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

# FSIS DIRECTIVE	5000.6	8/14/12

PERFORMANCE OF THE HAZARD ANALYSIS VERIFICATION (HAV) TASK

I. PURPOSE

The purpose of this directive is to provide instructions regarding how to perform the Hazard Analysis Verification (HAV) task. This directive incorporates the instructions contained in FSIS PHIS Directive 5000.1 regarding the performance of the HAV.

KEY POINTS:

- *Incorporates the instructions in FSIS PHIS Directive 5000.1, Chapter III, Section VI into this directive*
- *Provides instruction to inspection program personnel (IPP) regarding the performance of the HAV task*
- *Provides instruction to IPP regarding verification of the use and implementation of prerequisite programs*
- *Conducting a HAV task is not the same as conducting a Food Safety Assessment (FSA)*
- *This directive utilizes the same step-by-step format presented in the PHIS training materials*

IMPLEMENTATION:

FSIS will implement this directive on a phased-in basis. FSIS will initially select a representative sample of 30 establishments producing comminuted poultry products to implement HAV procedures in October. FSIS will select 3 establishments from each district, and will include large, small, and very small establishments. IPP at the selected establishments will receive the HAV task in their PHIS task list and are to complete a HAV procedure for all process categories in the establishment. FSIS is first implementing the HAV procedures at establishments producing comminuted poultry products in light of recent illness outbreaks related to *Salmonella* contamination in raw ground turkey products. After assessing the effectiveness of implementation of HAV procedures at these establishments, FSIS will make any necessary changes to the procedures and issue any necessary

clarifying instructions to IPP. FSIS will then implement HAV procedures on or after January 1, 2013, at establishments producing any type of meat or poultry product. IPP are not to perform the HAV task until they receive an instruction to do so through PHIS.

After the HAV task appears on the PHIS task list for an inspector's assignment, and before performing the task for the first time, Consumer Safety Inspectors are to take up to 2 hours of official time to read this directive and review the HAV section of the PHIS training materials.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR Part 417
Federal Register, Vol. 67, No. 194, October 7, 2002, Pages 62325
FSIS PHIS Directive 5000.1, Verifying an Establishment's Food Safety System
FSIS Directive 5020.1, Verification of Salmonella Initiative Program
FSIS PHIS Directive 5300.1, Managing the Establishment Profile in the Public Health Information System (PHIS)
FSIS PHIS Directive 13,000.1, Scheduling In-plant Inspection Tasks in the Public Health Information System
FSIS Meat and Poultry Hazards and Control Guide

V. DEFINITIONS

Critical Control Point (CCP): A point, step, or procedure in a food process at which control can be applied, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level (9 CFR 417.1).

Decision document: A document created by the establishment that summarizes information that it has accumulated as a means to support a decision in its food safety system.

Food safety hazard: Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption (9 CFR 417.1).

Food safety system: The total approach implemented to prevent foodborne illness. The food safety system includes the development and implementation of a Hazard Analysis and Critical Control Point (HACCP) Plan in accordance with 9 CFR Part 417 and a Sanitation Standard Operating Procedure (SOP) in accordance with 9 CFR Part 416. It also includes any programs or procedures that an establishment uses (e.g., prerequisite programs) to ensure that food safety hazards are prevented or controlled and that are supportive of decisions in the hazard analysis.

Hazard analysis: An evaluation conducted by the establishment of its operations that determines the food safety hazards specific to that operation that, if not controlled, are likely to cause injury or illness (9 CFR 417.2).

Hazard reasonably likely to occur: A food safety hazard for which a prudent establishment would establish controls because it has historically occurred, or there is a reasonable possibility that the hazard will occur, in the absence of any controls. For each hazard determined by the establishment to be reasonably likely to occur, the establishment must develop one or more CCPs to prevent, eliminate, or reduce the hazard to acceptable levels (9 CFR 417.1).

Meat and Poultry Hazards and Controls Guide (HCG): The Meat and Poultry Hazards and Control Guide is a guide published by FSIS and announced in the FSIS Constituent Update on October 7, 2005. The document identifies the process steps that are typically associated with each HACCP process category. The document also lists common food safety hazards that have historically been associated with each process step and identifies some of the controls frequently used by processors to address those hazards.

Prerequisite program: A procedure or set of procedures, for example, the Sanitation SOP (SSOP), that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food or to prevent hazards from occurring at certain stages in the process. The program is intended to demonstrate that potential hazards are prevented from being likely to occur or becoming serious enough to compromise food safety. The program is called “prerequisite” because it is considered by scientific experts to be a prerequisite to a HACCP plan.

VI. GENERAL

A. The following discussion provides IPP with an introduction to food safety systems and verification procedures using the HAV.

B. IPP verify that the development and implementation of the establishment’s food safety system (HACCP plans, SSOP, and other prerequisite programs) meets the five regulatory requirements (i.e., monitoring, verification, corrective actions, recordkeeping, and reassessment) addressed in 9 CFR part 417.

C. The purpose of the HAV task is broader than simply to identify isolated noncompliances. IPP are also to consider what their findings show about the overall effectiveness of the establishment’s food safety system. If IPP have concerns about the ability of the establishment’s food safety system to produce safe products, they are to discuss those concerns with their supervisor.

D. The HAV is not a Food Safety Assessment (FSA) or HACCP Implementation Task. IPP will conduct the HAV in order to verify that an establishment meets the regulatory requirements related to the development and implementation of the hazard analysis, and that the establishment has addressed the relevant food safety hazards for all the

establishment's processes, products, and intended uses in accordance with 9 CFR 417.2(a). IPP will identify obvious cases of noncompliance and other issues of concern that may require further consideration or investigation by an Enforcement Investigations and Analysis Officer (EIAO).

E. Routine HAV inspection tasks will be generated by PHIS on a quarterly basis in establishments that demonstrate good process control. In some situations (e.g., when there are repetitive noncompliance determinations or positive FSIS lab samples), PHIS will schedule additional directed HAV tasks.

F. The routine HAV task is performed to verify compliance with the regulatory requirements for the food safety system, including but not limited to the following situations:

1. Changes made to a HACCP system based on implementing a New Technologies Letter of No Objection or other situations where the establishment begins operating under a waiver.

2. Changes to the HACCP system (i.e., HACCP plan or Hazard Analysis) implemented following annual reassessment or reassessment because of changes that could affect the hazard analysis or alter the HACCP plan, such as unforeseen hazard or a new or revised policy.

3. Addition or removal of a critical control point (CCP) or other control measure based on the establishment's determination related to whether a food safety hazard is reasonably likely to occur (RLTO).

