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

FSIS PHIS DIRECTIVE	5000.1	4/11/11

VERIFYING AN ESTABLISHMENT'S FOOD SAFETY SYSTEM

CHAPTER I - GENERAL

I. PURPOSE

A. This directive provides comprehensive direction to Inspection Program Personnel (IPP) on how they are to protect the public health by properly verifying an establishment's compliance with the pathogen reduction, sanitation, and HACCP regulations. This directive also provides comprehensive direction for import inspection personnel to verify compliance with sanitation regulations in official import inspection establishments and for taking enforcement actions. This directive provides documentation procedures under the Public Health Information System (PHIS).

NOTE: In this directive, the term "Inspection Program Personnel" refers to both Consumer Safety Inspectors and Import Inspection Personnel.

B. Import Inspection Personnel are to refer only to the following chapters of this directive as they relate to sanitation (Sanitation Standard Operating Procedures (Sanitation SOPs),and Sanitation Performance Standards(SPS)) and documentation/enforcement at an Official Import Establishment

- Chapter I – General
- Chapter II – Sanitation
- Chapter V – Documentation and Enforcement
- Chapter VI – Rules of Practice

NOTE: In the chapters identified above Import Inspection Personnel are to use the same sections referenced for IPP interchangeably. For specific import methodology please see Attachment 2.

KEY POINTS:

- *Changes in inspection procedures resulting from the implementation of the Public Health Information System (PHIS) to replace the Performance Based Inspection System (PBIS);*

- *HACCP 01/02 procedures have been replaced by the HACCP Implementation Verification procedure for the respective HACCP categories. See Chapter II: HACCP for details;*

- *IPP are now to perform a new verification procedure: the Hazard Analysis Verification (HAV);*

- *Updated instructions for documenting results of verification activities in PHIS, including findings of regulatory compliance or noncompliance;*

- *Updated instructions for completing Noncompliance Records (NRs), Memorandums of Interview (MOIs), and other types of documentation within PHIS; and*

- *A new section on supervisory responsibilities with respect to this directive.*

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR parts 416, 417, and 500
9 CFR 310.25 and 381.94
The PHIS User Guide is available via the FSIS Intranet on the PHIS page under Resources

V. BACKGROUND

A. Section 608 of the Federal Meat Inspection Act (FMIA) and Section 456 of the Poultry Products Inspection Act (PPIA) authorize the Secretary to require meat and poultry establishments to be maintained and operated in such a sanitary manner as to prevent adulterated products from entering commerce.

B. Based on the authority of the FMIA and PPIA, FSIS applies the mark of inspection to products that Agency inspection personnel find are not adulterated. To produce unadulterated product, an establishment must operate in accordance with a food safety system that includes assessing what food safety hazards are reasonably likely to occur in the establishment's production process, maintaining the conditions prerequisite to producing a safe product, and maintaining those controls necessary to prevent the

development of hazards during the operation of the establishment.

C. To achieve these results, the establishment needs to have a valid food safety system. The food safety system that FSIS requires is the Hazard Analysis Critical Control Point system, or HACCP. A HACCP system consists of the following components:

1. A flowchart describing the steps in each process and product flow.

2. The hazard analysis and its supporting documentation.

3. The HACCP plans the establishment implements to control food safety hazards that have been identified as reasonably likely to occur.

4. Any programs or procedures the establishment uses to maintain sanitary conditions or to support decisions in the hazard analysis about hazards that are not reasonably likely to occur. These programs include the establishment's Sanitation Standard Operating Procedures (Sanitation SOPs), measures taken to meet the Sanitation Performance Standards, and any prerequisite programs or other supporting programs.

VI. COMMUNICATING WITH ESTABLISHMENT MANAGEMENT

A. When IPP rotate into an assignment, or when IPP are newly assigned to an establishment, they are to review the establishment's history, which is reflected in the establishment's home page in PHIS. If the IPP have questions or concerns about the establishment's history, they are to consult with the Frontline Supervisor (FLS) or the Regional Import Office Supervisor (RIFS). IPP are to be familiar with the following elements of the establishment history:

1. PHIS records of recent noncompliances at the establishment, especially those from the last 90 days, including the corrective and preventive measures that the establishment provided to address the noncompliances;

2. The results of any recent or ongoing FSIS verification sampling activities from the PHIS establishment home page;

3. The findings and outcomes from the most recent Food Safety Assessment conducted at the establishment. These results are available through PHIS; and

4. If an enforcement action has been deferred, or if a suspension has been held in abeyance at the establishment, the Agency's expectations, as described in the verification plan, the results of the Agency's findings from verifying the effectiveness of the corrective and preventive measures that were proffered by the establishment. IPP are also to become familiar with the conditions that led

the Agency to bring the enforcement action that has been deferred or resulted in the suspension that is in abeyance.

VII. ENTRANCE MEETING

A. When IPP rotate into an assignment or conduct an inspection at an establishment for the first time, they are to:

1. Review the establishment's Sanitation SOPs, HACCP plan, and prerequisite programs;

2. Review the establishment profile in PHIS to become familiar with the information in the profile. As IPP become familiar with the establishment operations, they are to update the PHIS establishment profile appropriately;

3. Have an entrance meeting (at the first weekly meeting) with the establishment management to familiarize themselves with the establishment and inquire about the specific operations of that establishment. Also, if the IPP have questions based on their review of the programs, they are to ask these questions at the meeting; and

4. Take notes at the entrance meeting and document the notes in a MOI in PHIS and provide a copy to the establishment.

B. IPP are to ask establishment management about the location of the applicable records and the local arrangements for FSIS personnel to access and review the records. Establishments are required to provide access to records needed by IPP to perform their duties. However, IPP are to review the necessary records in the location specified by establishment management. IPP are not to maintain any copies of the establishment's written programs or data from such programs in the inspection office.

C. PHIS has a feature that allows IPP to document notes or concerns for meetings with establishment management. IPP are to use this feature to generate an agenda for the weekly meeting. This feature will help ensure that all appropriate issues are covered and documented.

VIII. WEEKLY MEETING

A. IPP are to have weekly meetings with establishment management to discuss issues of concern. The meetings may involve discussing individual noncompliances, developing trends of noncompliance, findings on the part of the IPP that are not noncompliances but warrant discussion, or other topics that arise. Also, establishment management may wish to share information or concerns at the meetings.

B. On a periodic basis, about once a month, IPP are to ask establishment management at the weekly meeting whether it has made any changes in the production process or

other changes that could affect the safety of the product. If IPP learn that establishment management has made a change in its process, based on the nature of the change, IPP are to perform the appropriate verification activities outlined in this directive. If IPP are unsure how to proceed, they are to contact their supervisor for guidance.

C. IPP are to take notes at the weekly meetings and are to document the notes in a MOI in PHIS. IPP are to provide establishment management with a copy of the MOI.

D. IPP are to update the applicable sections of the establishment profile in PHIS as necessary to ensure that it accurately reflects establishment's operations and programs. See FSIS Directive 5300.1 for instructions on maintaining the establishment profile.

IX. GENERAL PHIS VERIFICATION THOUGHT PROCESS

A. IPP are to follow the thought process of:

1. Gather all available information;

2. Asses the significance and meaning of the information gathered;

3. Determine whether the information supports a finding of regulatory compliance; and

4. Put it all together.

B. To gather all available information, each verification procedure in this directive requires IPP to verify that the establishment complies with certain regulatory requirements. When they perform each verification procedure, IPP are to begin by collecting information that will help them determine whether the establishment is meeting the applicable regulatory requirements. In order to gather the appropriate information, IPP are to do the following:

1. Review establishment programs and supporting documentation;

2. Review establishment records documenting implementation of its programs;

3. Observe establishment employees implementing the establishment's programs and procedures;

4. Observe the conditions in the establishment; and

5. Observe product and occasionally take measurements as specified in the establishment programs.

C. To asses the significance and meaning of the information gathered, IPP are to consider what each piece of information, either taken separately or with other findings,

says about how the food safety system is functioning to ensure that products are safe and wholesome (not adulterated). IPP are also to consider information they have gathered in the context of past findings and to look for any patterns or trends in the findings. IPP are to consider the following:

1. Are conditions in the establishment getting worse over time?

2. Are the same or similar problems occurring repeatedly?

3. Is the establishment responding effectively and in a timely manner to problems that do arise?

D. To determine whether the information supports a finding of regulatory compliance, IPP are to decide whether, based on all the available information, one of the following findings emerges from the evidence:

1. That the establishment is not maintaining sanitary conditions;

2. That the establishment has produced or shipped adulterated products;

3. That the establishment's food safety system is not effectively controlling the relevant food safety hazard; and

4. That the establishment is not meeting the requirements in one or more regulations.

NOTE: If IPP are uncertain whether the information supports a particular determination, they are to discuss the issue with their immediate supervisor. IPP in slaughter establishments are to consult with a Public Health Veterinarian (PHV) or Supervisory Consumer Safety Inspector (SIPP) assigned to the establishment if they are uncertain about whether the available information supports a particular determination. PHVs are to consult with the FLS or RIFS as necessary. IPP in processing establishments are to consult with the IPP or FLS or RIFS.

E. To put it altoghther, it is important that IPP consider each piece of information in the context of the food safety system. For example, IPP may identify several minor concerns regarding the hazard analysis. Each one, by itself, may not be sufficient to determine noncompliance, but considered together in the context of the establishment's total system, the concerns may indicate that there is a potential systemic problem. Thus, each finding should be evaluated for what it shows regarding the effectiveness of the food safety system and the potential for developing product adulteration.

F. The following questions will help IPP to consider the significance of each finding for the food safety system:

1. Is this piece of information part of a pattern?

EXAMPLE: If the establishment skipped a measurement for a prerequisite program, is this an isolated incident, or does the establishment regularly fail to implement prerequisite procedures?

2. Is there other information to indicate that the system is working or is not working?

EXAMPLE: An establishment's prerequisite program for received products requires that they come with certificates of analysis (COA) from suppliers, as well as periodic testing of incoming product. If the establishment failed to receive a COA for a particular product, how did the establishment respond in its decisions on whether to use the product?

3. Does the information seem to agree with the other available information about the food safety system?

EXAMPLE: The establishment uses a prerequisite program to support that a hazard is not reasonably likely to occur in incoming products, and the records appear to show that the particular hazard is being prevented. The establishment's testing of finished product for the hazard finds positive results.

4. Do these results support each other, or is there an apparent contradiction?

G. When IPP document noncompliance related to the hazard analysis, supporting documentation, and prerequisite programs, they are to describe why the findings led them to a determination of noncompliance.

H. Many establishments have developed unique and complicated food safety systems. FSIS understands that IPP will not always be able to determine the significance of their findings. When IPP have concerns about the establishment's hazard analysis but are unable to determine whether their findings constitute noncompliance, they should discuss their concerns with their supervisor.

I. The safety of meat and poultry products depends on establishments developing and implementing of effective food safety systems. IPP are in the best position to identify concerns about the effectiveness of an establishment's food safety system because they are familiar with the daily operations and actual conditions in the establishment. By identifying concerns about the hazard analysis, supporting documentation, or prerequisite programs, IPP are acting to protect the public health by preventing products that present a risk from entering commerce.

J. If IPP have concerns that there are systematic problems with the establishment's food safety system, or that there is reason to believe that product may have become adulterated, IPP are to bring these issues to the attention of their supervisor immediately.

X. SUPERVISORY RESPONSIBILITIES

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

B. FSIS supervisory personnel are to engage in discussion with IPP about their findings related to the establishment's HACCP system. Supervisors are to assist IPP with concerns raised about establishment documentation and prerequisite programs that support decisions in the hazard analysis and assist IPP in making supportable decisions about whether the establishment documentation meets the requirements of 9 CFR 417.5(a)(1).

C. Supervisors are to discuss how establishment testing results and other data that may not explicitly be part of the establishment's CCPs or prerequisite programs might influence IPP's thought process regarding the effectiveness of an establishment's HACCP system. Supervisors are to assist IPP in considering an establishment's hazard analysis, prerequisite programs, HACCP plans, Sanitation SOPs, and other programs in an integrated way and discuss ways in which findings in one area may impact other parts of a particular establishment's HACCP system.

D. Supervisory personnel are to ensure 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

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

CHAPTER II - SANITATION

PART I – INTRODUCTION

A. The FMIA and PPIA both provide that a meat or poultry product is adulterated if it has "been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." 9 CFR 416.1 requires establishments to "be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated."

B. Insanitary conditions may be isolated (e.g., damaged box, product residue in containers from previous day's production) and only affect a limited area of an establishment and not affect the sanitary condition of other product or equipment. In such cases, IPP are to document the noncompliance, take the appropriate enforcement action (e.g., tag product or equipment), and verify that the situation is addressed.

C. In other instances, the insanitary conditions may be such that the product produced in the establishment has become contaminated with filth or otherwise rendered injurious to health. For example, if an inspector finds rodent infestation in an establishment, the product prepared, packed, or held under these conditions may have become contaminated with rodent excreta pellets, and IPP may need to immediately withhold the marks of inspection and contact the DO.

D. There are so many ways that insanitary conditions can cause product to be adulterated that they cannot all be listed. Instead, this chapter of this directive explains the intent of the sanitation regulations and gives examples of some of the ways IPP can determine whether a meat or poultry establishment is operating under insanitary conditions.

E. Inspected establishments are to satisfy two sets of regulatory requirements concerning sanitation: The Sanitation SOP requirements and the SPS. Under the Sanitation SOP requirements, each establishment is to develop, implement, and maintain written procedures for the actions it takes daily, before and during operations, to prevent product from being directly contaminated and adulterated. An establishment's Sanitation SOP typically covers the scheduled, daily pre-operational and operational cleaning and sanitation of equipment and surfaces that may contact product directly. The SPS regulations cover all of the other aspects of establishment sanitation that can affect food safety, e.g., pest control, adequate ventilation and lighting, and plumbing systems. These two sets of regulations overlap somewhat in the establishment activities they cover. Some establishments may address certain sanitation problems within their HACCP plans.

PART II - SANITATION PERFORMANCE STANDARDS (SPS)

I. VERIFYING SPS UNDER PHIS

A. IPP are to perform the SPS Verification procedure when it appears in the PHIS inspection task list as a routine procedure. IPP may also initiate the SPS Verification procedure as a directed procedure when conditions suggest that an insanitary condition may occur or when they observe noncompliance with the SPS regulatory requirements (9 CFR 416.1 – 416.5).

B. The SPS verification procedure in PHIS allows IPP to document verification of some or all applicable sanitation regulatory requirements. Each time they perform the SPS verification procedure, IPP are to verify one or more of the SPS regulatory requirements. Over the course of time, IPP are to verify all SPS regulatory requirements. In slaughter establishments, IPP are to verify that the establishment maintains control of the sanitary dressing process as part of the appropriate verification procedure in addition to verifying the other SPS requirements. IPP are to refer to the applicable directive on verifying sanitary dressing in slaughter establishments for specific instructions.

C. In general, IPP are to verify compliance with the SPS regulatory requirements by directly observing the conditions in the establishment and observing establishment employees. However, IPP are also to review any applicable establishment records to verify that the establishment maintains sanitary conditions. For example, 9 CFR 416.4(c) and 416.2(g) require establishments to maintain certain records (see specific sections below). Establishments may incorporate SPS procedures as part of its Sanitation SOPs, in which case they would have to meet the relevant recordkeeping requirements for Sanitation SOPs.

NOTE: Any establishment programs, documents, or records that relate to maintaining sanitary conditions (i.e. meeting the SPS requirements) are available to IPP for verification purposes. See FSIS Directive 5000.2 Review of Establishment Data by Inspection Personnel for additional information regarding establishment records.

D. When time allows, IPP are to verify multiple SPS regulatory requirements in multiple areas of the establishment each time they perform the SPS verification procedure.

