. Assistant Director/Assistant Section Manager
d. Director/Section Manager

B. The establishment may appeal in writing to the CM, who should forward as appropriate to the EIAO chain of command.
   a. EIAO
   b. EIAO Manager
   c. Assistant Director/Assistant Section Manager
   d. Director/Section Manager

CHAPTER XI – QUESTIONS

Refer questions through supervisory channels.



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