G. IPP are to verify whether the establishment meets regulatory requirements using a routine HAV, if the task is available on the establishment task list. If the routine HAV task is no longer available because it was recently performed, IPP are to schedule a directed HAV task as necessary. In some cases, IPP are to schedule directed HAV tasks when instructed by their supervisor or by an FSIS Notice or Directive to verify whether the establishment meets regulatory requirements for a specific process or HACCP processing category, such as in response to agency public health findings.

H. During the performance of both the routine and directed HAV, IPP are to gather information about the food safety system by considering the answers to questions based on the establishment's HACCP process categories or product types, assess that information as it compares to the regulatory requirements and as it affects food safety as a whole, and then determine compliance.

I. Until further notice, IPP do not need to enter the all hazard analysis steps, Critical Control Points (CCP), Critical Limits (CL), or prerequisite programs information into PHIS. However, if IPP observe new information related to the current plant profile during the performance of the HAV, they are to note the changes so that they can incorporate the changes into the establishment profile during the performance of the next monthly Update Establishment Profile task as addressed in FSIS PHIS Directive 5300.1.

VII. USING THE HCG AS A REFERENCE

A. The HCG is not a regulatory document. Therefore, establishments are not required to use the criteria identified in the HCG when identifying steps in their operations. Differences between the HCG and an establishment's hazard analysis are not, in themselves, sufficient to support findings of noncompliance with 9 CFR 417.2(a)(1). However, IPP are to use the HCG as a reference to help them assess whether an establishment has considered the potential hazards associated with a particular production process.
The HCG contains information about the processing steps that are frequently associated with particular product types and addresses hazards that have typically, or historically, been associated with each of these steps. IPP are to use the HCG as a helpful reference.

B. IPP are to refer to the HCG when they verify whether the establishment's flowchart and hazard analysis meet regulatory requirements and to determine whether the establishment considered all the possible hazards for each process step.

C. The information and suggested verification questions in each section of the HCG will assist IPP when gathering information, assessing the information, and then determining compliance during the HAV task.

D. IPP are to use the HCG when considering the following matters:

1. Does the establishment's flowchart and hazard analysis include all the applicable steps for the types of products that it produces?

2. Has the establishment considered the hazards that would typically be associated with the steps in its production process?

3. Has the establishment implemented measures to prevent or control the identified hazards at the relevant points in the process?

E. Because of differences in establishment processes and products, some of the information in the HCG may not apply to all establishments. If IPP have concerns about how the information in the HCG applies to a particular establishment's hazard analysis, they are to discuss the issue with their supervisor.

VIII. PERFORMING THE HAV TASK

A.IPP are to conduct the Routine HAV by reviewing documentation (through the PHIS recordkeeping component) and when possible, by direct observation. IPP are to review all hazard analyses for all process categories in the establishment. IPP also are to verify that the establishment has at least one Critical Control Point (CCP) for each hazard that is identified as being reasonably likely to occur in the process and has support for any decision that applicable hazards are not reasonably likely to occur (NRLTO). When the establishment uses a prerequisite program (such as a Sanitation SOP, Good Manufacturing

Practices (GMP), or purchase specifications) to support the determination that a hazard is NRLTO, IPP are to verify that, through the implementation of the program, the prerequisite program provides support for decisions in the hazard analysis. In addition, they are to verify that there is evidence the establishment implements the prerequisite program effectively to support its decisions and to achieve the expected results.

NOTE: See FSIS PHIS Directive 13,000.1, Scheduling In-plant Inspection Tasks in the Public Health Information System for instructions on using the PHIS tasks calendar to schedule inspection tasks.

B. In two-shift establishments, the routine HAV task will show up on the PHIS task list for both shifts each quarter. The first level supervisor of the inspectors in the establishment, who may be a Supervisory Public Health Veterinarian (SPHV), Public Health Veterinarian (PHV), Supervisor Consumer Safety Inspector (SCSI), or Front Line Supervisor (FLS), is to coordinate the work between the two shifts so that the routine HAV is only performed only on one of the shifts during a given quarter. IPP are to mark the HAV task on the other shift's task list as "not performed" with the justification "task assigned to another inspector." The supervisor is also to ensure that inspectors on both shifts have equal opportunities to perform the HAV over time.

C. IPP are also to add directed HAV tasks to the task list as advised by their supervisor or District Office personnel or as instructed through FSIS notices. In addition, PHIS will include directed HAV tasks in the task list in response to certain events or test results that indicate that the establishment may not be maintaining control of its food safety system (e.g., positive pathogen test results or a trend of food safety noncompliance).

NOTE: If both a routine and a directed HAV are included in the task list by PHIS, IPP are to conduct the directed HAV and mark the routine HAV as not preformed using "Higher priority task took precedence" as the justification.

D. When conducting a directed HAV task, IPP are to include all HACCP categories applicable to the operation. However, IPP are also to pay particular attention to the parts of the hazard analysis and supporting programs that relate the issue that prompted the directed HAV task.

> ***EXAMPLE:*** *When a FSIS ground beef sample tests positive for E. coli O157:H7, IPP are to focus on how the establishment addresses the biological hazard in their food safety system (i.e. HACCP plan or SSOP or other prerequisite program) while performing the directed HAV task.*

E. When performing any HAV task, IPP are to use the methodology described in Steps 1-9 below. Additional information regarding the thought processes related to many of the steps is included in Attachments 1 through 6 to this document.

F. IPP are to consider how their findings may affect the food safety system. When IPP are uncertain about the adequacy of the establishment's hazard analysis, they are to discuss

their concerns with their supervisor.

STEP 1- REVIEWING THE ESTABLISHMENT'S FLOWCHART (Attachment 3)

A. When they perform either the routine or directed HAV task, IPP are to become familiar with the production steps and product flow within the establishment by observing operations. If they have questions about the process steps and product flow, IPP are to ask establishment management for assistance in understanding the production process. In addition, IPP are to note how the establishment handles rework and returned products and are to observe whether and, if so, how these functions are reflected in the flow chart.

B. IPP are to compare the establishment's flowchart to the actual production process and to determine whether the flowchart accurately describes the steps of each process and the product flow within the establishment (9 CFR 417.2(a)(2))

C. IPP are to refer to the HCG as they consider an establishment's flowchart. The table on page 6 of the HCG lists the process steps that are frequently associated with each HACCP process category except slaughter. IPP are to review the process steps in the table for each process category in the establishment. The establishment process may not include all the steps listed in the HCG, but the steps in the table may help IPP identify steps in the establishment process that are not in the flowchart.