E. In many cases, IPP will even be able to verify one or more SPS requirements while observing the establishment during other verification activities. Whenever IPP are observing conditions and operations in the establishment as part of their verification or other duties, they are to be aware of the sanitary conditions and verify that the establishment is meeting the SPS requirements by maintaining the facilities, equipment, and utensils in a sanitary manner and by following practices that protect product from adulteration.

F. IPP use the SPS Verification procedure to verify compliance with the SPS

requirements in one or more areas of the establishment. If IPP determine that the establishment is meeting the sanitation regulatory requirements in a particular area of the establishment, they are to document those findings of compliance in the PHIS in accordance with Chapter IV of this document. IPP are to use professional knowledge and good judgment in making the determination whether the establishment meets SPS requirements. IPP are to assess the situation in the establishment and then determine whether the situation creates insanitary conditions, causes adulteration of product, or prevents FSIS from performing inspection. This means that there can be conditions in the facility that are less than perfect but that would not represent noncompliance with the SPS regulatory requirements because they are not creating insanitary conditions, adulterating product, or preventing FSIS personnel from performing inspection activities.

G. If the establishment is not meeting the regulatory requirements, IPP have the responsibility to document how the establishment is not meeting regulatory requirements in PHIS and initiate the appropriate regulatory control actions to gain regulatory compliance. The examples used in this section are to demonstrate the decision-making process that IPP may use in making regulatory compliance determinations.

II. GENERAL SPS REGULATIONS

Section 416.1 of 9 CFR states: *Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.*

A. 9 CFR 416.1 gives the general requirement for each establishment to ensure that the entire establishment is operated and maintained in a sanitary manner to prevent product adulteration. The FSIS regulations in 9 CFR 416.2 to 416.5 set forth more specific performance standards that each official establishment is to meet to prevent the creation of insanitary conditions that could cause the adulteration of meat and poultry products. An establishment must meet these sanitation requirements for the federal mark of inspection to be applied to its products. Some of the SPS address conditions within or around the establishment (e.g., ventilation, lighting, facility and equipment construction, and maintenance of the grounds). Other SPS address establishment operations and so may be met by an establishment through its Sanitation SOP (e.g., sanitizing of food contact surfaces) or its HACCP plan (e.g., water reuse).

B. In all cases, when they determine noncompliance with the SPS requirements, IPP are to cite the applicable specific performance standard in 9 CFR 416.2 to 416.5. IPP are also to cite 9 CFR 416.1 in situations where findings indicate that an establishment systematically fails to maintain sanitary conditions, and that product adulteration may occur as a result. When considering whether to cite 9 CFR 416.1, IPP are to consider whether their findings support that the establishment has systematically failed to maintain the facility in a sanitary manner. Multiple isolated SPS noncompliances do not necessarily demonstrate noncompliance with 9 CR 416.1. IPP are to consider whether those individual noncompliances can be tied together to show a pattern or trend of

systematic failure to maintain sanitary conditions.

C. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.1:

1. Insanitary conditions from one or more causes occur throughout the establishment or in multiple different areas at the same time indicating systematic failure to maintain control of sanitary conditions.

EXAMPLE: IPP observe rodent droppings in several different product storage areas and establishment records indicate that the pest management contractor has missed his three previous monthly visits. This combination of findings indicates that the rodent droppings are likely to be a systematic problem resulting from the establishment's failure to implement a consistent pest management program.

2. Insanitary conditions from the same cause occur in one or more areas repeatedly and the establishment's responses do not effectively prevent repetitive noncompliances.

EXAMPLE: IPP document noncompliance with 9 CFR 416.2(d) for condensation in the storage cooler and several of the other refrigerated portions of the establishment four times over the course of several weeks. Establishment management proposes several different ways to resolve the problem, but their implementation is haphazard and is not effective to prevent the condensation. This combination of findings indicates that the condensation is a systematic problem resulting from the establishment's failure to take effective actions to prevent the repeated formation of insanitary conditions.

III. GROUNDS AND PEST CONTROL

Section 416.2 (a) of 9 CFR states: *The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.*

A. IPP are to observe conditions on the grounds around the establishment to verify that there are no situations that could cause an insanitary condition in the establishment. IPP are also to observe conditions around and within the establishment to verify that there are no areas that would allow harborage or breeding of pests (e.g. rodents or insects). IPP are also to verify that the establishment has a pest management program. Although an establishment must have a pest management program, it need not be written. If establishment management decides to have a written program, it may or may not be included in the Sanitation SOP. If the establishment has included a written pest

management program as part of the Sanitation SOP, IPP are to verify that the procedures in the Sanitation SOP are being implemented and monitored, that the establishment is documenting in the Sanitation SOP records the monitoring of the procedures, and that any necessary corrective actions are taken.

B. IPP are also to review any available information regarding any chemicals used for pest control and observe how the establishment uses those chemicals. IPP are to verify that the substances are safe and effective under the conditions of use and that they are stored and used in a manner that will not result in product adulteration. IPP are to review any applicable documentation about the pest control substances. IPP are to request more information from establishment management when necessary to determine whether pest control substances are safe for their intended uses within the establishment.

C. If the establishment contracts with an outside company for pest control service, IPP are to verify that establishment management understands the contractor's pest control program, maintains documentation to demonstrate that any chemicals used by the contractor are safe and effective under the conditions of use. IPP are also to observe conditions in and around the establishment to verify that the contractor's program works to prevent breeding and harborage of pests.

D. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.2(a):

1. There are areas around or within the establishment that allow harborage or breeding of pests. These might include tall weeds, discarded equipment, poorly maintained trash receptacles, or similar situations close to the establishment.

2. There is evidence of pests or pest activity within the establishment (e.g. rodent droppings or flies in production areas).

3. Establishment management is unable to demonstrate that pest control substances are safe under the conditions of use.

4. Establishment employees do not use pest control substances in accordance with label directions.

5. Pest control substances are used or stored in a manner that results in insanitary conditions.

6. There is any other condition on the grounds of the establishment that results in insanitary conditions within the establishment.

E. IPP are to use judgment in making determinations of noncompliance. A determination of noncompliance depends on the formation of insanitary conditions.

EXAMPLE: IPP observe tall weeds around the facility. Before making a determination about regulatory compliance, IPP are to determine whether the weeds and grass permit harborage and breeding. If the weeds are scattered and do not permit harborage and breeding, there is not noncompliance. If the weeds are so dense as to permit concealment and breeding, there is noncompliance with these regulations.

F. IPP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

IV. CONSTRUCTION

Section 416.2 (b) of 9 CFR states:

(1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

A. When verifying compliance with 9 CFR 416.2(b), IPP are to assess the construction of the facility in one or more areas.

B. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.2(b):

1. The establishment's structures, rooms, and compartments cause insanitary conditions or product adulteration because they are not of sound construction, maintained in good repair, or are to small to allow appropriate processing, handling, or storage of product.

2. The establishment does not clean and sanitize the walls, floors, and ceilings as necessary to prevent insanitary conditions.

3. The establishment does not maintain walls, floors, ceilings, and any outside

openings in a manner that prevents entry of vermin such as flies, rats, and mice.

4. The establishment does not handle, process, or store edible products and inedible products in a manner that prevents insanitary conditions. The establishment does not implement adequate measures to prevent possible cross-contamination between inedible and edible products. Such measures might include separate areas for processing, handling, or storage of inedible items or other measures to prevent cross-contamination.

C. If IPP observe insanitary conditions resulting from the construction, maintenance, size, or layout of establishment facilities, the establishment does not comply with 9 CFR 416.2(b). IPP are to evaluate all the information associated with the observation before making a compliance decision.

EXAMPLE: IPP observe an area in the establishment that appears to be of insufficient size to allow for storing of product in a manner that prevents insanitary conditions and consequent product adulteration. If the establishment is able to maintain this area in a sanitary condition, the establishment is in compliance with the regulation. If there is not adequate space in the area to permit the area to be maintained in a sanitary manner, there is noncompliance with this provision. For example, if the floors and walls cannot be cleaned regularly because of the overcrowded conditions, there is noncompliance with this provision.

D. IPP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

V. LIGHTING

Section 416.2 (c) of 9 CFR states: *Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.*

A. IPP are to verify that the establishment meets the lighting requirements by observing the lighting conditions in the establishment. The following questions will help IPP to gather the necessary information to determine compliance with 9 CFR 416.2(c):

1. Are the intensity and quality of lighting adequate for establishment employees to ensure that the products being processed, handled, stored, or examined are unadulterated, and that sanitary conditions are maintained?

2. Are the intensity and quality of lighting adequate for the establishment to determine that equipment and utensils are appropriately cleaned?

3. Are the intensity and quality of lighting adequate in the hand-washing areas,

dressing and locker rooms, and toilets for the establishment to determine that sanitary conditions are maintained?

B. If the lighting in one or more areas of the establishment is not sufficient for establishment employees to maintain sanitary conditions and to ensure that product does not become adulterated, the establishment does not comply with 9 CFR 416.2(c)

C. The regulation does not require specific amounts of lighting. Therefore, IPP cannot determine compliance based on light meter measurements. IPP are to assess the condition in each area of the establishment to determine whether the lighting is adequate for the establishment to ensure that sanitary conditions are maintained, and that product is not adulterated. If this is the case, there is compliance with this provision. If the lighting is not adequate to ensure that sanitary conditions are maintained and that product is not adulterated, there is noncompliance with this provision.

D. If one light is inoperable, there may or may not be a noncompliance. IPP are to assess whether its absence makes establishment employees unable to maintain sanitary conditions or detect product adulteration. If the light is adequate for establishment employees to maintain sanitary conditions and prevent product adulteration, there is compliance.

EXAMPLE: If IPP observe that the lighting at a zero-tolerance CCP is not adequate to enable establishment employees to determine whether contamination on product is fecal material, the lighting is inadequate, and there is noncompliance.

VI. VENTILATION

Section 416.2 (d) of 9 CFR states: *Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.*

A. IPP are to verify compliance with 9 CFR 416.2(d) by observing one or more areas of the establishment to assess whether the establishment ventilation is sufficient to maintain sanitary conditions.

B. In some situations, condensation may be an unavoidable consequence of certain types of operations. When condensation occurs, IPP are to consider whether establishment management has assessed the cause of the condensation and implemented reasonable measures to prevent it. Establishments may not be able to completely control condensation in certain areas, even after taking all reasonable measures to ensure adequate ventilation. In these cases, IPP are to verify that the establishment maintains the surfaces where condensation occurs in a clean and sanitary condition as if they were food contact surfaces (see example below).

C. One or more of the following findings evidence that the establishment does not

comply with 9 CFR 416.2(d):

1. The ventilation is not sufficient to control vapors or odors to the extent that product might become adulterated.

2. The ventilation is not sufficient to control vapors or odors to the extent that would interfere with establishment employees or IPP being able to detect adulterated product.

3. The ventilation is not sufficient to control condensation. In some rare situations, the establishment may not be able to completely prevent condensation – see note above.

EXAMPLE: Establishment A cooks product in liquid in a large vat. Because of the steam that rises from the vat, there has been a history of condensation forming on the steel structures in that area of the plant. The establishment has taken several actions to address this condensation, including improving the fit of the lid on the cooking vat to reduce the escaping steam, and adding two fans to improve air circulation in the area. These measures have reduced the condensation. However, condensation still occurs on the bottom of a drip pan above the cooking vat when the lid is removed for loading or unloading. The condensation usually evaporates within a few minutes due to the new fans. In this situation, IPP determine that the establishment is in compliance with 9 CFR 416.2(d) because they have taken reasonable measures to minimize the condensation. IPP verify that the establishment maintains the bottom surface of the drip pan in a sanitary manner so any condensation cannot adulterate product.

EXAMPLE: IPP observe fog in the cooked meats cooler. When entering the cooler, it appears that the ventilation is not adequate to control vapors. IPP assess the situation and determine that the establishment has just placed 10 trays of warm product in the area. IPP observe that the vapor in the room dissipates before forming any moisture on the ceiling. In this situation, the establishment is in compliance with 9 CFR 416.2(d). If the vapor coming from the warm product were forming moisture on the ceiling, creating an insanitary condition, there would be noncompliance with this provision.

D. PP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

VII. PLUMBING AND SEWAGE

Section 416.2 (e) of 9 CFR states: *Plumbing systems must be installed and maintained to:*

(1) Carry sufficient quantities of water to required locations throughout the establishment;

(2) Properly convey sewage and liquid disposable waste from the establishment;

(3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;

(5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and

(6) Prevent the backup of sewer gases.

Section 416.2 (f) of 9 CFR states: *Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.*

A. When verifying compliance with 9 CFR 416.2(e) and (f), IPP are to observe one or more areas of the establishment and assess whether the plumbing system, drains, and sewage systems are installed and maintained in a manner to maintain sanitary conditions.

B. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.2(e):

1. The plumbing system does not provide sufficient quantities of water throughout the establishment to maintain sanitary conditions (e.g. for washing utensils, equipment, hands when necessary to maintain sanitary conditions).

2. The plumbing system allows sewage or disposable waste to accumulate in the establishment.

3. The plumbing system does not provide adequate floor drainage.

4. The plumbing system allows back-flow conditions or includes cross-connections that could cause insanitary conditions or product adulteration (e.g. between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing).

5. The plumbing system does not prevent the backup of sewer gases.

C. One or more of the following findings evidence that the establishment does not

comply with 9 CFR 416.2(f):

1. The sewage system allows sewage to back up into areas where product is processed, handled, or stored.

2. If the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment is unable to provide an approval letter upon request.

D. IPP are to verify the presence of an approval letter once for a new sewage system and upon any modifications of that system.

EXAMPLE: IPP observe an area of the plant where several water-cooking units are being drained simultaneously. There is a gutter drain that the water is drained into, and the end of a cleanup hose is submerged in the gutter drain. IPP know this could result in noncompliance if the system allows backflow thorough the cleanup hose but decide to evaluate the situation further. IPP find a vacuum breaker at the cleanup station to prevent back siphonage. IPP determine the establishment is in compliance with 9 CFR 416.2(e)(5). If there were nothing to prevent back siphonage, there would be noncompliance with this provision.

E. IPP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

VIII. WATER SUPPLY AND WATER, ICE, AND SOLUTION REUSE

WATER SUPPLY AND USE

Section 416.2 (g)(1) of 9 CFR states: *A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for employee sanitary facilities, for cleaning rooms and equipment, utensils, and packaging materials). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.*

9 CFR 416.2(g)(4) states: *Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1)*

of this section.

9 CFR 416.2(g)(5) states: *Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.*

9 CFR 416.2(g)(6) states: *Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.*

A. When verifying compliance with 9 CFR 416.2(g), IPP are to observe one or more areas of the establishment where water is used and review establishment records as necessary to verify that the water supply meets the requirements of 9 CFR 416.2(g)(1).

B. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.2(g)(1):

1. There is reason to believe that the establishment is using a water supply that does not comply with the National Primary Drinking Water regulations in 40 CFR 141 because of the appearance, taste, or odor of the water or other available information (e.g. city boil order).

2. The establishment water supply does not provide adequate water pressure, at a suitable temperature, in all areas where required, for example, for processing product; for cleaning rooms and equipment, utensils, and packaging materials; for employee sanitary facilities.

3. The establishment uses a municipal water supply and is unable to provide a water report certifying the potability of the water supply upon request.

4. IPP are to verify the availability of a water report for new establishments and when they have reason to question the potability of the establishment water supply.

5. The establishment uses a private well and is unable to provide documentation certifying the potability of the well water within the previous 6 months.

C. If the establishment has an on-site advanced wastewater treatment facility, IPP are to observe establishment operations and review relevant records to verify that the reconditioned water is used in accordance with 9 CFR 416.2(g)(4).