D. When the establishment flowchart does not include all the steps in the establishment's production process or does not accurately describe product flow, the flowchart does not comply with 9 CFR 417.2(a)(2).

E. Questions that IPP are to ask regarding the flow chart include, but are not limited to, the following:

1. Does the flowchart reflect all the steps identified by the establishment as being the actual production process? If not, it does not comply with 9 CFR 417.2(a)(2).

2. Does the flowchart, or hazard analysis, identify the intended use or consumers of each product, and is the identified use consistent with the actual production? If not, noncompliance with 9 CFR 417.2(a)(2) exists.

NOTE: Instructions for documenting noncompliances are addressed in Section VIII, Step 9 of this Directive.

STEP 2- REVIEWING THE HAZARD ANALYSIS

A. There is no required format or specified structure of the hazard analysis. It is up to the establishment to determine the format that will enable it to ensure that the hazards associated with the entire production process have been addressed as required by 9 CFR 417.2(a)(1).

B. FSIS does not dictate the level of detail that must be in a hazard analysis; however IPP are to verify that the hazard analysis contains the required information for the entire production process. The establishment may have decided to incorporate several production activities into one step in the operation. The establishment must consider all the food safety hazards associated with all the activities conducted at that step in order to meet the requirement of 9 CFR 417.2(a). The hazard analysis must document the operations considered at each step of the process.

C. IPP are to review the information for each process step in the HCG and compare it to the establishment's hazard analysis for that step. IPP are to consider the verification questions from the HCG and their knowledge of the actual establishment process to assess whether the establishment's hazard analysis has considered the appropriate hazards for each step in its production process.

D. IPP are to review the establishment's hazard analyses for all products produced in the establishment in all HACCP categories. Questions that IPP are to ask regarding the hazard analysis include, but are not limited to, the following:

1. Does the hazard analysis reflect all the steps in the flowchart and the actual production process. If not, it does not comply with 9 CFR 417.2(a)(1).

2. Has the establishment determined that certain hazards are not reasonably likely to occur because of the intended use of the product?

    a. If so, does the establishment have documentation (e.g., labeling records, shipping invoices, letter of intent from receiving establishments or other records) to support the intended use?

    b. If not, the establishment does not comply with 9 CFR 417.2(a)(2).

E. IPP are to consider general questions such as those provided below when evaluating the hazard analysis:

1. Has the establishment addressed this process step in the hazard analysis?

2. Does the establishment have a prerequisite program that addresses this step?

3. Has the establishment identified any hazards associated with this step?

4. Is this process step a CCP?

5. Is the establishment following all procedures identified in the hazard analysis?

6. Does the establishment maintain records associated with this step?

7. Do the establishment's records contain information that indicates that a

reassessment of the hazard analysis or HACCP plan is necessary?

8. Are the records made available to FSIS?

F. IPP are also to consider the suggested verification questions that are presented on page 7 of the HCG for each specific process step.

G. For each food safety hazard identified in the hazard analysis, IPP are to ask the following questions:

1. Does the establishment consider the identified food safety hazard to be reasonably likely to occur (RLTO) in the production process?

2. If so, does the establishment include one or more CCPs to control the hazard in the HACCP plan associated with that product? If not, noncompliance with 9 CFR 417.2(a)(2) exists.

H. Does the establishment consider the identified food safety hazard to be not reasonably likely to occur (NRLTO) in the production process? If so, does the establishment maintain support (e.g., a prerequisite or other supporting program) for this decision? If not, noncompliance with 9 CFR 417.5(a)(1) exists.

I. If IPP are uncertain whether the establishment has considered the appropriate hazards at each process step, they are to contact their supervisors for assistance in order to determine whether noncompliance with 9 CFR 417.2(a)(1) exists.

STEP 3- REVIEWING SUPPORT FOR CCPs AND CRITICAL LIMITS (Attachment 4)

A. During the HAV, IPP are to review establishment records to verify that the establishment has evidence to support the development of CCPs, critical limits, and monitoring and verification procedures.

B. 9 CFR 417.5(a)(2) requires the establishment to maintain the following types of supporting documentation for the HACCP plan:

1. Decision making documents associated with the selection and development of CCPs and critical limits;

2. Documents supporting the selection of monitoring procedures and their frequencies; and

3. Documents supporting the selection of verification procedures and their frequencies.

C. FSIS does not dictate a specific format how this documentation is to be maintained by the establishment. The documentation should describe how the establishment reached the applicable decision and may refer to additional supporting documents.

EXAMPLE: *Establishment A has an antimicrobial intervention CCP in the process that identifies the concentration of the intervention solution as the critical limit. The establishment maintains the following supporting documents to meet the requirement of 9 CFR 417.5(a)(2):*

1. *A decision memo that describes how establishment management selected the CCP based on a particular scientific article that addresses the establishment's particular hazard and product.*

2. *A copy of the referenced scientific article.*

NOTE: The documents that follow are examples of documents that an establishment might have on file to meet validation requirements discussed in Step 7 and Attachment 6 of this directive.

3. *A document from the test kit manufacturer that describes a method for monitoring the concentration of the antimicrobial solution to support the establishment's monitoring procedure.*

4. *A written decision document to monitor the critical limit once per day because the establishment mixes the antimicrobial solution daily.*

5. *A written decision document stating that the establishment will verify that it maintains the necessary minimum concentration of anti microbial weekly because historical records show consistent control of this CCP.*

D. IPP are to verify that the establishment maintains supporting documentation to support its decisions at each CCP.

NOTE: IPP are to pay particular attention to verifying that the establishment has supporting documentation for any CCPs that have been added or modified since the last HAV procedure.

E. If the establishment does not have documentation to support the development of CCPs, critical limits, and monitoring and verification procedures, a failure to comply with 9 CFR 417.5(a)(2) exists.

F. IPP are not tasked with determining the adequacy of the documentation; however, if they have concerns about the documentation, they are to discuss the issue with their supervisor prior to making a compliance determination.

STEP 4- SUPPORT FOR DECISIONS

A. IPP are to verify that the establishment maintains copies, per 9 CFR 417.5(a)(1) and 9 CFR 417.5(a)(2), of all the documents referenced in the hazard analysis that are designated as support for the decisions regarding the prevention or elimination of food safety hazards or their reduction to an acceptable level.

B. IPP are to review the available documentation to determine how it is being used:

1. Records being used as support that a food safety hazard is NRLTO are to be reviewed in accordance with the instructions in Step 5 below.

2. Records being used as support for all other decisions are to be reviewed in accordance with the instructions in Step 6 below.

STEP 5- REVIEWING NRLTO DECISIONS INCLUDING PREREQUISITE PROGRAMS (Attachment 5)

A. When an establishment determines in its hazard analysis that a food safety hazard is NRLTO because the use of a prerequisite program is preventing the hazard (i.e., the data from the program shows that the hazard is not occurring), FSIS considers any information concerning the prerequisite program and its implementation, and any data generated as part of the prerequisite program, to be supporting documentation. Such documentation must be maintained in accordance with 9 CFR 417.5(a)(1) and must be made available to FSIS upon request per 9 CFR 417.5(f). IPP are to review the outcomes of the prerequisite program to verify that the establishment is following the procedure, that the procedure is revised as needed, and that the procedure is effective in accomplishing its objectives.

B. Based on the information they gather from the records and observations, IPP are to consider whether the establishment is implementing the prerequisite program or other control measures in a manner that supports the relevant hazard analysis decisions.

C. IPP are to consider the following questions when reviewing any written information that the establishment uses to support a decision, as it relates to a prerequisite program, that a hazard is NRLTO:

1. Is the program written, and if so, does it describe procedures that the establishment will implement to support that a hazard is NRLTO?

2. Does the program describe the records that the establishment will keep to demonstrate that the program is being implemented as written?

NOTE: While there are no regulations that explicitly address prerequisite program recordkeeping, any records that the establishment elects to maintain regarding its prerequisite program need to demonstrate that the establishment is implementing the

prerequisite program sufficiently to support any relevant decisions made in the hazard analysis.

3. Does the establishment maintain records that show that the implementation of the prerequisite program continually supports that a hazard is prevented from becoming RLTO?

4. Does the program describe activities that the establishment will conduct if it fails to implement the program, or if it finds that the implementation of the program has failed to prevent a hazard from becoming RLTO?

D. If the establishment's prerequisite program is not designed in the manner defined by the criteria in paragraph C above, it is likely that the establishment has not met the requirements of 9 CFR 417.5(a)(1). IPP are to contact their supervisors for assistance if they have concerns about whether the prerequisite program is designed to prevent the relevant hazard.

E. IPP are to verify that the establishment implements any prerequisite programs used to support a decision in that a hazard is NRLTO in a way that supports the decision in the hazard analysis for the specific product. For each such prerequisite program, IPP are to verify implementation of the program by following these steps:

1. IPP are to review any records generated by the prerequisite program for the specific production selected to be verified during the performance of the HAV.

2. IPP are to observe establishment employees implementing the procedure in the prerequisite program.

3. Based on their observations, IPP are to verify that establishment employees implement the prerequisite program as written.

4. IPP are to verify that the records show that the prerequisite program continues to demonstrate that the relevant food safety hazard is not reasonably likely to occur, and that the records support the decisions in the hazard analysis on an ongoing basis.

F. One or more of the following findings are evidence that the establishment has not met the requirements of 9 CFR 417.5(a)(1):

1. The establishment employees are not implementing the procedures in the prerequisite program sufficiently to prevent the relevant hazard.

2. The prerequisite program records indicate consistent or repeated failures to implement the procedures in the prerequisite program, resulting in a lack of support that the relevant hazard is NRLTO.

3. The prerequisite program records do not demonstrate that the prerequisite program is effectively preventing the relevant hazard from being reasonably likely to occur.

G. In most cases, minor failures, such as failing one time to document the implementation of the prerequisite program, would not support a finding of noncompliance.

> ***EXAMPLE:*** *Establishment A implements a prerequisite program to maintain raw product coolers below 35 degrees Fahrenheit (F) to prevent the identified hazard (pathogen growth) from being reasonably likely to occur. On two separate days last week, the employee recording the cooler temperature records did not record information specified in the written program. This minor failure to follow the program would not represent a failure to support the hazard analysis, as long as there is no reason to believe that the 35 degree F temperature was not maintained. Therefore, the establishment is in compliance with 9 CFR 417.5(a)(1).*

H. In contrast, repeated failure to implement procedures in a prerequisite program, or evidence that the program is not effectively preventing the hazard, is an indication that the establishment does not have adequate support for the relevant decisions in its hazard analysis. Failure to support hazard analysis decisions is cause for IPP to document noncompliance with 9 CFR 417.5(a)(1) and may be grounds for an enforcement action.

> ***EXAMPLE:*** *Establishment B implements a prerequisite program of purchase specifications to support that the hazard of E. coli O157:H7 is not reasonably likely to occur in received beef trimmings. The prerequisite program states that Establishment B will receive a Certificate of Analysis (COA) for each lot of trimmings as one way to demonstrate that the hazard is not reasonably likely to occur. IPP observe that the establishment does not have a COA for the lot of trimmings they are grinding. This finding would call into question the establishment's decision that E. coli O157:H7 is not reasonably likely to occur. Therefore, the finding would represent noncompliance with 9 CFR 417.5(a)(1) because the establishment does not have the records specified in the prerequisite program to support that the hazard of E. coli O157:H7 was not reasonably likely to occur.*

I. If IPP are uncertain whether the implementation and records of a prerequisite program support the hazard analysis decisions, they are to discuss the issue with their supervisor.

STEP 6- REVIEWING OTHER SUPPORTING DOCUMENTATION

A. IPP are to verify that the establishment maintains copies of all the documents referenced in the hazard analysis that are designated as support for the decisions regarding the prevention or elimination of food safety hazards or their reduction to an acceptable level. In many cases, this supporting documentation will take the form of scientific documents, establishment historical records, or other establishment generated data. Questions that IPP are to consider in regard to supporting documentation include, but are not limited to:

1. If establishment records or data are being used, does the establishment include a

decision document that explains why the data or records support its decision?

2. If a scientific document is being used, is the establishment following the criteria addressed in the document?

3. If multiple records are being used to support a single outcome (e.g., multiple slaughter interventions used to support a specific log reduction), does the establishment provide a decision document that explains how the documents support the outcome?

B. If the establishment does not maintain copies of the documents referenced in the hazard analysis, it does not comply with 9 CFR 417.5(a)(1).

C. If IPP have concerns that the documents referenced in the hazard analysis do not support the relevant decisions, they are to discuss the issue with their supervisors.

STEP 7- VERIFY ESTABLISHMENT VALIDATION (Attachment 6)

A. 9 CFR 417.4 requires that each establishment validate the adequacy of its HACCP system in controlling the food safety hazards identified in its hazard analysis.