D. One or more of the following findings evidence that the establishment does not

comply with 9 CFR 416.2(g)(4):

1. The establishment uses reconditioned water on raw product, facilities, equipment, or utensils but does not implement a separate rinse with potable water (as defined in 416.2(g)(1)).

2. The establishment is unable to demonstrate that the on-site advanced wastewater treatment facility ensures that the reconditioned water meets the criteria prescribed in paragraph (g)(1).

REUSE OF WATER, ICE, AND SOLUTIONS FOR RTE PRODUCT

Section 416.2(g)(2) of 9 CFR states: *Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook* RTE *product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.*

A. IPP are to determine whether the establishment is reusing water, ice, or solutions (such as brine, liquid smoke, or propylene glycol) to chill or cook RTE product. If so, IPP are to observe the operations that involve reuse of water, ice, or solutions and review any related establishment records to verify that the reuse meets the requirements of 9 CFR 416.2(g)(2). Also, establishments that reuse water, ice, or solutions to cook or chill RTE product need to consider that reuse in the hazard analysis and support any resulting decisions regarding chemical, physical, or microbiological hazards.

B. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.2(g)(2):

1. The establishment reuses water, ice, or solutions that are not maintained free of pathogenic organisms and fecal coliform organisms to cook or chill RTE product.

2. The establishment reuses water, ice, or solutions to cook or chill RTE product but does not implement measures to reduce chemical, physical, and microbiological contamination to prevent adulteration of product.

3. The establishment did not include reuse of water, ice, or solutions in the hazard analysis for the relevant step in the process. IPP are also to cite 9 CFR 417.2(a) when documenting noncompliance in this case.

4. The establishment considered water, ice, or solution reuse in the hazard analysis but does not maintain adequate documentation to support the resulting decisions about chemical, physical, and microbiological hazards that are not reasonably likely to occur. IPP are also to cite 9 CFR 417.5(a)(1) when documenting noncompliance in this case.

5. The establishment considered water, ice, or solution reuse in the hazard analysis and found a food safety hazard reasonably likely to occur, but did not implement a CCP in the HACCP plan to address this hazard. IPP are also to cite 9 CFR 417.2(c)(2) when documenting noncompliance in this case.

REUSE OF WATER, ICE, AND SOLUTIONS FOR RAW PRODUCT

Section 416.2(g)(3) of 9 CFR states: *Water, ice, and solutions to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on* RTE *product.*

A. 9 CFR 416.2(g)(3) states that water may be reused "for the same purpose." This means that water used to wash or otherwise process raw product may be reused to wash or otherwise process raw product, even at a different point in processing, provided that "measures are taken to reduce physical, chemical, or microbiological contamination." In general, water can be reused at the same point or a prior point in the production process (i.e., "up-stream").

EXAMPLES INCLUDE:

1. An establishment could reuse poultry chiller water in a scalding tank (scalder is "upstream" from chiller).

2. Water used to process RTE product could be reused to wash or process raw product.

3. Water used to process raw product may **not** be reused to process RTE product.

4. An establishment may **not** reuse poultry chiller water for cooking or cooling packaged RTE product.

B. IPP are to determine whether the establishment is reusing water, ice, or solutions to chill or wash raw product. If so, IPP are to observe the operations that involve reuse of water, ice, or solutions and review any related establishment records to verify that the reuse meets the requirements of 9 CFR 416.2(g)(3). Also, establishments that reuse water, ice, or solutions to chill or wash raw product need to consider that reuse in the hazard analysis and support any resulting decisions regarding chemical, physical, or microbiological hazards.

C. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.2(g)(3):

1. The establishment reuses water, ice, or solutions to chill or wash raw product but does not implement measures to reduce chemical, physical, and microbiological contamination to prevent adulteration of product.

2. The establishment did not include reuse of water, ice, or solutions in the hazard analysis for the relevant step in the process. IPP are also to cite 9 CFR 417.2(a) when documenting noncompliance in this case.

3. The establishment considered water, ice, or solution reuse in the hazard analysis but does not maintain adequate documentation to support the resulting decisions about chemical, physical, and microbiological hazards that are not reasonably likely to occur. IPP are also to cite 9 CFR 417.5(a)(1) when documenting noncompliance in this case.

4. The establishment considered water, ice, or solution reuse in the hazard analysis and found a food safety hazard reasonably likely to occur, but did not implement a CCP in the HACCP plan to address this hazard. IPP are also to cite 9 CFR 417.2(c)(2) when documenting noncompliance in this case.

D. IPP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

IX. DRESSING ROOMS AND LAVATORIES

Section 416.2 (h) of 9 CFR states:

(1) Dressing rooms, toilet rooms and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

A. IPP are to observe the dressing rooms, restrooms, and lavatories (sinks) in one or more areas of the establishment to verify that their number, placement, and maintenance are sufficient to ensure that establishment employees are able to maintain sanitary conditions.

B. There are no specific requirements for number or size of restrooms and lavatories within the establishment. IPP are to observe establishment employees entering processing areas and during operations to determine whether they are able to maintain clean hands and outer clothing when entering or returning to edible areas of the establishment and during operations. IPP are to support any findings of noncompliance with these requirements with a description of the resulting insanitary conditions they observed.

C. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.2(h):

1. The dressing rooms and restrooms in the establishment are not sufficient in number, size, or location to allow employees to use them without causing insanitary conditions when returning to production areas.

2. The dressing rooms and restrooms are not maintained in a sanitary condition and in good repair. For example, overflowing toilets, backed up drains, accumulation of waste on the floor would all represent noncompliance.

3. Dressing rooms, toilet rooms, and urinals are not separate from the rooms and compartments in which products are processed, stored, or handled.

4. The establishment does not have sufficient number of lavatories (sinks) in or near restrooms and elsewhere in the establishment to allow employees to wash hands after using restrooms or to wash hands or gloves when they become soiled during operations.

5. Lavatories (sinks) are not equipped with water of an appropriate temperature and soap to ensure adequate cleaning of hands, gloves, or utensils.

6. Lavatories (sinks) are not equipped with towels or other method sufficient for employees to dry their hands prior to returning to work.

7. Refuse receptacles are not constructed or maintained in a manner that prevents insanitary conditions.

EXAMPLE: IPP are observing operations in an area of the establishment where edible product is being handled. There are several employees working in this rather large room. IPP observe that there is only one lavatory close by. IPP consider that there may be noncompliance with this requirement but decide to evaluate the situation further before making a compliance determination. IPP observe that the employees are handling product, and when employees' hands are contaminated, they go to the lavatory and wash their hands. Based on this observation, IPP determine that in this situation, the establishment is in compliance with 9 CFR 417.2(h)(2). If the employees were not washing their hands when contaminated because the lavatory was not appropriately located in this area, there would be noncompliance with this provision.

D. IPP are to document the results of their verification, including any noncompliance in a manner that accords with Chapter V of this document.

X. EQUIPMENT AND UTENSILS

Section 416.3 of 9 CFR states:

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment or utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

A. IPP are to observe establishment operations in one or more areas of the establishment to verify that the establishment maintains equipment and utensils used for handling edible products in a sanitary manner. IPP are also to verify that the establishment maintains designated receptacles for inedible materials and uses them in a way that prevents any insanitary conditions.

B. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.3:

1. The equipment and utensils used for processing and otherwise handling edible product or ingredients are of material or construction that does not allow thorough cleaning. IPP are to base this finding on observation that the establishment is unable to thoroughly clean one or more pieces of equipment or utensils.

2. Equipment or utensils are constructed, located, or operated in a manner that prevents IPP from inspecting the sanitary condition of the equipment or utensils.

3. Receptacles used for storing inedible material are constructed or maintained in a manner that allows insanitary conditions to occur.

4. Receptacles used for storing inedible products are not marked conspicuously

and distinctively to identify them for inedible use.

C. There is no single acceptable method to conspicuously identify inedible product containers. Establishments may designate inedible and other containers through permanent marking, color-coding, or other similar system. IPP are not to concern themselves with what method the establishment uses to designate inedible containers but are to determine whether the system works effectively to prevent insanitary conditions or product adulteration.

EXAMPLE: IPP observe a closed system of product handling equipment that had not been disassembled for cleaning. IPP assess the situation further before making a compliance determination. After asking establishment management, IPP determine that this system is cleaned-in-place, and that there are inspection openings at every change of direction to allow for verification of the effectiveness of the sanitation procedures. IPP inspect the system through the openings and find that the closed system is being adequately cleaned. Therefore the establishment is in compliance with 9 CFR 416.3. If the closed system did not permit inspection or was not in a sanitary condition, there would be noncompliance with this provision.

D. IPP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter IV of this document.

XI. SANITARY OPERATIONS

Section 416.4 of 9 CFR states:

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food-processing environment must be available to FSIS inspection program employees for review.

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

A. IPP are to observe one or more areas of the establishment to verify that the establishment cleans and sanitizes food contact surfaces and non-food-contact

surfaces as frequently as necessary to prevent insanitary conditions. IPP are to assess whether products are protected from adulteration during processing, handling, storage, loading, and unloading, and during transportation. IPP are also to observe the handling, and storage of cleaning compounds, sanitizing agents, processing aids, and other chemicals in the establishment. IPP are also to review any associated documentation to verify that these compounds are being used, handled, and stored in a safe and effective manner.

B. In slaughter establishments, IPP are to observe slaughter operations to verify that the establishment maintains control of the sanitary dressing process as part of the requirement of 9 CFR 416.4(d) to protect product from adulteration during processing and handling. IPP are to refer to FSIS Directives 6410.1, 6410.2, and 6410.3 for instructions on verifying control of sanitary dressing procedures in beef slaughter, other livestock slaughter, and poultry slaughter, respectively.

C. If IPP observe that food contact surfaces of facilities, equipment, or utensils are not cleaned and sanitized frequently enough to prevent insanitary conditions and product adulteration, the establishment does not comply with 9 CFR 416.4(a).

D. IPP are to consider whether their finding represents Sanitation SOP noncompliance as well (see Sanitation SOP section below). If so, IPP are to document the noncompliance as Sanitation SOP noncompliance.

E. If IPP observe that non-food-contact surfaces of facilities, equipment, or utensils are not cleaned and sanitized frequently enough to prevent insanitary conditions and product adulteration, the establishment does not comply with 9 CFR 416.4(b).

F. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.4(c):

1. The establishment is unable to provide documentation to demonstrate the safety of each chemical compound for the intended use in a food processing environment.

NOTE: There are many different types of documentation that may fulfill this requirement. FSIS does not require specific types of documentation. IPP are to consider where and how the establishment intends to use each chemical compound when determining whether the documentation supports its safety.

2. The establishment uses, handles, or stores cleaning compounds, sanitizing agents, processing aids, and other chemicals in a manner not consistent with the manufacturer recommendations or other documentation.

G. If IPP observe that the establishment does not protect product from adulteration during processing, handling, storage, loading and unloading, and transportation, the establishment does not comply with 9 CFR 416.4(d).

EXAMPLE: IPP observe several vats of meat in the raw product storage area that are not covered. They also observe several other vats of meat stored in this area that are covered. The IPP think that there might be noncompliance with 9 CFR 416.4(d) but decide to evaluate the situation further before making a compliance determination. The IPP observe the overhead in the area and do not observe any conditions that would constitute insanitation or that would cause product adulteration. The IPP observe that an employee comes into the area and takes a vat of product out of this area. The IPP follow the employee to determine whether the product is adequately protected from adulteration while being transferred to another area. The IPP find no conditions that would require the product to be covered during transit. Therefore, the IPP determine that the establishment is in compliance with 9 CFR 416.4(d). If the IPP had observed that there was a condition in the establishment that could adulterate product during storage or handling, there would be noncompliance with this provision.

H. IPP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

XII. EMPLOYEE HYGIENE

Section 416.5 of 9 CFR states:

(a) Cleanliness. All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

(b) Clothing. Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

A. The regulations pertaining to employee hygiene apply to FSIS personnel as well as to plant personnel. As representatives of a public health agency, it is imperative that IPP lead through example by meeting all provisions in 9 CFR 416.3 and 416.5 during the performance of their official duties within federally inspected meat and poultry product establishments. IPP are to adhere to establishments' special requirements as well. In this manner, FSIS personnel can aid in maintaining the sanitary conditions inside the facilities to which they are assigned.

B. IPP are to observe establishment employees in one or more areas of the establishment to verify that they meet the provisions of 9 CFR 416.5.

C. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.5:

1. Establishment personnel in contact with product, food-contact surfaces, and product-packaging materials do not adhere to hygienic practices while on duty, resulting in insanitary conditions.

2. Aprons, frocks, and other outer clothing worn by persons who handle product are not made of material that is disposable or readily cleaned.

3. Establishment personnel do not wear clean garments at the start of the day or do not change garments during the day as often as necessary to prevent insanitary conditions.

NOTE: The regulations do not require that establishment employees wear frocks or smocks but require outer clothing to be of material that is disposable or readily cleanable.

4. Persons who appear to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination are not excluded from any operations that could result in product adulteration and the creation of insanitary conditions. If IPP have questions about an employee having an infectious disease, he or she should discuss this with establishment management. IPP are not trained to diagnose infectious diseases.

EXAMPLE: The IPP observe an employee preparing to start to work in the raw product area. The employee puts on an apron. The IPP observe that the apron is dirty from the previous day's production. The IPP think that there is noncompliance with this provision but decide to evaluate this situation further before making a compliance determination. They observe the employee go to the washroom and clean the apron thoroughly before starting to work. The IPP determine that there is compliance with (9 CFR 416.5(b). If the employee had not cleaned the apron appropriately before going to work, there would be noncompliance with this provision.

D. IPP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

PART III SANITATION STANDARD OPERATING PROCEDURES (SANITATION SOPs)

I. SANITATION SOPs

A. The Sanitation SOP regulations require that the establishment develop Sanitation SOPs to describe the specific procedures that the establishment will perform to prevent direct contamination or adulteration of products. The Sanitation SOP regulatory requirements are:

1. Implementation and monitoring of Sanitation SOP (9 CFR 416.13);

2. Maintenance of Sanitation SOP (ensuring its effectiveness) (9 CFR 416.14);

3. Sanitation SOP corrective actions (9 CFR 416.15); and

4. Sanitation SOP recordkeeping (9 CFR 416.16)

B. If IPP find that an establishment has not developed written Sanitation SOPs, they are to withhold the marks of inspection and contact their supervisor immediately.

C. Establishments are required to prevent contamination or adulteration of products during all operations. However, establishments are not specifically required to perform particular Sanitation SOP procedures daily. Establishments may elect to perform some sanitation procedures at a frequency less than daily if they can demonstrate that they continue to prevent product contamination or adulteration. For instructions on how to verify Sanitation SOP requirements in these establishments, IPP are to refer to FSIS Directive 5000.5.

II. VERIFYING SANITATION SOP REGULATORY REQUIREMENTS IN PHIS

A. Establishments are required to develop and implement Sanitation SOPs and to monitor the implementation and make adjustments as necessary to ensure that the Sanitation SOPs are effective at preventing contamination or adulteration of product. The IPP's primary role is not to identify areas that are clean and areas that are dirty for the establishment. The IPP's primary role is to use their findings to determine whether or not the establishment is implementing Sanitation SOPs effectively to prevent contamination or adulteration of products. IPP are to perform two general types of Sanitation SOP verification procedures to verify that an establishment is meeting the regulatory requirements for Sanitation SOPs. Each type includes a recordkeeping verification procedure and a review and observation (e.g. "hands-on") procedure. The general types of Sanitation SOP procedures are:

1. Pre-Operational Sanitation SOP Verification (01B): IPP are to use the recordkeeping and review and observation inspection procedures to verify that the establishment implements the procedures in the Sanitation SOP effectively to

prevent contamination of food contact surfaces or adulteration of products prior to operations. Inspectors will verify that the establishment meets all Sanitation SOP regulatory requirements (monitoring, recordkeeping, maintenance, corrective action).

2. Operational Sanitation SOP Verification (01C): IPP are to use the recordkeeping and review and observation inspection procedures to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products during operations. IPP will verify that the establishment meets all Sanitation SOP regulatory requirements (monitoring, recordkeeping, maintenance, corrective action).

B. IPP are to review the Sanitation SOPs in preparation to verify pre-operational Sanitation SOP requirements. IPP are to be familiar with the procedures and the monitoring procedures and frequencies specified in the Sanitation SOPs.

C. When performing the recordkeeping versions of the Sanitation SOP verification procedures (01B01, 01C01), IPP are to review the daily pre-operational or operational Sanitation SOP records to verify that the records demonstrate the following:

1. That the establishment is following the pre-operational and operational procedures specified in the Sanitation SOPs as written;

2. That the monitoring activities are conducted at the specified frequencies;

3. That the designated establishment employees implemented appropriate corrective actions when necessary;

4. That records are being authenticated by the establishment employee responsible for implementation and monitoring of the Sanitation SOP; and

5. That the outcome of the establishment's Sanitation SOP is to maintain product contact surfaces in a clean and sanitary condition.

D. When performing the review and observation (i.e. "hands-on") versions of the Sanitation SOP verification procedures (01B, 01C), IPP are to verify that the establishment is implementing and monitoring the Sanitation SOPs effectively. IPP are to verify that the establishment is implementing the SSOP to meet Sanitation SOP regulatory requirements for pre-operational and operational sanitation by:

1. Inspecting one or more areas of the establishment to ensure procedures are effective in preventing direct contamination or other adulteration of product;

2. Observing establishment employees performing the monitoring procedures;

3. Observing establishment employees implementing corrective actions; and

4. Comparing inspection findings to what the establishment has documented.

E. IPP may not be able to verify the corrective action regulatory requirement each time they perform the pre-operational sanitation verification procedure. IPP are to verify that the establishment meets the corrective action requirement of 9 CFR 416.15 when they find that the establishment's Sanitation SOP has failed to prevent product contamination.

F. If IPP perform their review and observation procedure at the same time the establishment is monitoring their operational procedures, IPP are to observe establishment employees performing the monitoring procedures at that time.

G. When an establishment operates on Saturdays, Sundays, and holidays, IPP are to conduct pre-operational and operational sanitation procedures in the same manner and frequency as they do during the week.

III. SANITATION SOP OPERATIONAL AND PREOPERATIONAL VERIFICATION PROCEDURES

A. Inspection personnel are to target completion of preoperational and operational Sanitation SOP verification tasks at frequencies established by the Agency as described in the following guidance. IPP are to:

1. Perform two preoperational Sanitation SOP verification tasks per week at each establishment in an assignment, including one review and observation (01B02) and one record review (01B01). The records review and review and observation forms of verifications (01B01 or 01B02) are to be performed at an approximately equal amount;

2. Perform one operational Sanitation SOP verification task at each establishment in an assignment during each shift – either review and observation (01C02) or record review (01C01). The records review and review and observation forms of verification (01C01 and 01C02) are to be performed at an approximately equal amount; and

3. Perform additional "inspector directed" (See FSIS PHIS Directive 13,000.1) sanitation SOP verifications as warranted by conditions observed at establishments. For example, if during the performance of verifications unrelated to sanitation inspection personnel observe insanitary conditions, they are to perform an operational Sanitation SOP verification task using the review and observation methodology. Inspection personnel are also to perform Sanitation SOP tasks as directed by their supervisor.

NOTE: For instructions on how to schedule tasks in PHIS, see FSIS PHIS Directive

13,000.1, Scheduling In-plant Inspection Tasks in the Public Health Information System.

B. In patrol assignments, there are times when inspection personnel cannot perform preoperational Sanitation SOP verifications using the review and observation methodology in each establishment once per week due to simultaneous start times or having more than five establishments on the patrol. In such cases, inspection personnel are to use judgment and their knowledge of establishments' compliance histories with sanitation requirements to decide where and when to do preoperational Sanitation SOP verifications and which methodology to use. Likewise, supervisors are to follow good judgment and their knowledge of plants' operations and histories when reviewing task data to determine if the appropriate mix of verification methodologies was used.

IV. SELECTING EQUIPMENT AND AREAS FOR PRE-OPERATIONAL SANITATION SOP VERIFICATION

A. When performing hands-on sanitation inspection, IPP are to follow the instructions in FSIS Directive 5000.4.

B. If IPP perform their review and observation procedure at the same time the establishment is monitoring their pre-operational procedures, IPP are to perform the observation component of this procedure at that time. In some cases, the establishment might conduct its monitoring of the implementation of the Sanitation SOP procedures before IPP arrive at the establishment. In these situations, IPP are to seek direction from supervisory personnel as to how frequently they should directly observe the establishment conduct monitoring. The supervisor is to consider several factors when making this decision: 1) establishment compliance history, 2) documentation in the FSIS file, and 3) information from Sanitation SOP records.

V. IMPLEMENTATION AND MONITORING OF SANITATION SOPs

Section 416.13 of 9 CFR states:

(a) *Each official establishment shall conduct the pre-operational procedures in the Sanitation SOPs before the start of operations.*

(b) Each official establishment shall conduct all other procedures in the Sanitation SOPs at the frequencies specified.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOPs.

A. IPP are to observe food contact surfaces and products, observe establishment employees, and review Sanitation SOP records to determine whether the establishment is implementing and monitoring the Sanitation SOPs effectively to prevent contamination or adulteration of products. IPP are also to review the results of any

sampling programs the establishment uses to monitor or assess the effectiveness of the Sanitation SOPs.

B. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.13:

1. Establishment employees do not implement the pre-operational procedures in the Sanitation SOPs prior to operations.

NOTE: Establishments may elect to perform some sanitation procedures at a frequency less than daily if they can demonstrate that they continue to prevent product contamination or adulteration. For instructions on how to verify Sanitation SOP requirements in these establishments, IPP are to refer to FSIS Directive 5000.5.

2. Establishment employees do not implement the operational procedures in the Sanitation SOPs at the specified frequencies during operations.

3. IPP observe unclean food contact surfaces or contamination of products resulting from failure to implement the Sanitation SOPs or because the Sanitation SOPs were not effective.

4. The establishment's corrective actions do not restore sanitary conditions prior to beginning operations when IPP or establishment employees observe unclean food contact surfaces prior to operations.

5. Establishment employees do not monitor the implementation of the Sanitation SOPs at least daily.

NOTE: If the Sanitation SOPs specify a frequency for monitoring, establishment employees are to perform the monitoring at the specified frequency. If the Sanitation SOPs do not specify a frequency, establishment employees must monitor at least daily.

C. If environmental sampling is included in the Sanitation SOP, IPP are to verify that the establishment is following those procedures. IPP are to observe the establishment collecting samples, review sample results, and verify that the establishment takes corrective actions specified in the Sanitation SOP for results that do not meet the specified criteria. IPP are to complete this verification as part of the applicable Sanitation SOP verification procedure.

D. IPP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

VI. MAINTENANCE OF SANITATION SOPs

Section 416.14 of 9 CFR states: *Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOPs and the procedures therein in preventing direct*

contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

A. IPP are to note any changes within the establishment facilities, equipment, utensils, operations, or personnel that would alter the effectiveness of the Sanitation SOPs. IPP are to observe food contact surfaces and products, observe establishment employees, and review Sanitation SOP records to verify that the establishment routinely evaluates the effectiveness of the Sanitation SOPs and revises them as necessary to maintain their effectiveness. IPP are also to review the results of any sampling programs the establishment uses to monitor or assess the effectiveness of the Sanitation SOPs.

B. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.14:

1. The establishment fails to routinely evaluate the effectiveness of the Sanitation SOPs or revise them as necessary to maintain their effectiveness.

2. The establishment fails to make revisions to the Sanitation SOPs to improve their effectiveness in response to repeated findings (by FSIS or the establishment) of unclean contact surfaces or product contamination.

3. The establishment fails to revise the Sanitation SOPs if necessary to keep them effective and current in response to changes in facilities, equipment, utensils, operations, or personnel.

NOTE: The establishment is not required to revise the Sanitation SOPs in response to a change unless the revisions are required to keep the Sanitation SOPs effective in preventing contamination or adulteration of products.

4. The establishment fails to revise the Sanitation SOPs when sampling results or other data do not meet the establishment's criteria for Sanitation SOPs effectiveness or show a trend of decreasing effectiveness.

EXAMPLE: Establishment A performs weekly microbial testing ("aerobic plate count") of food contact surfaces prior to and during operations to assess the effectiveness of the Sanitation SOPs. During their Sanitation SOP verification procedures, IPP review the results of these microbial tests. Historically, the results have generally been less than 100 colony forming units per square centimeter for pre-operational samples and less than 10,000 colony forming units per square centimeter for operational samples. IPP note that over the course of three weeks the pre-operational results have risen to 5000 cfu/sq. cm. During this time, IPP have not observed any unclean product surfaces. Though there are no regulatory standards for aerobic plate count, IPP are concerned that these results indicate a trend of decreasing Sanitation SOPs effectiveness. IPP discuss the issue with establishment management at the next weekly meeting. The QC manager states that they have noticed the trend in the results

and upon investigation, found that a cleaning employee had been mixing the sanitizing solution at the wrong concentration. They have revised the Sanitation SOPs to include sanitizer mixing instructions and implemented a new monitoring procedure to observe the mixing process. IPP determine that the establishment has met the requirement of 416.14 to evaluate and revise the Sanitation SOPs in response to these results.

C. Construction and removal of walls, ceilings, and floors may cause harborage sites for *L. monocytogenes* to be dislodged from otherwise protected areas. When a RTE establishment is undergoing construction, IPP are to ask whether the establishment has stepped up its ongoing verification activity or taken other measures to ensure that the current Sanitation SOP or other procedures are adequate to prevent insanitary conditions.

D. IPP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

VII. SANITATION SOP CORRECTIVE ACTIONS

Section 416.15 of 9 CFR states:

(a) *Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOPs or the procedures specified therein, or the implementation or maintenance of the Sanitation SOPs, may have failed to prevent direct contamination or adulteration of product(s).*

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOPs and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOPs or the procedures specified therein.

A. When IPP or establishment personnel find that the Sanitation SOPs have failed to prevent direct contamination of products, IPP are to verify the establishment's compliance with 9 CFR 416.15. IPP are to review Sanitation SOPs records and, when possible, observe establishment employees implementing corrective actions to verify that establishment corrective actions meet all the requirements of 9 CFR 416.15.

B. IPP are to determine that the Sanitation SOPs may have failed to prevent direct contamination of product and verify corrective action requirements under the following circumstances:

1. IPP or establishment personnel find that product has become contaminated because of a failure of the Sanitation SOPs.

2. IPP or establishment employees find that product contact surfaces have become

unclean or contaminated during operations due to a failure of the Sanitation SOPs.

C. When IPP or establishment employees observe contaminated contact surfaces before operations the establishment is not required to take corrective actions per 9 CFR 416.15 because the contaminated surface has not affected product before operation. The establishment is required to restore sanitary conditions prior to beginning operations as part of implementing the SSOP procedures in accordance with 9 CFR 416.13. However, the establishment is not required to implement preventive measures or ensure product disposition as long as no product has become contaminated. In these cases, the establishment is still required to evaluate the effectiveness of the Sanitation SOPs and revise them when necessary to maintain their effectiveness in accordance with 9 CFR 416.14.

D. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.15:

1. The establishment does not implement corrective actions when the Sanitation SOPs have failed to prevent product contamination or have resulted in unclean food contact surfaces during operations.

2. The establishment's corrective actions do not ensure appropriate disposition of any contaminated product.

3. The establishment's corrective actions do not restore sanitary conditions.

4. The establishment's corrective actions do not prevent recurrence of product contamination.

5. The establishment's corrective actions do not include reevaluation and modification of the Sanitation SOPs when necessary.

6. The establishment's corrective actions do not include appropriate improvements in the implementation of the Sanitation SOP procedures when necessary.

E. IPP are to take the appropriate control action (see Chapter V) when there is direct product contamination or other adulteration of product. IPP are not to release product or equipment affected by the control action and are not to "close out" the NR until they have verified that the establishment has restored sanitary conditions, has completed the proper product disposition, and has implemented preventive measures (see 9 CFR 416.15).

F. When IPP find product contact surfaces unclean prior to operations, they are to take a regulatory control action, when necessary, to prevent contamination or adulteration of product. That regulatory control action is not to be relinquished until the establishment has restored sanitary conditions.

G. IPP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document. When IPP document compliance with corrective action requirements, they are to record a brief description of their observations that support a finding of compliance.

XVIII. SANITATION SOP RECORDKEEPING

Section 416.16 of 9 CFR states:

(a) *Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOPs shall authenticate these records with his or her initials and the date.*

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

A. IPP are to review establishment Sanitation SOP records and observe establishment employees to verify that the establishment meets the requirements of 9 CFR 416.16.

B. One or more of the following findings evidence that the establishment does not comply with 9 CFR 416.16:

1. The establishment does not maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken.

2. The establishment employee responsible for implementing or monitoring the procedures in the Sanitation SOPs does not authenticate the records with his or her initials and the date.

3. The establishment maintains the Sanitation SOP records on computers but there are no controls to ensure the integrity of the electronic data.

4. The establishment does not maintain Sanitation SOP records for at least 6 months.

5. The establishment does not make Sanitation SOP records available to FSIS

personnel as required. Records must be available for IPP review at the beginning of the same shift on the next operating day. Records stored off-site must be provided within 24 hours of a request. If the establishment does not make records available within a reasonable period of time, IPP are to notify their supervisors immediately.

C. IPP are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

CHAPTER III - HACCP

PART I – INTRODUCTION

I. GENERAL

A. An establishment's food safety system, that is its HACCP system, consists of the plans, programs, measures, and procedures that it implements to prevent, eliminate, or otherwise control identified food safety hazards in the products it produces. CSIs apply the mark of inspection to products when they are able to find that the products are not adulterated. The most basic step in producing product that is not adulterated is to produce the product in accordance with the elements of a valid HACCP system

B. As CSIs verify an establishment's food safety system, their focus needs to be on its overall effectiveness. Hands-on sensory inspection to determine whether individual product units are wholesome is less important than assessment of the ongoing effectiveness of the establishment's food safety system. Sensory inspection is not effective at identifying all products that may be unsafe or unwholesome. By verifying that an establishment is implementing an effective HACCP system FSIS can best ensure that the establishment is producing wholesome, unadulterated products.

C. CSIs are to review an establishment's records and consider what they indicate about the ongoing effectiveness of its food safety system. In conjunction with this record review, CSIs are to observe establishment employees executing the establishment's food safety system.

D. CSIs are to document their findings in accordance with Chapter V of this directive. When necessary, CSIs are to take a regulatory action to stop ongoing product adulteration and to prevent adulterated product from entering commerce.

E. This chapter contains two parts.

1. Part I --provides background information to help CSIs understand the purposes and design of food safety systems.

2. Part II -- provides instructions to CSIs on how to verify that an establishment meets the HACCP regulatory requirements, and on how to verify that the food safety system is being effectively implemented. Part II includes two subparts on verifying the establishment hazard analysis and verifying the establishment implementation of the HACCP system.

II. HAZARD ANALYSIS

A. The hazard analysis forms the foundation of the establishment's food safety system. 9 CFR 417.2(a) requires that an establishment consider any food safety hazards that might occur in the production process, assess which hazards are reasonably likely to

occur, and develop measures to control those hazards that are reasonably likely to occur. The hazards associated with a particular product depend on the incoming materials, the production steps, and the characteristics of the finished product. For example, RTE products are associated with different hazards than raw products.