B. The establishment is to maintain the initial validation records for the life of the HACCP system to meet the requirements of 9 CFR 417.5(a)(1) and 9 CFR 417.5(a)(2). When IPP review the documents used to validate the establishment's scientific or technical support, they are to verify the following:

1. The establishment maintains references and copies of relevant portions of text from the scientific literature, textbooks, compliance guidelines, or regulations to support the effectiveness of the interventions in its HACCP system.

2. The establishment maintains data developed by processing authorities or other scientific experts to support the effectiveness of a unique process or unusual use of technology that is not supported by the published reference documents.

3. The establishment's CCPs, prerequisites, or other programs incorporate the limits described in the scientific supporting documentation.

4. The establishment maintains additional data to support the adequacy of control measures that do not incorporate the exact limits from scientific references.

C. When IPP review the records that document initial in-plant validation, they are to verify that the records demonstrate the following:

1. The establishment can implement the HACCP system's preventive measures and controls as written;

2. Establishment employees can fully perform all elements of specified corrective action when there is a deviation from a critical limit;

3. The preventive measures and controls, when implemented, are effective in preventing or controlling the applicable food safety hazard.

4. Recordkeeping procedures associated with CCPs are complete, accurate, and usable by the establishment; and

5. Records generated by prerequisite programs or other interventions or processes designed to prevent or control identified hazards show that the programs are being implemented to support the relevant decisions in the hazard analysis on an ongoing basis.

D. One or more of the following findings provides evidence that the establishment does not comply with the listed regulatory requirements:

1. The establishment does not maintain documents to support the scientific or technical basis for the CCPs and prerequisite programs used to prevent or control identified food safety hazards (9 CFR 417.5(a)(1)).

2. The establishment control measures (CCPs or prerequisite programs) do not incorporate the parameters described in the scientific references, and the establishment does not have data to support the technical adequacy of the control measures (9 CFR 417.5(a)(1)).

3. The establishment does not perform initial in-plant validation of control measures in the HACCP system (including CCPs and prerequisite programs) during the initial 90-day validation period (9 CFR 417.4(a)(1) or 9 CFR 417.4(a)(2))

4. The establishment does not make documents or data available to IPP to demonstrate both parts of validation (9 CFR 417.5(a)(1)).

5. The initial validation records do not demonstrate that establishment employees are able to implement the control measures and corrective actions as written in the HACCP system (9 CFR 417.4(a)).

6. The initial validation records do not demonstrate that the HACCP system is effective at preventing or controlling the identified food safety hazards (9 CFR 417.4(a)(1)).

7. If IPP have concerns about the adequacy of the establishment's validation records, they are to discuss the issue with their supervisor.

E. IPP are not to cite the lack of in-plant validation data as the only reason for the documentation of noncompliance. FSIS realizes that some establishments may not have kept their initial in-plant demonstration documents from when HACCP was originally

implemented. If IPP have concerns regarding the establishment's in-plant validation data they are to discus the issue with their supervisor for guidance.

F. During the HAV, IPP are to review establishment records to verify that the establishment has evidence to support the development of the CCPs, critical limits, and monitoring and verification procedures. IPP are to verify that the establishment maintains these types of supporting documents for each CCP. When performing the HAV task, IPP are to review both the documents that provide the scientific and technical support and the documents associated with the initial in-plant demonstration. IPP are to verify that the establishment maintains both types of validation documents.

NOTE: IPP are to pay particular attention to verifying that the establishment has supporting documentation for any CCPs that have been added or modified since the last review.

G. If IPP have concerns about whether the documentation is adequate, they are to discuss the issue with their supervisor prior to making a compliance determination.

STEP 8- VERIFYING THE REASSESSMENT REQUIREMENTS

A. A reassessment must be conducted under the following conditions:

1. In an establishment that has a HACCP plan, reassessment of the food safety system, including the hazard analysis and any prerequisite programs, is required:

    a. At least annually;

    b. Whenever changes occur that could affect the hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3));

    c. As part of the corrective actions when an unforeseen hazard has occurred (9 CFR 417.3(b)(4); or

    d. When otherwise directed by the Agency based on the regulations (e.g., in a *Federal Register* notice)

2. Establishments that do not have a HACCP plan because they determined that no hazards are reasonably likely to occur must reassess their hazard analysis whenever any changes occur that could affect the hazard analysis or alter the HACCP plan (9 CFR 417.4(b)).

NOTE: Changes that may affect the hazard analysis or alter the HACCP plan include, but are not limited to, new outbreak information or changes in raw materials, product formulation, slaughter or processing methods or systems, production volume, personnel, packaging, finished product distribution systems, or the intended use or consumers of the finished product.

B.IPP are to review establishment records and ask establishment management about reassessments it may have conducted since the previous HAV task. IPP are also to consider whether there have been any changes within the establishment that could affect the hazard analysis (including prerequisite programs) or alter the HACCP plan. IPP are also to consider whether any unforeseen hazards have occurred since the last HAV that would have required reassessment.

C. One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.4(a):

1. In an establishment that has a HACCP plan (9 CFR 417.4(a)):

    a. Changes that could affect the hazard analysis or HACCP plan or unforeseen hazards have occurred, but the establishment has not performed a reassessment.

    b. The establishment did not perform a reassessment at least once in the previous calendar year (i.e. the 12-month period ending on the previous December 31st).

    c. The reassessment was not performed by an individual trained in accordance with 9 CFR 417.7.

2. If an establishment does not have a HACCP plan because the hazard analysis indicates that no food safety hazards are reasonably likely to occur, the following findings may evidence that the establishment does not comply with 9 CFR 417.4(b):

    a. Changes that could affect the hazard analysis have occurred, but the establishment has not performed a reassessment.

    b. The reassessment was performed by an individual not trained in accordance with 9 CFR 417.7.

    c. The reassessment is not documented in accordance with 9 CFR 417.4(a)(3)(ii)

NOTE: Federal Register, Volume 77, No. 89, Tuesday, May 8, 2012, effective June 7, 2012, states the following: 9 CFR 417.4(a)(3)(ii)- *Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.*

STEP 9- DOCUMENTING RESULTS IN PHIS

HAV RESULTS

A. If, while performing the HAV, IPP do not identify any noncompliance and find no evidence of potential problems in the food safety system, they are to document the results of the HAV task in PHIS and document that there is compliance with each of the regulatory requirements. If IPP are unable to determine whether their findings represent regulatory noncompliance, they are to discuss the issue with their supervisor before making a determination.

B. If IPP identify noncompliance, they are to document the noncompliance in accordance with FSIS PHIS Directive 5000.1, Verifying an Establishment's Food Safety System and, if needed, discuss the noncompliances with their supervisor to determine if additional action may be necessary.