B. It is the establishment's responsibility to determine whether a particular hazard is reasonably likely to occur in its specific process or product. A hazard may be reasonably likely to occur if it has occurred multiple times in the past, or if it has a reasonable chance of occurring during the production process in the absence of controls. The establishment must maintain documents supporting the decisions that it makes during the hazard analysis. This documentation must include information to support decisions regarding hazards that are not reasonably likely to occur. The documentation must also include information to support decisions about how to control hazards that are reasonably likely to occur in the product or process.

III. FSIS MEAT AND POULTRY HAZARDS AND CONTROLS GUIDE

A. The FSIS Meat and Poultry Hazards and Controls Guide ("the Guide") describes the types of biological, chemical, and physical hazards that have traditionally been associated with particular types of products or production steps. In general, the Hazards and Controls Guide describes those hazards that are commonly associated with each process step. However, because the particular features of an establishment's process or product will vary, there may be hazards associated with the product that are not identified in the Hazards and Controls Guide. In other cases, some of the typical hazards identified in the Guide may not be associated with the production of a specific product.

IV. PREVENTING VS. CONTROLLING AN IDENTIFIED HAZARD

A. An establishment may reach one of three conclusions regarding each applicable hazard:

1. The hazard is not reasonably likely to occur because of basic features of the production process, raw materials and ingredients, or intended use of the product. To support this decision, the establishment must maintain documentation to demonstrate that the nature of the actual process or product is such that it prevents the hazard from occurring.

EXAMPLE: Establishment A receives raw boneless beef cuts and processes them into steaks, roasts, and non-intact products. The establishment considers whether Specified Risk Materials (SRMs) are reasonably likely to occur in the product that it receives. It determines that, since boneless cuts of beef do not contain SRMs, SRMs are not reasonably likely to occur. The establishment supports this decision with records of invoices for incoming products showing that it receives only boneless products.

2. The hazard is not reasonably likely to occur because the establishment

implements one or more prerequisite programs to ensure that it does not occur. To support the decision, the establishment refers to the applicable programs in the hazard analysis, has written prerequisite programs, and implements the procedures in the prerequisite programs as written. In addition, the establishment maintains records that demonstrate the effective implementation of the prerequisite programs.

EXAMPLE: Establishment A produces raw ground beef. On the basis of its hazard analysis, the establishment concludes that contamination with metallic foreign material is not reasonably likely to occur in the product because the establishment implements a prerequisite program for metal detection. The hazard analysis refers to the written metal detection program to justify the decision that the physical hazard is not reasonably likely to occur in the product. The written metal detection program describes the steps the establishment takes to ensure that the metal detector functions effectively and specifies records that document implementation of the program. Establishment employees implement the program as written and the records document that each batch of product was subject to metal detection as described in the program.

3. The hazard is reasonably likely to occur in the production process. The establishment is not required to support this decision. The establishment is required to implement one or more critical control points (CCP) in its HACCP plan to prevent, eliminate, or reduce the hazard to acceptable levels.

EXAMPLE: The establishment produces post-lethality exposed poultry hot dogs. The hazard analysis determines that the presence of *Listeria monocytogenes* is a food safety hazard that is reasonably likely to occur in the establishment's products between cooking and packaging (post-lethality). The establishment implements a post-lethality treatment CCP after packaging that is validated to reduce *Listeria monocytogenes* by 2 logs. In this way, the establishment ensures that any *Listeria monocytogenes* that contaminated the hot dogs will be eliminated from the packaged product. The establishment is not required to support the decision that *Listeria monocytogenes* is a hazard reasonably likely to occur in this case. However, the establishment is required to support the development and validation of the post-lethality CCP.

PART II – VERIFYING HACCP IN PHIS

I. CSIs METHODS TO VERIFY HACCP REGULATORY REQUIREMENTS

A. CSIs are to verify HACCP regulatory requirements by performing the HACCP verification tasks that appear on the PHIS task list. The HACCP verification procedures will appear on the establishment's inspection task list according to the specific HACCP process categories (listed in 9 CFR 417.2(b)) entered in the establishment profile in PHIS. CSIs are also to initiate directed HACCP verification tasks when they observe noncompliance or are instructed to do so by their supervisor.

EXAMPLE: If an establishment produces a fully cooked, shelf stable product, there will be HACCP verification procedures for the HACCP category of Heat Treated, Shelf Stable (03F) on the task list. Each procedure in PHIS directs CSIs to the applicable policy documents and provides instructions to help them understand how to verify HACCP requirements for the particular HACCP process or product type.

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

B. Each HACCP procedure has two components: a recordkeeping component and a review and observation component. CSIs are to use either, or a combination, of these components to verify regulatory compliance. For example, CSIs may review monitoring records at one CCP and take a measurement, or observe the establishment taking a measurement, at another CCP to verify that the monitoring requirement is met.

C. During the recordkeeping component of a verification procedure, CSIs are to gather information by reviewing establishment records associated with the food safety system. Depending on the procedure, these records might include the hazard analysis, records of any prerequisite or supporting programs, the HACCP plans, or HACCP records of monitoring, verification, corrective actions, and reassessment activities.

D. 9 CFR 417.5(f) requires the establishment to make all such records available for official review. Some establishments, however, control access to their food safety records. In such situations, IIC needs to work with the establishment to develop a mechanism to allow CSIs to have access to food safety records within a reasonable time of a request. If the establishment does not provide access to the records needed to perform the verification procedures, CSIs are to document noncompliance with 417.5(f) and bring the matter to the attention of his or her immediate supervisor.

E. During the review and observation component of a verification procedure, CSIs are to gather information by (1) watching establishment employees perform the procedures described in the HACCP plan or prerequisite program, (2) taking measurements, or (3) observing the product or conditions within the establishment.

F. When taking a measurement, CSIs are to use the calibrated instrument that the establishment uses for the monitoring or verification activities and to use the procedures described in the HACCP plan.

G. There are two general types of HACCP verification procedures. They are:

1. Hazard Analysis Verification (HAV): This procedure directs the CSIs to review the hazard analysis for all HACCP process categories in the establishment. CSIs are to use the recordkeeping, review, and observation components to verify that:

    a. The establishment's flowchart and hazard analysis match the actual production process.

    b. The establishment's hazard analysis considers the applicable food safety hazards for the process, product, and intended use in accordance with 9 CFR 417.2(a), and determines whether each hazard is reasonably likely to occur.

    c. The establishment has developed CCPs for hazards that are reasonably likely to occur in accordance with 9 CFR 417.2(c)(2) and maintains support for the development of those CCPs in accordance with 9 CFR 417.5(a)(2).

    d. The establishment supports the decisions it has made that certain hazards are not reasonably likely to occur in accordance with 9 CFR 417.5(a)(1) by maintaining applicable supporting documentation or by implementing any prerequisite programs or other measures that make the hazards not reasonably likely to occur.

    e. The establishment has met the requirement to validate the HACCP system by maintaining applicable scientific and technical documentation and by collecting in-plant validation data in accordance with 9 CFR 417.4(a)(1).

    f. The establishment has met the reassessment requirement in accordance with 9 CFR 417.4(a)(3) or 417.3(b).

2. HACCP Implementation: CSIs are to use the recordkeeping and review and observation components to verify that the establishment is effectively implementing the procedures set out in its HACCP system. CSIs are to verify that the establishment meets all HACCP regulatory requirements, including monitoring, verification, recordkeeping, and corrective action for all CCPs for a specific production. As part of verifying the recordkeeping requirement, CSIs are also to verify the implementation of prerequisite programs or other control measures the establishment uses to show that specific hazards are not reasonably likely to occur.

H. If an establishment determines that no food safety hazards are reasonably likely to occur, it is not required to develop CCPs or a HACCP plan. CSIs will not perform HACCP implementation verification in these cases. However, CSIs will perform the HAV procedure in these establishments to verify that they have support for their decision that no hazards are reasonably likely to occur.

I. In thermal processing (e.g. canning) establishments that elect to control microbiological hazards by implementing the canning regulations (9 CFR 318.300 to 318.309 or 381.300 to 381.309), CSIs are to verify implementation of those regulations when performing HACCP verification (see FSIS Directive 7530.2).

SUBPART A -- HAZARD ANALYSIS VERIFICATION PROCEDURE (HAV)

I. GENERAL

A. CSIs are to verify that an establishment meets the regulatory requirements for the hazard analysis by performing a Hazard Analysis Verification (HAV) procedure. A single HAV includes the hazard analysis and supporting documents for all HACCP process categories in an establishment. CSIs are to use the recordkeeping component to verify that the establishment's hazard analysis addresses the relevant food safety hazards for the process, product, and intended use in accordance with 9 CFR 417.2(a). CSIs also are to verify that the establishment has at least one CCP for each hazard that is reasonably likely to occur in the process and has support for any decisions that applicable hazards are not reasonably likely to occur. When the establishment uses a prerequisite program (such as a Sanitation SOP, GMP, or purchase specifications) to support the determination that a hazard is not reasonably likely to occur, CSIs are to verify that the establishment implements that program effectively to support the decision.

NOTE: When CSIs are uncertain about the adequacy of the establishment's hazard analysis, they are to discuss the issue with their supervisor.

B. CSIs are to perform the HAV procedure when it appears in the PHIS inspection task list. PHIS will add a routine Hazard Analysis Verification procedure to the establishment task list at a frequency that is based on risk factors it identifies in the establishment profile and the historical performance of the establishment's food safety system. A routine HAV procedure is likely to be scheduled relatively infrequently in establishments that demonstrate good process control. During these routine HAV procedures, CSIs are to verify that an establishment's hazard analysis and any supporting documentation, including prerequisite programs, meet HACCP regulatory requirements by considering the answers to a series of questions that are determined by the establishment's HACCP process categories or product types.

NOTE: See and 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.

C. PHIS may also add directed Hazard Analysis Verification procedures to the task list in response to certain events or 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 noncompliances). In some cases, CSIs may initiate the Hazard Analysis Verification procedure as instructed by their supervisor or DO personnel. During these directed HAV procedures, CSIs are to include all HACCP categories as in a routine HAV procedure. However, CSIs are also to pay particular attention to the parts of the hazard analysis and supporting programs that relate to the findings that led to the directed HAV procedure.

EXAMPLE: When a ground beef sample taken by FSIS is positive for *E. coli* O157:H7, CSIs are to focus on aspects of the hazard analysis that address the control and prevention of *E. coli* O157:H7 while performing the resulting directed HAV procedure.

D. When performing the HAV procedure, CSIs are to verify that the establishment has performed a hazard analysis in accordance with 9 CFR 417.2(a). CSIs are to use the thought process and methodology described below in performing this procedure.

E. The purpose of the HAV procedure is broader than simply to identify isolated noncompliances. CSIs are also to consider what their findings show about the overall effectiveness of the establishment's food safety system. If CSIs 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.

II. USING THE FSIS MEAT AND POULTRY HAZARDS AND CONTROLS GUIDE AS A REFERENCE

A. CSIs are to refer to the FSIS Meat and Poultry Hazards and Control Guide ("the Guide") as they consider an establishment's flowchart and hazard analysis. The information and suggested verification questions in each section of the Guide will assist CSIs in assessing the information they gather during the HAV procedure.

B. CSIs are to use the Guide to inform their consideration of 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 hazards at the relevant points in the process?

C. The information in the Guide is not regulatory. The Guide contains information

about the processing steps that are frequently associated with particular product types, and about hazards that have historically or typically been associated with each of these steps.

D. The process steps and hazards described in the Guide do not apply equally to all establishments. Because of differences in establishment processes and products, some of the information in the Guide will not apply to some establishments. CSIs are to interpret the Guide as a helpful reference but not as an absolute standard. If CSIs have concerns about how the information in the Guide applies to a particular establishment's hazard analysis, they are to discuss the issue with their supervisor.

III. REVIEWING THE ESTABLISHMENT'S FLOWCHART

A. The first step in reviewing the establishment's hazard analysis is to be familiar with the production process for each type of product the establishment produces. When they perform the HAV, CSIs 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, CSIs are to ask establishment management for assistance in understanding the production process. CSIs are to note how the establishment handles rework or returned products.

B. CSIs are to compare the establishment's flowchart to the actual production process and 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. CSIs are to refer to the Guide as they consider an establishment's flowchart. The table on page 6 of the Guide lists the process steps that are frequently associated with each HACCP process category. CSIs 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 Guide, but the steps in the table will help CSIs identify steps in the establishment process that are not in the flowchart.

D. The establishment may have a single flowchart that shows the entire production process or may have multiple flowcharts that each show a part of the process. In some establishments, the flowchart will be part of the HACCP plan, while in others it will be a separate document. All of these approaches to presenting the information are acceptable. CSIs are not to focus on the format or structure of the flowchart. They are to verify that the flowchart or flowcharts contain the required information for the entire production process.

E. FSIS does not dictate the level of detail in the establishment flowchart. The establishment may incorporate several production steps into one flowchart step. However, the establishment must consider all the food safety hazards associated with all the activities embedded in that flowchart step 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 (cutting, needle tenderizing, injecting, and tumbling). The flowchart may group these activities in to the single step of "processing" as long as the flowchart or hazard analysis lists each activity included in that step.

F. 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).

IV. REVIEWING THE HAZARD ANALYSIS

A. When they perform the HAV, CSIs are to review the establishment's hazard analyses for all products produced in the establishment in all HACCP categories. CSIs are to verify that each hazard analysis reflects all the steps in the flowchart and the actual production processes. If a hazard analysis does not reflect all the steps in the establishment's actual production process, it does not comply with 9 CFR 417.2(a)(1).

B. CSIs are to verify that the flowchart or hazard analysis identifies the intended use or consumers of each product. If the establishment does not identify the intended use or consumers for all finished products, it does not comply with 9 CFR 417.2(a)(2).

C. In some cases, an establishment may determine that certain hazards are not reasonably likely to occur because of the intended use of the product. In these cases, CSIs are to verify that the establishment has documentation to support the intended use. This support might include labeling records, shipping invoices, letters of intent from receiving establishments or other records that demonstrate how the establishment ensures that products will be appropriate for their intended use.

D. CSIs are to compare the hazard analysis to the Guide to verify that the establishment has at least considered the relevant hazards for each step in the process. CSIs are to review the entry for each establishment process step in the Guide and compare the information to the establishment hazard analysis for that step. CSIs are to consider the general verification questions on page 7 of the Guide as well as the suggested verification questions for each specific process step.

E. CSIs are to consider the verification questions from the Guide, the information in the Guide, and their knowledge of the actual establishment process to assess whether the establishment hazard analysis has considered the appropriate hazards for each step in the establishment's production process. If the establishment's hazard analysis does not consider the relevant food safety hazards at each step in the production process, it does not comply with 9 CFR 417.2(a)(1). CSIs are to contact their supervisors for assistance if they are uncertain whether the establishment has considered the appropriate hazards at each process step.

F. CSIs are not to focus on the format or structure of the hazard analysis. They are to

verify that the hazard analysis contains the required information for the entire production process.

G. For each food safety hazard identified in the hazard analysis, CSIs are to determine whether the establishment considers it reasonably likely to occur in the production process or not reasonably likely to occur in the production process (9 CFR 417.2(a)(1)).

H. A hazard is reasonably likely to occur if it historically has occurred or there is a reasonable possibility that it will occur in the particular product in the absence of controls. For each hazard reasonably likely to occur, the establishment must develop one or more CCPs to prevent, eliminate, or reduce the hazard to acceptable levels (9 CFR 417.2(c)(2)).

I. For each hazard that is reasonably likely to occur in a product, CSIs are to verify that the establishment has included one or more CCPs to control that hazard in the HACCP plan associated with that product. If the establishment does not include one or more CCPs to control each hazard identified as reasonably likely to occur, the HACCP plan does not comply with 9 CFR 417.2(c)(2). CSIs will verify the effective implementation of these CCPs to control the hazards when they perform the HACCP implementation verification procedure.

J. If the establishment determines that one of the applicable hazards is not reasonably likely to occur, CSIs are to determine what information the establishment uses to support that decision. This supporting information may be a program (prerequisite or other supporting program) that the establishment implements or some other documentation that shows that the hazard is not reasonably likely to occur. If the hazard analysis does not document support for a decision that a hazard is not reasonably likely to occur, it does not comply with 9 CFR 417.5(a)(1).

V. REVIEWING SUPPORT FOR CCPs AND CRITICAL LIMITS

A. During the HAV, CSIs are to review establishment records to verify that the establishment has information to support the development of CCPs, critical limits, and monitoring and verification procedures. CSIs are to use the same thought process as above to verify that these supporting documents are applicable to the establishment's actual process, and that they support the relevant establishment programs or interventions.

B. 9 CFR 417.5(a)(2) requires that the establishment 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.

C. The documentation above may take many forms. 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 minimum concentration as the critical limit. The establishment maintains the following supporting documents to meet the requirement of 9 CFR 417.5(a)(2):

1. A decisionmaking document that describes how establishment management designed the CCP based on a particular scientific article because the article addresses the establishment's particular hazard and product.

2. A copy of the referenced scientific article.

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 memo to monitor the critical limit once per day because the establishment mixes the antimicrobial solution daily.

5. A written decision memo stating that the establishment will follow the verification procedures listed in 9 CFR 417.4(a)(2) and stating that the frequency will be weekly because historical records show consistent control of this CCP.

D. When they perform the HAV procedure, CSIs are to verify that the establishment maintains these types of supporting documents for each CCP. CSIs 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.

E. If the establishment does not have documentation to support the development of CCPs, critical limits, and monitoring and verification procedures, it does not comply with 9 CFR 417.5(a)(2). If CSIs have concerns about whether the documentation is adequate, they are to discuss the issue with their supervisor.

VI. REVIEWING PREREQUISITE AND OTHER SUPPORTING PROGRAMS

A. When the establishment determines that a particular hazard is not reasonably likely to occur because the establishment implements a prerequisite program (including Sanitation SOP, SOP, GMP, purchase specifications, or other programs), CSIs are to verify that the program supports the decision.

B. As part of the HAV, CSIs are to review the contents of any prerequisite programs the establishment uses to support a decision that a hazard is not reasonably likely to occur. CSIs are to consider whether the prerequisite program has the following characteristics:

1. The program is written and describes procedures that the establishment will implement to show the hazard is not reasonably likely to occur.

2. The program describes records that the establishment will keep to demonstrate that the program is being implemented as written.

3. The program describes records that the establishment will keep to demonstrate that the program effectively prevents the hazard.

4. The program describes actions that the establishment will take when it fails to implement the program, or when it finds that the program has failed to prevent the hazard.

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

D. While performing the HAV, CSIs are also to verify that establishment employees are implementing any prerequisite programs or other measures the establishment uses to support a decision that a hazard is not reasonably likely to occur. CSIs are to verify that the establishment implements any prerequisite programs or other control measures in a way that supports the decision in the hazard analysis for the specific production. For each prerequisite program or other program the establishment uses to support a decision that a hazard is not reasonably likely to occur, CSIs are to verify implementation of the program by following these steps:

1. CSIs are to review the records generated by the program for the specific production selected to be verified during the HACCP verification procedure.

2. CSIs are to observe establishment employees implementing the procedures in the program.

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

4. CSIs 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.

E. Based on the information they gather from the records and observations, CSIs 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. In other words, CSIs are to verify that establishment employees are implementing the procedures in the prerequisite program in a manner that continues to prevent the relevant hazard from being reasonably likely to occur. CSIs are also to verify that the records generated by the prerequisite program demonstrate that they continue to show the relevant food safety hazard is not reasonably likely to occur.

F. 9 CFR 417.5(f) requires that all records required under Part 417 be available for official review by FSIS inspection personnel. CSIs are to contact their supervisor if the establishment does not make prerequisite programs, prerequisite program records, or other supporting documents available for review.

G. One or more of the following findings evidence that the establishment has not met the requirement 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 that prevent the relevant hazard.

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

H. While there are no regulations that explicitly address prerequisite program recordkeeping, the establishment's records need to demonstrate that the establishment has a basis (i.e., the prerequisite program) to support the relevant decisions on an ongoing basis.

I. In most cases, minor failures in prerequisite records would not support a finding of noncompliance. For example, missing an occasional record entry, failing to put a time or initials, or a similar deficiency does not necessarily mean that the prerequisite program is not being implemented effectively. In contrast, failing to implement procedures in a prerequisite program, or evidence that the program is not effectively preventing the hazard, means 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 Inspection Program Personnel to document noncompliance with 9 CFR 417.5(a)(1) and may be grounds for additional enforcement action.

EXAMPLE: Establishment A implements a prerequisite program to maintain raw product coolers below 35 degrees to prevent the hazard of pathogen growth from being reasonably likely to occur. On 3 separate days last week, the employee recording the cooler temperature records did not record his initials as 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 temperature was not maintained. Therefore, the establishment is in compliance with 9 CFR 417.5(a)(1).

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. CSIs 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.

J. If CSIs 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.

VII. REVIEWING OTHER SUPPORTING DOCUMENTATION

A. During the HAV, CSIs are to review any other documentation that the establishment uses to support a decision that a food safety hazard is not reasonably likely to occur. In many cases, this supporting documentation will take the form of scientific documents, plant historical records, or other plant-generated data. CSIs are to verify that the establishment maintains the documents referenced in the hazard analysis to support the relevant decision regarding a hazard being not reasonably likely to occur.

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 CSIs 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.

VIII. VERIFY ESTABLISHMENT VALIDATION

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

B. Validation is composed of two parts:

1. The first part is the 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. The second part is the 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 implemented within a particular establishment, and that when the are, they achieve the intended food safety objectives.

C. The scientific support and initial in-plant validation documents support the decisions made in the hazard analysis and the adequacy of the establishment's control measures (CCPs and prerequisite programs) to prevent or control those hazards.

D. During the HAV procedure, CSIs are to review both the documents that provide the scientific and technical support and the documents associated with the initial in-plant demonstration. CSIs are to verify that the establishment maintains both types of validation documents.

E. During the period of initial validation for a new or modified HACCP system, CSIs are to verify that the scientific and technical support for the interventions and control measures in the HACCP system are complete and provide support that the HACCP system will, in theory, effectively prevent or control the relevant food safety hazards. The records to document initial in-plant validation may not be complete at this time. Once the establishment completes the 90-day initial validation, CSIs are to verify that the establishment has developed data to demonstrate that it can achieve its food safety objectives by implementing the food safety system as designed.

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

1. That 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 the HACCP system.

2. That 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. That the establishment's CCPs, prerequisites, or other programs incorporate the parameters described in the scientific supporting documentation.

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

G. When CSIs 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.

H. One or more of the following findings 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 additional 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 (a)(2)).

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

5. The records of initial validation 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 records of initial validation 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 CSIs have concerns about the adequacy of the establishment's validation records, they are to discuss the issue with their supervisor.

IX. VERIFYING THE REASSESSMENT REQUIREMENTS

A. The establishment is required to reassess its food safety system (including the hazard analysis and any prerequisite programs) at least annually, and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)) and as part of the corrective action when an unforeseen hazard has occurred (9 CFR 417.3(b)(4)). Establishments that do not have a HACCP plan because they determined that no hazards were reasonably likely to occur must reassess their hazard analysis and any prerequisite programs whenever any changes occur that could reasonably affect whether a food safety hazard is reasonably likely to occur (417.4(b)). Changes that may affect the hazard analysis or alter the HACCP plan include, but are not limited to 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. Under 9 CFR 417.7, the individual who performs a reassessment or makes modifications to the HACCP plan must have successfully completed a training course in the application of the seven HACCP principles to meat or poultry product processing.

C. CSIs are to review establishment records and ask establishment management about reassessments conducted since the previous HAV procedure. CSIs 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. CSIs are also to consider whether any unforeseen hazards have occurred since the last HAV that would have required reassessment. CSIs are to ask establishment management whether the individual performing any reassessments or making modifications to the HACCP plan have been trained in accordance with 9 CFR 417.7(c).

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

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

2. 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).

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

E. There is no requirement for the establishment to provide documentation of training. CSIs are to accept oral statements that establishment employees have been trained in

accordance with 9 CFR 417.7.

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

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

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

X. DOCUMENTING COMPLIANCE OR NONCOMPLIANCE

A. If CSIs 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 procedure in PHIS and document that there is compliance with each of the regulatory requirements.

B. If CSIs identify noncompliances, they are to document these noncompliances in accordance with Chapter V of this document and discuss the noncompliances with their supervisor to determine if additional action may be necessary.

C. If CSIs are unable to determine whether their findings represent regulatory noncompliance, they are to discuss the issue with their supervisor before making a determination.

SUBPART B -- THE HACCP IMPLEMENTATION VERIFICATION PROCEDURE

I. GENERAL

A. CSIs are to verify that the establishment implements its HACCP system in accordance with the regulations in 9 CFR Part 417 by performing the HACCP Implementation Verification procedure. CSIs are to use the recordkeeping, review, and observation activities to verify that an establishment is effectively implementing the procedures set out in its HACCP plan. CSIs are to verify that establishments are meeting all the HACCP regulatory requirements including monitoring, verification, recordkeeping, and corrective action at all CCPs for a specific production. CSIs are to document any noncompliance they find in performing their verification activities.

B. As part of verifying the recordkeeping requirement, CSIs are to verify the implementation of prerequisite programs or other control measures the establishment uses to support that specific hazards are not reasonably likely to occur. CSIs are to use the recordkeeping, review, and observation components to verify that the establishment is implementing its prerequisite programs and other control measures as written and that the records generated for the program continue to support the decision that the applicable hazard is not reasonably likely to occur in the process. In other words, CSIs

are to verify that the prerequisite program demonstrates that the relevant food safety hazard is not reasonably likely on an ongoing basis.

C. As part of the HACCP recordkeeping requirements, CSIs are to verify that the establishment completes pre-shipment review for before the affected product enters commerce. PHIS will allow CSIs to enter partial verification results but will not consider the procedure complete until all applicable regulatory requirements have been verified, including the pre-shipment review. PHIS will hold that procedure as incomplete in the inspector's calendar until the inspector documents verification results for all mandatory regulatory requirements.

D. CSIs are also to follow the instructions in FSIS Directive 7530.2 when they perform the HACCP verification procedure when a thermal processing canning establishment addresses microbiological hazards by following the canning regulations (9 CFR 318/381.300-311).

II. VERIFYING IMPLEMENTATION OF THE HACCP PLAN

A. CSIs are to perform the HACCP implementation verification procedures for the applicable HACCP process category as often as they appear in the PHIS inspection task list. PHIS will add routine HACCP Implementation Verification procedures to the establishment task list for the HACCP process categories listed in the establishment profile. PHIS may also add a directed HACCP implementation verification procedure to the task list in response to certain events or results (e.g. positive pathogen test results or a trend of food safety noncompliances) suggest that the establishment is not controlling its food safety system. CSIs are to perform the HACCP Implementation procedures listed in the task list.

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

B. CSIs are to initiate a HACCP Verification procedure as a directed procedure as necessary to respond to findings of noncompliance or as instructed by their immediate supervisor, FLS, DO, or Headquarters personnel.

III. CSI VERIFICATION OF HACCP IMPLEMENTATION

A. CSIs are to be familiar with the establishment's hazard analysis, HACCP plan, and any prerequisite or other programs that the establishment uses to support that specific food safety hazards are not reasonably likely to occur. If CSIs identify regulatory noncompliances, they are to consider whether those noncompliances indicate that the establishment has produced or shipped adulterated products.

B. PHIS will assign procedures to CSIs to verify HACCP implementation in an establishment based on the HACCP process categories specified in the establishment's

profile. When they verify HACCP implementation, CSIs are to verify all applicable HACCP regulatory requirements at each process step and verify implementation of any prerequisite programs that apply to the selected product by performing the following steps:

1. Select the product type and specific production:

    a. CSIs are first to select a type of product within the specified HACCP process category. If the establishment produces multiple types of products within the HACCP category, CSIs are to ensure that they verify HACCP implementation for all product types produced in the establishment over the course of time. The CSIs are to select a product type that the establishment is currently producing.

    b. Next, CSIs are to select a specific production of the selected product type, such as the product produced during a specific time period, a specific production lot, or other designated product. CSIs are to verify that the establishment has met all applicable HACCP regulatory requirements at each step and any prerequisite programs applicable to that specific production by following the instructions in sections B. through H. that follow.

2. Review the HACCP plan for the selected product type:

    a. Before performing a HACCP verification procedure, CSIs are to review the relevant HACCP plan to ensure they have full knowledge of its contents. CSIs need to be familiar with the written procedures for monitoring and verification at each CCP. CSIs are also to be familiar with any prerequisite programs or other control measures that the establishment uses to support that an identified food safety hazard is not reasonably likely to occur. CSIs may also review the HACCP plan again if questions arise during the verification procedure.

    b. When reviewing the monitoring and verification procedures and frequencies in the HACCP plan, CSIs need to be able to understand exactly what the establishment is doing at the CCP. If CSIs do not understand how the establishment is performing the monitoring activity at the CCP, they are to seek clarification of the monitoring procedure from establishment management before continuing with the HACCP verification procedure. In this case, CSIs are to carefully consider whether the HACCP plan adequately describes the monitoring procedures and frequencies.

    c. CSIs are to particularly note the most recent date when the HACCP plan was signed by a responsible establishment representative. If the date is recent, CSIs are to pay close attention to the contents of the HACCP plan

because a recent date on the HACCP plan may indicate that the establishment has recently revised the monitoring or verification procedures in the HACCP plan.

d. 9 CFR 417.2(d) requires the establishment is to sign and date the HACCP plan upon initial acceptance, after any modifications, and after the annual reassessment required by 9 CFR 417.4(a)(3).

e. One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.2(d):

    i. Establishment management has not signed and dated the HACCP plan.

    ii. Establishment management has not signed and dated the HACCP plan at least once since January 1 of the previous calendar year.

    iii. Establishment management has modified the HACCP plan without updating the signature and date.

f. When CSIs identify an addition to or modification of the CCPs in the HACCP plan, they are to note the changes and update the PHIS establishment profile to accurately reflect the revised content of the HACCP plan. CSIs are to follow the instructions in FSIS PHIS Directive 5300.1 on how to update the HACCP information in the PHIS establishment profile.

3. Verify the monitoring requirements:

a. The establishment is required to develop and implement procedures to monitor each of the CCPs to ensure compliance with the critical limits (9 CFR 417.2(c)(4)).

b. When they verify HACCP implementation, CSIs are to verify the monitoring requirements by performing the following activities:

    i. Review the HACCP plan to determine whether the HACCP plan design includes the monitoring procedures and frequencies that are used to monitor the critical control points. Since the establishment can modify the HACCP plan without notifying CSIs, CSIs are to ensure that they are familiar with the monitoring procedures and frequencies in the HACCP plan by reviewing the HACCP plan each time they verify the monitoring requirement.

    ii. Observe an establishment employee performing the monitoring activities listed in the plan to determine whether the procedures are

being executed as written in the HACCP plan.

iii. Occasionally perform the establishment monitoring procedure to verify that product meets the critical limit. When CSIs take measurements to verify that product meets the critical limit, they are to use the calibrated instrument that the establishment uses for the monitoring or verification activities.

c. Based on reviewing the monitoring records or on the basis of observing the establishment performing the monitoring procedures, determine whether the monitoring procedures described in the HACCP plan are being performed in the manner and at the frequencies specified in the HACCP plan.

d. One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.2(c)(4):

i. The HACCP plan does not include a written monitoring procedure to ensure that product meets the critical limit at each CCP.

ii. Establishment employees do not implement the monitoring procedures as written in the HACCP plan.

iii. Establishment employees do not implement the monitoring procedures at the frequency specified in the HACCP plan.

iv. CSIs observe a deviation from the critical limit that was not detected by the establishment monitoring procedure. This finding includes any time CSIs observe the deviation in product that has already passed the CCP, product that is at the point of the CCP that would not be selected for monitoring by the establishment, or product that was selected for monitoring but the deviation was not detected by the establishment.

e. If CSIs find a monitoring noncompliance, they are to take a regulatory control action, if necessary, to prevent adulterated product from entering commerce.

f. In addition, CSIs are to consider whether the noncompliance may have resulted in adulterated product entering commerce. If they find that adulterated product may have entered commerce, CSIs are to notify DO personnel through supervisory channels immediately.