C. If IPP have questions regarding whether the establishment is implementing the prerequisite program as described or does not maintain sufficient records to support its decisions, IPP may wish to discuss their concerns with their supervisor. The supervisor may determine that it is necessary to request the assistance of an EIAO, who may conclude that the prerequisite program is not capable of supporting the decisions made in the hazard analysis. If the supervisor or EIAO determines that the implementation of the prerequisite program no longer supports the decisions made in the hazard analysis, IPP are to do the following:

1. Document an Noncompliance Record (NR) as set out in FSIS PHIS Directive 5000.1, Chapter IV, citing 9 CFR 417.5(a)(1)

2. Verify that the establishment conducts the following activities:

    a. Reassesses its hazard analysis as required in 9 CFR 417.4(b) because the decisions made in the hazard analysis may no longer be supported as per 9 CFR 417.5(a)(1); and

    b. Provides data supporting the decisions made during this reassessment as required in 9 CFR 417.5(a)(1)

D. If IPP determine that the failure to implement a prerequisite program results in a hazard being RLTO, or that an unforeseen hazard has occurred, they are to:

1. Describe those findings in a record-keeping noncompliance citing 9 CFR 417.5(a)(1)

2. Verify that the establishment performs and documents corrective actions in accordance with 9 CFR 417.3(b), including controlling the affected product;

2. Retain affected product if the establishment does not have other information to

demonstrate that the product is not adulterated; and

3. Seek guidance through supervisory channels regarding what additional actions may be necessary.

E. In establishments that utilize alternative procedures in place of waived provisions of the regulations as set out in a *Salmonella* Verification Program (SIP) letter, IPP are to document noncompliance in accordance with the instructions in FSIS Directive 5020.1, XII.

QUESTIONNAIRE TAB IN PHIS

When documenting the performance of the HAV, the Questionnaire tab will be available in PHIS. IPP are to complete the questionnaire each time they perform the HAV.

IX. SUPERVISORY PERSONNEL RESPONSIBILITIES

A. "Supervisory personnel" refers to any Office of Field Operations (OFO) personnel that supervise IPP who conduct verification activities in official establishments, including Supervisory Public Health Veterinarians (SPHV), Supervisory Consumer Safety Inspectors (SCSI), the Inspector-in-Charge (IIC), Multi-IPPs Supervisors, and Front Line Supervisors (FLS).

B. The supervisor plays a key role in ensuring that decisions made by IPP are consistent with FSIS statutory authority and Agency policy, and that the IPP's duties are performed in accordance with prescribed inspection methods and procedures addressed in this directive.

C. FSIS supervisory personnel are to discuss the key points identified in this directive with IPP. In addition, supervisory personnel are to discuss the verification responsibilities addressed in this directive to ensure that IPP understand their role in verifying the hazard analysis.

D. FSIS supervisory personnel are to discuss that IPP are responsible to verify that establishments have documentation, in accordance with 9 CFR 417.5(a)(1), to support food safety decisions that an establishment has made in its hazard analysis.

E. Supervisory personnel are to verify that IPP are correctly applying the inspection methodology, are making informed decisions, are properly documenting findings, and are taking the appropriate enforcement actions as instructed in this directive.

F. Supervisory personnel are to refer to the current version of the FSIS Guide for Conducting In-Plant Performance System (IPPS) Assessments for additional guidance and instructions.

X. DATA ANALYSIS

Annually, the Data Analysis and Integration Group within the Office of Data Integration and Food Protection will review PHIS data on verification activities to determine whether any noncompliance trends that exist are related to the HAV. The analysis will include a review of repetitive noncompliances that are linked by the IPP to determine whether a trend exists. Results from these analyses are to be shared with OFO and the Office of Policy and Program Development to determine whether the findings suggest potential improvements that can be made in verification procedures or instructions to IPP.

XI. SUBMITTING QUESTIONS REGARDING THIS DIRECTIVE THROUGH askFSIS

A. Please refer questions through askFSIS at http://askfsis.custhelp

B. When submitting a question via askFSIS, log into askFSIS then, using the **Submit a Question** tab, enter the following information in the fields provided:

- Subject Field: Enter **FSIS Directive 5000.6** or **HAV**
- Question Field: Enter your question with as much detail as possible.
- Product Field: Select **General Inspection Policy** from the drop-down menu.
- Category Field: Select **Regulations/Agency Issuances** from the drop-down menu.
- Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu.
- When all fields are complete, press the **Submit** button.