4. Verify the verification requirements:

a. The establishment is required to develop and implement procedures to

verify the ongoing effective implementation of the HACCP plan (9 CFR 417.2(c)(7) and 417.4(a)(2)). The verification procedures provide for the calibration of process monitoring instruments, direct observation of monitoring activities and corrective actions, and review of HACCP records unless one or more activity is not applicable in a particular establishment. The verification procedures may also include other activities the establishment develops to verify the effective implementation of the HACCP plan (e.g. microbial sampling of products).

b. When they verify HACCP implementation, CSIs are to perform the following activities to verify that the establishment is meeting the verification regulatory requirements:

   i. Review the HACCP plan to determine whether it lists direct observation procedures and frequencies, records review procedures and frequencies, and process monitoring equipment calibration verification procedures and frequencies. Because the establishment can modify the HACCP plan without notifying CSIs, CSIs are to ensure that they are familiar with the verification procedures and frequencies in the establishment's HACCP plan by reviewing the HACCP plan each time they verify the verification requirement.

   ii. Observe an establishment employee performing the verification activities listed in the plan to determine whether the procedures are being executed as written in the HACCP plan.

   iii. Review the HACCP records or observe the establishment performing the verification procedures to determine whether the verification procedures are being performed at the frequencies specified in the HACCP plan.

   iv. If product sampling is included in the HACCP plan as a CCP verification procedure, observe an establishment employee taking samples and review the results. If the establishment received positive results that indicate the presence of a food safety hazard, CSIs are to verify that the establishment met the corrective action requirements of 9 CFR 417.3.

NOTE: CSIs are to use good judgment in recognizing that there are times when a HACCP plan might not contain all three ongoing verification activities listed in 9 CFR 417.4(a)(2)(i)(ii)(iii). If an establishment has a CCP that is monitored without the use of process monitoring equipment, there would be no need for process monitoring equipment calibration verification procedures. If an establishment only has one employee, it would not be possible for that person to conduct a direct observation of the

monitoring activity. In this situation, the HACCP plan would not need to list a direct observation of the monitoring activities.

c. It is important that the establishment implement corrective actions that meet the requirements of 9 CFR 417.3(a) each time that a deviation from a critical limit occurs, and the requirements of 9 CFR 417.3(b) each time an unforeseen hazard occurs.

d. Since it cannot be predicted when a deviation from a critical limit or an unforeseen hazard will occur, it would be counterproductive to require that the establishment have specific procedures and frequencies in its HACCP plan for directly observing corrective actions. It is necessary, however, for an establishment to directly observe corrective actions frequently enough to verify that these actions are being performed by establishment employees in a manner that meets the applicable regulatory requirements. Under the regulations, the establishment is to document these direct observations in the same manner that it documents other verifications.

e. The verification procedures may be particular to each CCP or may apply more broadly across all CCPs. For example, an establishment may use thermometers to monitor several different CCPs. It would not be necessary to have a specific thermometer calibration procedure for each CCP. The establishment could have a single thermometer calibration procedure that covers the HACCP plan as a whole.

f. In some very small establishments, direct observation of monitoring may be impractical because there is no employee available to perform the direct observation. In these cases, direct observation of monitoring may not be required if there simply is no practical way for the establishment to accomplish it.

g. If the monitoring procedure involves automatic monitoring devices and does not require any human action to accomplish the monitoring of the critical limit, then direct observation of the automatic portion of the monitoring procedure is not required.

h. One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.4(a)(2):

    i. The HACCP plan does not include written verification procedures and frequencies for calibration of any process monitoring instruments used to monitor the CCPs (also noncompliance with 417.2(c)(7)). Calibration methods should be in accordance with accepted procedures or manufacturer instructions (with supporting documentation in either case).

NOTE: If the establishment does not use any process control instruments for its monitoring procedures, calibration is not required.

ii. The HACCP plan does not include written verification procedures and frequencies for direct observation of monitoring activities (also noncompliance with 417.2(c)(7)).

iii. The HACCP plan does not include written verification procedures and frequencies for review of records (also noncompliance with 417.2(c)(7)).

iv. The HACCP plan does not include written description of additional verification procedures (if any) and frequencies the establishment uses to verify the effective implementation of the HACCP plan (e.g. microbiological sampling) (also noncompliance with 417.2(c)(7)).

v. Establishment employees do not implement the verification procedures as written in the HACCP plan.

vi. Establishment employees do not implement the verification procedures at the frequencies specified in the HACCP plan.

vii. The establishment verification employee does not actually observe the monitoring employee performing the monitoring procedure during the direct observation verification procedure.

NOTE: An establishment verifier conducting the same monitoring activity as the monitoring employee does not meet the regulatory requirement for the direct observation verification activity described in 9 CFR 417.4(a)(ii).

viii. The verification results indicate that the establishment is not implementing the HACCP plan as written, and the establishment has not corrected the situation.

ix. The verification results indicate that the HACCP plan is not effectively controlling the food safety hazards, and that the establishment has not corrected the situation.

i. If CSIs find a verification noncompliance, they are to consider whether the noncompliance may have resulted in adulterated product entering commerce. For example, if the verification results show that establishment employees have not been implementing the monitoring procedure correctly, is there sufficient information to determine whether the product met the critical limit? If the establishment cannot demonstrate that the product met the critical limit, CSIs are to take a regulatory control action on any affected product to prevent it from entering commerce. If

adulterated product may have entered commerce, CSIs are to contact their supervisor immediately to discuss the issue.

5. Verify recordkeeping requirements:

   a. The establishment is required to develop a recordkeeping system to document the actual values and observations obtained during monitoring of the CCPs (9 CFR 417.2(c)(6)). The establishment is also required to maintain records documenting the monitoring of CCPs and their critical limits, including actual times, temperatures, or other quantifiable values; the calibration of process monitoring instruments; corrective actions; verification procedures and results; and product names, codes, lots, or other product identification (9 CFR 417.5(a)(3)).

   b. Each record entry is to be made at the time the event occurs and must include the date and time and must be signed or initialed by the employee making the entry (9 CFR 417.5(b)).

   c. The establishment may record and maintain HACCP records on computers provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures (9 CFR 417.5(d)). Such controls typically include features to ensure that each entry can be attributed to the particular employee making the entry and that an entry cannot be subsequently changed without a record of the change.

   d. The establishment needs to provide access to HACCP records for official review by FSIS inspection personnel (9 CFR 417.5(f)). Records may be stored off-site after six months, provided they can be retrieved and provided on-site within 24 hours of a request by FSIS inspection personnel (9 CFR 417.5(e)(2)).

   e. When they verify HACCP implementation, CSIs are to review establishment HACCP records that document the monitoring of CCPs and their critical limits; verification procedures and frequencies; and corrective actions taken in response to a deviation from a critical limit, a deviation not covered by a critical limit, or an unforeseen hazard. CSIs are also to observe establishment employees performing recordkeeping procedures. CSIs are to verify that the establishment HACCP records meet the regulatory requirements described above.

   f. One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.2(c)(6):

      i. The establishment's HACCP plan does not provide for a recordkeeping system for documenting the monitoring data.

ii. The monitoring records do not contain actual values or observations, e.g., a “check mark” or “Okay” instead of the actual value.

g. One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.5(a)(3):

i. Establishment monitoring records do not document all monitoring activities or do not include actual times, temperatures, or other quantifiable values.

ii. Establishment verification records do not document all verification activities or do not include the results of verification procedures.

iii. Establishment corrective action records do not document all corrective actions performed by the establishment.

iv. Establishment HACCP records (including pre-shipment review) do not include product names, product codes, or other identifying information sufficient to demonstrate which specific production is covered by a particular record.

h. When they observe that records are missing, CSIs are to carefully consider whether the record is missing because the establishment employee failed to perform the specified task or because the employee failed to make the appropriate record entry. If CSIs determine that the employee failed to perform the specified procedure (monitoring, verification, or corrective action), they are to document noncompliance with the applicable regulation (9 CFR 417.2(c)(4), 417.4(a), or 417.3, respectively) rather than 9 CFR 417.5(a)(3).

i. One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.5(b):

i. Establishment employees do not make entries in HACCP records at the time that specific events occur.

NOTE: Some establishments may choose to record HACCP results on “scratch paper” and then transfer the results to a clean record at a later time (significantly after the event occurred). This practice is allowed, but the initial “scratch paper” record needs to meet HACCP recordkeeping requirements and must be retained as an official HACCP record. Scratch paper used during a monitoring procedure is not a HACCP record when the data is transcribed to the HACCP record immediately when the employee finishes taking the measurements.

ii. Establishment records do not clearly state the date and time when

each entry was made.

NOTE: The establishment may elect not to enter a date or time for every separate entry in the HACCP record when they make several entries at the same time or on the same date. This practice is acceptable as long as the inspector is able to determine the time and date when each entry was made. For example, an establishment may place a single date at the top of a record form to cover all entries made during that day.

iii. Establishment employees do not sign or initial their entries in HACCP records.

j. In an establishment that documents or maintains electronic HACCP records, if the establishment cannot demonstrate how the computer system ensures the integrity of the records, it does not comply with 9 CFR 417.5(d). When making this determination, CSIs are to consider whether the computer system ensures that each electronic entry can be attributed to the employee making the entry, and that record entries cannot be changed without a record of the change.

k. 9 CFR 417.5(f) requires all records required under Part 417 be available for official review by FSIS inspection personnel. CSIs are to contact their supervisor if the establishment does not make HACCP records, including supporting documents, available for review.

l. Some establishments keep their HACCP records in secured areas (locked cabinets or offices). In these cases, IICs are to work with establishment management to develop a method for an establishment employee to provide access to the secured area upon request. CSIs are to follow any such established procedure when requesting access to records. CSIs are only to request those records normally required to perform their verification duties. They are not to test the establishment by requesting additional records.

6. Verify implementation of prerequisite programs or other control measures used to support that specific food safety hazards are not reasonably likely to occur:

a. The establishment is required to maintain documentation to support the decisions in the hazard analysis (9 CFR 417.5(a)(1)). If the establishment uses prerequisite programs or other control measures to support a decision that a particular hazard is not reasonably likely to occur, the records of the ongoing implementation of those prerequisite programs are part of the supporting documentation required by 9 CFR 417.5(a)(1).

b. When the verify HACCP implementation, CSIs are to verify that the establishment implements any prerequisite programs or other control measures in a way that supports the decision in the hazard analysis for

the specific production. For each prerequisite program or other program the establishment uses to support a decision that a hazard is not reasonably likely to occur, CSIs are to verify implementation of the program by following these steps:

i. CSIs are to review the records generated by the program for the specific production selected to be verified during the HACCP verification procedure.

ii. CSIs are to observe establishment employees implementing the procedures in the program.

iii. Based on their observations, CSIs are to verify that establishment employees implement the prerequisite programs as written.

iv. CSIs are to verify that the records show that the prerequisite program continues to support the decision that that the relevant hazard is not reasonably likely to occur on an ongoing basis.

c. Based on the information they gather from the records and observations, CSIs 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. In other words, CSIs are to verify that establishment employees are implementing the procedures in the prerequisite program in a manner that continues to show that the relevant hazard is not reasonably likely to occur. CSIs are also to verify that the records generated by the prerequisite program demonstrate that it continues to be effective in preventing the relevant food safety hazard.

d. 9 CFR 417.5(f) requires that all records required under Part 417 be available for official review by FSIS inspection personnel. CSIs are to contact their supervisor if the establishment does not make prerequisite programs, prerequisite program records, or other supporting documents available for review.

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

i. The establishment employees are not implementing the procedures in the prerequisite program sufficiently to prevent the relevant hazard from being reasonably likely to occur.

ii. The prerequisite program records indicate consistent or repeated failures to implement the procedures that prevent the relevant hazard from being reasonably likely to occur.

iii. The prerequisite program records do not demonstrate that the program continues to support the hazard analysis decision that the relevant hazard is not reasonably likely to occur.

f. While there are no regulations that explicitly address prerequisite program recordkeeping, the establishment's records need to demonstrate that the establishment has a basis (i.e., the prerequisite program) to support the relevant decisions on an ongoing basis.

g. In most cases, minor failures in prerequisite records would not support a finding of noncompliance. For example, missing an occasional record entry, failing to put a time or initials, or a similar deficiency does not necessarily mean that the prerequisite program is not being implemented effectively. In contrast, failing to implement procedures in a prerequisite program, or evidence that the program is not effectively preventing the hazard from occurring, means 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 Inspection Program Personnel to document noncompliance with 9 CFR 417.5(a)(1) and may be grounds for additional enforcement action.

EXAMPLE: Establishment A implements a prerequisite program to maintain raw product coolers below 35 degrees to support that the hazard of pathogen growth is not reasonably likely to occur. On 3 separate days last week, the employee recording the cooler temperature records did not record his initials as 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 temperature was not maintained. Therefore, the establishment is in compliance with 9 CFR 417.5(a)(1).

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 program is preventing the hazard. CSIs 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 program prevented the hazard of *E. coli* O157:H7.

h. If CSIs 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.