C. Questions can also be referred to the Policy Development Division by telephone at 1-800-233-3935.

Acting Assistant Administrator
Office of Policy and Program Development

ATTACHMENT 1

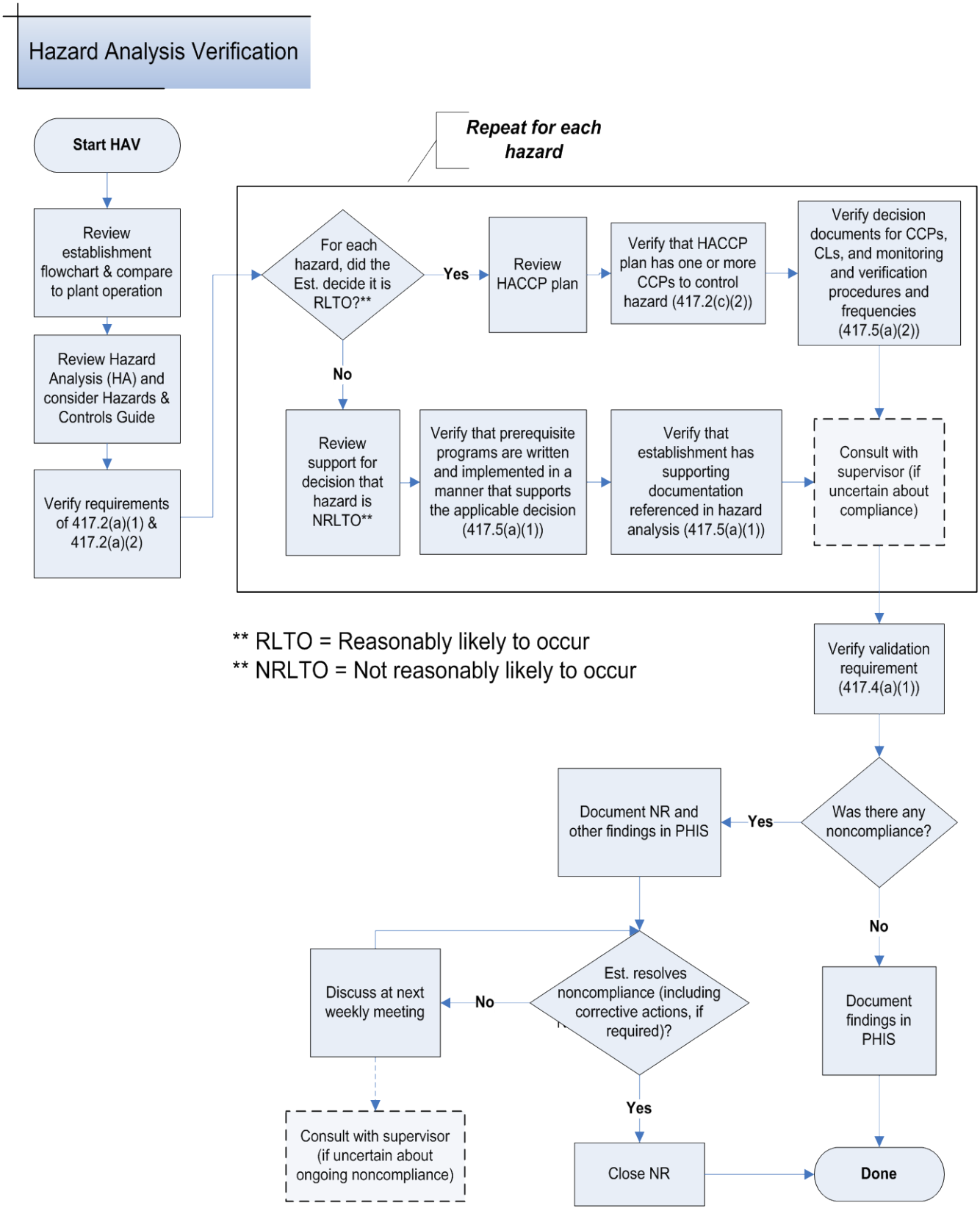
Hazard Analysis Verification (HAV) Flow: Refer to applicable sections of this Directive for additional information about each step.

Step:	Description:	Verification Questions:	Reg. citation
Step 1	Review flowchart and compare to production process.	• Does the flowchart represent the actual production process?	417.2(a)(2)
Step 2	Review the hazard analysis and consider guidance in the FSIS Meat and Poultry Hazards and Controls Guide.	• Does the flowchart or hazard analysis identify the intended use or consumers of the product? • Does the hazard analysis appear to consider the relevant food safety hazards for the establishment's process, product, and intended use? • For each hazard, does the establishment consider it reasonably likely to occur or not reasonably likely to occur (NRLTO)?	417.2(a)(2) 417.2(a)(1)
Step 3	For each hazard the establishment considers reasonably likely to occur, verify that the HACCP plan includes one or more CCPs to control it. *If no hazards are reasonably likely to occur, skip to step 4.*	• Does the establishment have one or more CCPs to control the hazard in each product or process where it is reasonably likely to occur? • Does the establishment have information to support the CCPs, critical limits, monitoring, and verification procedures?	417.2(c)(2) 417.5(a)(2)
Step 4	For each hazard the establishment considers not reasonably likely to occur, determine what evidence the establishment uses to support the decision.	• Does the establishment prevent the hazard by implementing a prerequisite or other supporting program (SSOP, GMP, SOP, etc.)? – *proceed to step 5.* • Does the establishment support the decision with other documentation besides a prerequisite or	417.5(a)(1)

		other supporting program? *– proceed to step 6.*	
Step 5	Review prerequisite programs and other supporting programs, including written programs, records, and employee activities.	• Does the written program appear to be designed to prevent the relevant hazard? • Do the records and your observations indicate the program is consistently being implemented as written? • Do the records and your observations indicate that the program prevents the relevant hazard on an ongoing basis?	417.5(a)(1)
Step 6	Review other supporting documentation.	• Does the establishment have copies of the documents referenced in the hazard analysis? • Do the documents appear to apply to the current establishment process?	417.5(a)(1)
Step 7	Review establishment validation documents, including scientific supporting documents and validation data. Verify implementation of the pre-requisite program is as described in the written program.	• Do the establishment CCPs and prerequisite programs follow the parameters in the scientific documents? • Does the validation data seem to show that the establishment's CCPs and prerequisite programs are effectively controlling or preventing the relevant hazards?	417.4(a)(1)
Step 8	Verify reassessment requirements. Check most recent signature date for each HACCP plan.	• Has the establishment reassessed at least once in the most recent calendar year? • Has the establishment reassessed, if necessary, in response to any changes that could affect the hazard analysis? • Has the establishment reassessed, if necessary, in response to any unforeseen	417.4(a)(3) 417.3(b)

		hazard? • Has the establishment documented the results of the reassessment?	417.4(a)(3)(ii)
Step 9	Document your findings.	• No problems detected – document HAV results in PHIS. • Clear case of noncompliance – document HAV results on NR in PHIS and notify your supervisor. • Concerns about the establishment HACCP system – discuss situation with your supervisor for assistance in determining how to proceed. Document HAV results in PHIS.	

ATTACHMENT 2



ATTACHMENT 3-FLOW CHART

A. The establishment may have a single flowchart that shows the entire production process or may have multiple flow charts that show each part of the process. In some establishments, the flowchart may be part of the HACCP plan, while in others it may be a separate document. All of these approaches to presenting the flow chart are acceptable.

B. There is no required format or specified structure of the flow chart. It is up to the establishment to determine the format it wishes to use that will enable the establishment to ensure that the flow chart for the entire production process contains the information required by 9 CFR 417.2(a)(2).

C. It is up to the establishment to decide what it will define as a "step" in its operation. In addition, FSIS does not dictate the level of detail that must be in a flow chart. The establishment may decide to incorporate several production activities into one step in the flow chart. However, the establishment must consider all the food safety hazards associated with all the activities conducted at that step in order to meet the requirement of 9 CFR 417.2(a). The flowchart or hazard analysis must document the operations considered at each step of the process.

> ***EXAMPLE:*** *An establishment may perform several different activities when processing raw, non-intact products (e.g., cutting, needle tenderizing, injecting, and tumbling). The establishment can group these activities into the single step of "processing" on the flowchart, as long as the hazard analysis addresses all the potential hazards associated with each activity.*

ATTACHMENT 4- REVIEWING SUPPORT FOR CCPS AND CRITICAL LIMITS

A. 9 CFR 417.5(a)(2) requires the establishment to maintain the following types of supporting documentation for the HACCP plan:

    1. Decisionmaking documents associated with the selection and development of CCPs and critical limits;

    2. Documents supporting the selection of monitoring procedures and their frequencies; and

    3. Documents supporting the selection of verification procedures and their frequencies.

B. 9 CFR 417 does not dictate a specific format regarding how supporting documentation must look or how it is used by the establishment. The documentation should describe how the establishment reached its decision and may refer to additional supporting documents.

C. If the establishment does not have documentation to support the development of CCPs, critical limits, and monitoring and verification procedures, a failure to comply with 9 CFR 417.5(a)(2) exists.

ATTACHMENT 5- PREREQUISITE PROGRAMS

A. The Federal Register, Vol. 61, July 25, 1996, Page 38806 established Sanitation SOPs as prerequisite programs and indicates that "Sanitation SOPs are important tools for meeting existing statutory sanitation responsibilities and preventing direct product contamination or adulteration."

B. Further, in the Federal Register, Vol. 67, October 7, 2002, Page 62325, FSIS addressed the use of prerequisite programs in relation to the control of *E. coli* O157:H7 and stated that "FSIS expects the supporting documentation concerning prerequisite programs other than Sanitation SOPs to include the programs' procedures and operational controls in writing".

C. In addition, Federal Register, Vol. 68, June 6, 2003, Page 34224 addressed the use of prerequisite programs, in relation to the control of *Listeria* monocytogenes (Lm), stating that establishments must maintain "decision-making documentation" that is associated with the hazard identification and selection of CCPs in a HACCP plan. An establishment is required by 9 CFR 417.5 to maintain such documentation because the existence of an effective Sanitation SOP or other prerequisite program affects the outcome of an establishment's hazard analysis."

D. Prerequisite programs are the foundation on which effective HACCP systems are built because they provide the basic environmental and operation conditions that are necessary for safe food production. In many cases, establishments reference prerequisite programs in the hazard analysis as playing an important role in ensuring that potential hazards are not reasonably likely to occur (NRLTO). Prerequisite programs may frequently function across product lines and are often managed as facility-wide programs rather than being process or product specific. A prerequisite program's purpose is not to ***control*** a food safety hazard that was identified through the hazard analysis as being RLTO, but instead, its purpose is to ***prevent*** the hazard from ***becoming*** RLTO. Keep in mind, in absence of the prerequisite program, the identified hazard will exist, and a HACCP plan is required to be developed.

E. Prerequisite programs can represent a wide range of establishment programs and may encompass food quality issues. Programs referenced in the hazard analysis as support that potential hazards are not reasonably likely to occur need to include information that is sufficient to ensure that data continue to support decisions in the hazard analysis.

F. Certain prerequisite programs address specific regulatory requirements, such as Sanitation SOPs or pest control programs. Whether those regulatory requirements are being met will be verified by FSIS as part of their verification activities.

G. Incidental occurrences of failing to fully implement prerequisite programs may not create a food safety concern or necessitate action on the product. In contrast, deviations from the controls in a HACCP plan would cause food safety concerns and generally require action on the affected product.

H. When a prerequisite program is used to support decisions in the hazard analysis, it is considered to be supporting documentation in accordance with by 9 CFR 417.5(a)(1) , and any records associated with the prerequisite program must be available for FSIS review. FSIS has recommended that the documentation include records that demonstrate that the program is being implemented and is effective, and that the potential food safety hazard is not RLTO. Without this documentation, FSIS would question the adequacy of the establishment's HACCP system and hazard analysis.

I. The regulations in 9 CFR part 417 do not include specific requirements (e.g., monitoring, recordkeeping, corrective actions) for prerequisite programs. However, without maintaining some level of documentation that demonstrates that the prerequisite program has been effectively implemented and serves its intended purpose, it may be difficult for establishments to support a decision that a food safety hazard is not RLTO or to comply with the requirements of 9 CFR 417.5(a)(1) and 9 CFR 417.5(a)(2).

J. When the establishment determines that a particular hazard is not RLTO because the establishment implements a prerequisite program (including Sanitation SOP, SOP, Good Manufacturing Practices (GMP), purchase specifications, or other program), it is necessary that the establishment actually have a prerequisite program, is implementing it appropriately, and have records associated with the prerequisite program that are sufficient to support that the hazard is not RLTO to comply with 9 CFR 417.5(a)(1).

K. It is essential that the establishment's employees implement the procedures in the prerequisite program in a manner that prevents the relevant hazard from being reasonably likely to occur and that generates records that show that the relevant food safety hazard is not reasonably likely to occur.

L. 9 CFR 417.5(f) requires that all records required under 9 CFR Part 417 be available for official review by FSIS inspection personnel.

N. In general, the failure to comply with one aspect of the prerequisite program may not result in direct product contamination or adulteration; however, the safety of the product or the adequacy of the food safety system may need further evaluation.

O. In addition, if prerequisite program records are being maintained, failure to fully complete the record does not automatically mean that the prerequisite program is not being implemented effectively, or that the records do not support the decisions made in regard to the program. However, failing to implement the procedures in a prerequisite program, or evidence that the program is not effectively preventing the hazard, indicates that the establishment does not have adequate support for the relevant decisions in its hazard analysis. Failure to support hazard analysis decisions is cause for IPP to document noncompliance with 9 CFR 417.5(a)(1) and may be grounds for an additional enforcement action.

ATTACHMENT 6 - VALIDATION

A. Validation is composed of two parts:

1. Scientific support: the theoretical principles, expert advice from processing authorities, scientific data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately address specific hazards.

2. In-plant validation: the in-plant observations, measurements, microbiological test results, or other information demonstrating that the control measures, as written into a HACCP system, can be effectively implemented within a particular establishment, and that when the are, they achieve the intended food safety objective.

B. Generally, establishments should use the same critical operational parameters as those in the support documents. In some circumstances, establishments may be able to support using critical operational parameters that are different from those in the support documents (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures). In these cases, establishments should provide justification for why the levels chosen are at least as effective as those in the support documents. This justification is needed because higher levels of a critical operational parameter may not always be equally effective. For example, antimicrobial agents may only be effective within a range of concentrations, after which point efficacy may decrease. Similarly, higher processing temperatures may result in the surface of the product drying out before adequate lethality is achieved. In addition to ensuring that the levels chosen are at least as effective as those in the support document, establishments should ensure the levels are also safe and suitable.

NOTE: Critical operational parameters are the specific conditions that the intervention or treatment must operate under for it be effective. Such parameters include but are not limited to pH, concentration, time, temperature, humidity, dwell time, water activity, pressure, or other equipment settings or calibration.