7. Verify the corrective action requirements:

   a. As part of the HACCP plan, establishments are required to develop corrective actions to be followed when a deviation from a critical limit occurs (9 CFR 417.3(a)). These corrective actions must identify and eliminate the cause of the deviation, reestablish control of the CCP, prevent recurrence of the deviation, and ensure that no adulterated product enters commerce. When a deviation from a critical limit occurs, the establishment must implement the corrective actions specified in the HACCP plan.

   b. The establishment is to also implement corrective actions when a deviation that is not covered by written corrective actions or some other unforeseen hazard occurs (9 CFR 417.3(b)). To meet the requirements of 9 CFR 417.3(b), the establishment must segregate and hold the affected product, perform a review to determine the acceptability of the affected product, take any necessary actions to ensure adulterated product does not enter commerce, and reassess the HACCP plan.

   c. When they verify HACCP implementation, CSIs are to verify that establishments meet the corrective action requirements whenever an event occurs that requires a corrective action. CSIs are to verify that the establishment implements corrective actions whenever inspection findings or establishment records (e.g. monitoring records) establish that a deviation from a critical limit or other unforeseen hazard has occurred. If necessary, CSIs are to initiate a directed HACCP implementation procedure to document their verification of corrective action requirements when a routine HACCP inspection procedure is not available.

   d. CSIs may not be able to verify corrective action requirements during a routine HACCP implementation verification procedure if no corrective action is required for that specific production.

   e. CSIs are to verify that the establishment's actions meet all the applicable requirements of 9 CFR 417.3(a) or (b) by performing the following activities:

      i. Review the corrective action records associated with the deviation from the critical limit and observe the establishment executing the corrective actions.

      ii. Compare the establishment's recorded corrective actions with the regulatory requirements listed in 9 CFR 417.3(a) to determine whether the corrective actions taken in response to the deviation from the critical limit meet all of these requirements.

iii. Observe establishment emloyees executing the corrective actions to verify that the establishment has identified the appropriate affected product.

iv. Observe establishment employees executing the corrective actions to verify that the establishment has identified and eliminated the cause of the deviation.

v. Observe establishment employees executing the corrective actions to verify that the establishment's corrective actions have the CCP under control after the actions are taken.

vi. Observe establishment employees executing the corrective actions to verify that preventive measures are established.

vii. Observe establishment employees executing the corrective actions to verify that the establishment prevents product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering into commerce.

f. One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.3(a):

i. The establishment does not implement a corrective action specified in the HACCP plan in response to a deviation from a critical limit.

ii. The establishment's corrective action does not identify and eliminate the cause of the deviation.

iii. The establishment's corrective action does not result in the CCP coming back under control.

iv. The establishment's corrective action does not prevent adulterated product from entering commerce.

v. The establishment's corrective action does not prevent recurrence of the deviation.

g. One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.3(b):

i. An unforeseen hazard occurs or there is a deviation not covered by a specified corrective action and the establishment fails to take the corrective actions required by 9 CFR 417.3(b).

ii. The establishment's corrective action does not segregate and hold all affected product.

iii. The establishment does not perform a review to determine the acceptability of the affected product.

iv. The establishment's corrective action does not prevent adulterated product from entering commerce.

v. The establishment does not reassess the relevant HACCP plan to determine whether to address the unforeseen hazard.

h. CSIs are to take regulatory control action to prevent adulterated product from entering commerce when it becomes apparent that the establishment intends to release product but cannot demonstrate that it is not adulterated. For example, if the establishment signs pre-shipment review before performing necessary corrective actions. Once the establishment has signed pre-shipment review, FSIS considers the product to be in commerce. CSIs are to retain the affected product before it leaves the establishment if they find evidence that the establishment's intended actions will result in adulterated product entering commerce.

i. CSIs are to verify that the establishment applies corrective actions to all product affected by the deviation or unforeseen hazard. The CSIs are to consider how the establishment defined the affected product and verify that additional products are not implicated by the deviation or unforeseen hazard. CSIs are to consider any available information about the establishment process that could indicate whether additional product was affected. These sources of information may include other establishment HACCP monitoring or verification records, SSOP records, establishment testing results, and the records of any related prerequisite programs.

j. When CSIs document compliance with the corrective action requirement, they are to briefly describe their observations that support a finding of compliance as described in Chapter V of this document.

8. Verify the pre-shipment review requirements:

a. Before shipping product in commerce, establishments are required to review the records associated with the production of the product to ensure that the product meets all critical limits, and that any necessary corrective actions have been taken (9 CFR 417.5(c)). FSIS expects the pre-shipment review to be conducted, dated, and signed by an individual who did not produce the HACCP records except in establishments that have too few employees to accomplish this result.

b. FSIS considers product to be “produced and shipped” when the establishment completes pre-shipment review. Verifying that the establishment has completed pre-shipment review enables CSIs to know whether the company has taken full and final responsibility for applying its HACCP controls to the product that it has produced.

c. CSIs are to understand that pre-shipment review can be accomplished if the product is at a location other than the producing establishment, as long as the review of appropriate documents and compliance with 9 CFR 417.5(c) occurs before the product leaves the control of the producing establishment.

d. When they verify HACCP implementation, CSIs are to review establishment pre-shipment review records for the selected product to verify that the establishment meets the requirement of 9 CFR 417.5(c).

e. Occasionally, when verifying HACCP implementation, CSIs are to observe the establishment employee perform the pre-shipment review. This type of observation is particularly important if the CSI is new to the establishment. Once the observation verification has been performed, this regulatory requirement can be verified using the recordkeeping component of the HACCP verification procedure.

f. One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.5(c):

    i. The establishment ships product in commerce without performing a pre-shipment review.

    ii. The establishment transports product to another location prior to pre-shipment review and cannot demonstrate that it maintains control of the product.

    iii. An establishment employee does not sign and date the pre-shipment review.

    iv. An establishment employee does not review the appropriate HACCP records associated with the production covered by the pre-shipment review. The appropriate HACCP records typically include the records of any monitoring activities, verification activities, or corrective actions that were performed during the production period covered by the pre-shipment review.

g. CSIs are to determine noncompliance with 9 CFR 417.5(a)(3) if the pre-shipment review records do not identify the specific production to which they apply (e.g., product codes, lot codes, product name, production

periods).

9. Consider the implications of any noncompliance:

    a. When CSIs complete the HACCP implementation verification procedure, they are to document their findings of compliance or noncompliance in accordance with Chapter V of this document. If CSIs cannot complete the whole verification procedure in one day, they are to enter partial findings in PHIS and then complete the procedure at a later date.

    b. In addition to documenting any findings of noncompliance, CSIs are to consider all their findings in the context of the establishment's food safety system. Whether they identify specific regulatory noncompliance, CSIs are to think about the broader implications of their findings. Documenting individual regulatory noncompliances is important, but to protect public health, CSIs are also to identify those establishments where vulnerabilities in the food safety system may result in increased food safety risks.

    c. CSIs are to consider the following questions:

        i. Are there potential shortcomings in the establishment's decisions regarding hazards that are reasonably likely to occur in its production process?

        ii. Is there a pattern of repeated failure to implement the HACCP procedures as written?

        iii. Is there reason to believe that the establishment's food safety system is not effectively preventing or controlling the applicable food safety hazards?

        iv. Has product been prepared, packed, or held under insanitary conditions where it may have become contaminated with filth or rendered injurious to health?

        v. Has the establishment produced adulterated products or shipped adulterated products in commerce?

        vi. Do the establishment's records show any pattern or trend of increasing microbial levels or provide any other indication of an increasing potential for failure of the food safety system or product adulteration?

    d. CSIs are also to consider whether their findings indicate systemic or ongoing problems with the establishment's food safety system, and whether those problems could result in the establishment producing

adulterated or misbranded products.

e. If CSIs have concerns that there may be systematic problems with the establishment's food safety system, or there is reason to believe that product may have become adulterated, CSIs are to bring the issues to the attention of their supervisor immediately.

CHAPTER IV - PATHOGEN REDUCTION ACTIVITIES

I. TESTING FOR GENERIC *E. coli*

A. The purpose of generic *E. coli* testing is to verify the effectiveness of sanitation and process control in slaughter facilities. The following discussion explains how IPP are to verify that the establishment is maintaining such controls.

B. Establishments that slaughter livestock (excluding catfish) or poultry must test carcasses of the species slaughtered in the greatest number for *Escherichia coli* Biotype 1 (generic *E. coli*) in a manner that meets the requirements in 9 CFR 310.25(a) or 381.94(a), respectively. Each establishment must develop written sampling procedures that identify the employees designated to collect samples, the locations of sampling, how randomness is achieved, and measures to ensure sample integrity.

C. Before an establishment is granted inspection, the Frontline Supervisor (FLS) is to verify that the establishment's written *E. coli* testing procedures meet the basic regulatory requirements. The FLS is to complete the *E. coli* Basic Compliance Checklist (FSIS Form 5000-3) to document his or her findings. This procedure is performed by the FLS only when the establishment initially receives a grant of inspection. When the procedure is performed, the FLS is to use this checklist to verify that the written procedures meet the regulatory requirements:

1. Do the written procedures contain procedures for collecting samples for *E. coli* testing?

2. Do the written procedures identify the establishment employee designated to collect the samples for *E. coli* testing?

3. Do the written procedures address the location of sampling?

4. Do the written procedures describe how sampling randomness is achieved?

5. Do the written procedures describe how the samples are to be handled to ensure sample integrity?

6. Do the sampling procedures and frequencies meet the applicable requirements of 9 CFR 310.25(a) or 381.94(a)?

NOTE: If the FLS determines that the generic *E. coli* written procedures do not meet regulatory requirements, he or she is to meet with establishment management to inform them of the shortcomings in the generic *E. coli* testing procedures. If the establishment fails to adequately respond to the FLS's request, he or she should contact the DO to inform it of the situation. (See FSIS PHIS Directive 5220.1, Granting, Refusing, Voluntary Suspension or Voluntary Withdrawal of Federal Inspection Service.)

D. The DM is not to grant inspection to a slaughter establishment until the establishment has developed a written program for generic *E. coli* testing that meets the applicable regulatory requirements.

E. Once a slaughter establishment has been granted inspection, CSIs are to verify that the establishment meets the applicable requirements for generic *E. coli* testing. Each official establishment that slaughters livestock or poultry is required to test for *Escherichia coli* Biotype I (generic *E. coli*). CSIs will verify that these establishments meet the *E. coli* regulatory requirements. The basic regulatory requirements are in 9 CFR 310.25(a)(1) – (4) for livestock slaughter establishments. The basic regulatory requirements for poultry slaughter establishments are set out in 9 CFR 381.94(a)(1) – (4). CSIs will complete the E. coli Testing Checklist (FSIS Form 5000-4) in PHIS to document their findings. CSIs are to document the results of their verification, including any noncompliance, according to the instructions in Chapter V of this document.

F. CSIs are to perform the Generic *E. coli* verification procedure on a routine basis at the frequency specified in the PHIS inspection task list. CSIs are also to initiate a directed Generic *E. coli* verification procedure if they observe noncompliance at other times or when instructed to do so by supervisors or other policy issuances.

G. CSIs are to observe establishment employees collecting samples for generic *E. coli* and review the establishment's records to verify that the establishment collects for generic *E. coli* from the type of livestock or poultry it slaughters in the greatest numbers. In general, CSIs are to judge which type of livestock or poultry is slaughtered in the greatest numbers based on historical slaughter numbers (e.g. the previous year's totals) unless the establishment can project that the majority type of animal will be different because of a change in operations.

H. Slaughtered livestock or poultry that will not receive the FSIS mark of inspection such as custom exempt livestock or religious exempt non-eviscerated poultry are exempt from generic *E. coli* testing.

I. If the establishment does not test for *E. coli* Biotype I, or if it does not collect samples from the type of livestock or poultry slaughtered in the greatest numbers, it does not comply with 9 CFR 310.25(a)(1) or 381.94(a)(1).

J. CSIs are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

II. SAMPLE COLLECTION

Paragraph 310.25(a)(2)(ii) states: *Sample collection. The establishment shall collect samples from all chilled livestock carcasses, except those boned before chilling (hot-boned), which must be sampled after the final wash. Samples must be collected in the following manner; (A) For cattle, establishments must sponge or excise tissue from the flank, brisket and rump, except for hide-on calves, in which case establishments must*

take samples by sponging from inside the flank, inside the brisket, and inside the rump. (B) For sheep, goat, horse, mule, or other equine carcasses, establishments must sponge from the flank, brisket, and rump, except for hide-on carcasses, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump. (C) For swine carcasses, establishments must sponge or excise tissue from the ham, belly and jowl areas.

Paragraph 381.94(a)(2)(ii) states: Sample collection. A whole bird must be taken from the end of the chilling process. If this is impracticable, the whole bird can be taken from the end of the slaughter line. Samples must be colleted by rinsing the whole carcass in an amount of buffer appropriate for that type of bird. Samples from turkeys also may be collected by sponging the carcass on the back and thigh.

A. CSIs are to review the establishment's written sampling procedures and observe establishment employees collecting samples to verify that the establishment collects samples at the locations and in the manner specified in 310.25(a)(2)(ii) or 381.94(a)(2)(ii).

B. One or more of the following findings evidence that the establishment does not comply with 9 CFR 310.25(a)(2)(ii) or 381.94(a)(2)(ii):

1. The establishment is not collecting samples at the point in the process specified in the applicable regulation:

    a. From chilled livestock carcasses or after the final wash for hot-boned carcasses.

    b. From poultry carcasses at the end of the chilling process.

2. The establishment is not collecting samples in the manner specified for the particular type of animal:

    a. By sponging or excising tissue from the flank, brisket, and rump in cattle.

    b. By sponging the flank, brisket, and rump of sheep, goats, horses or other equines.

    c. By sponging or excising tissue from the ham, belly, and jowl of swine.

    d. By sponging the inside of the flank, brisket, and rump from hide-on livestock carcasses (except swine).

    e. By whole bird rinse from chickens.

    f. By whole bird rinse or sponging of the back and thigh from turkeys.

g. By sponging of the back and thigh from ratites.

C. CSIs are to document the results of their verification, including any noncompliance, in the manner specified in Chapter V of this document.

III. SAMPLING FREQUENCY

Paragraph 310.25(a)(1)(i) states: Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

Paragraph 310.25(a)(2)(iii) states: Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the volume of production at the following rates:

Cattle, sheep, goats, horses, mules and other equines: 1 test per 300 carcasses, but at a minimum of one sample during each week of operation.

Swine: 1 test per 1,000 carcasses, but at a minimum of one sample during each week of operation.

Paragraph 381.94(a)(2)(iii) states: Sampling frequency. Slaughter establishments except very low volume establishments defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the establishment's volume of production at the following rates:

Chickens: 1 sample per 22,000 carcasses, but a minimum of one sample during each week of operation.

Turkeys, ducks, geese, and guineas: 1 sample per 3,000 carcasses, but a minimum of one sample during each week of operation.

Paragraph 310.25(a)(2)(iv) states: Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with §417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

Paragraph 310.25(a)(2)(v) states: Sampling in very low volume establishments. (A)

Very low volume establishments annually slaughter no more than 6,000 cattle, 6,000 sheep, 6,000 goats, 6,000 horses, mules or other equines, 20,000 swine, or a combination of livestock not exceeding 6,000 cattle and 20,000 total of all livestock. Very low volume establishments that collect samples by sponging shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments collecting samples by excising tissue from carcasses shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

Paragraph 381.94(a)(2)(v) states: <u>Sampling in very low volume establishments.</u> (A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, 60,000 squabs, 6000 ratites,or a combination of all types of poultry not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments that slaughter turkeys, ducks, geese or guineas in the largest number must collect at least one sample during each week of operation, after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first.

A. CSIs are to review the establishment's written program, observe establishment employees collecting samples, and review establishment records to verify that they are collecting samples at the required frequency specified in 9 CFR 310.25(a)(2) or 381.94(a)(2).

B. One or more of the following findings evidence that the establishment is not complying with the sampling frequency provisions of 9 CFR 310.25(a)(2) or 381.94(a)(2):

1. An establishment that is not very low volume does not sample at the specified frequency and has not incorporated an alternate sampling frequency as a verification procedure in the HACCP plan.

2. An establishment that does not qualify as a very low volume plant is sampling at the rate specified for very low volume rate of slaughter.

3. A very low volume establishment does not collect at least one sample per week beginning the first full week of June until it has collected 13 samples.

C. CSIs are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

IV. SAMPLE ANALYSIS

Paragraph 310.25(a)(1)(ii) states: *Obtain analytic results in accordance with paragraph (a)(3) of this section.*

Paragraph (a)(3) states: Analysis of samples. Laboratories may use any quantitative method for analysis of E. coli that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists) or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

A. CSIs are to review the establishment's written programs and records to verify that the laboratory analyzing the samples uses an AOAC Official Method or another method that meets the criteria in paragraph (a)(3) of 9 CFR 310.25 or 381.94. CSIs are to determine whether the establishment should have documentation to demonstrate that the laboratory method meets these criteria.

B. One or more of the following findings evidence that the establishment does not comply with 9 CFR 310.25(a)(3) or 381.94(a)(3):

1. The establishment does not maintain documentation regarding the analytical method used by the laboratory.

2. The documentation indicates that the laboratory method is not either an AOAC official method or approved and published by another scientific body as specified in paragraph (a)(3).

C. CSIs are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

V. RECORDING OF TEST RESULTS

Paragraph 310.25(a)(1)(iii) states: *Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.*

Paragraph (a)(4) states: Recording of test results. The establishment shall maintain accurate records of all test results, in terms of CFU/cm^2 of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

A. CSIs are to review establishment records to verify that they accurately document the generic *E. coli* results in terms of colony forming units per square centimeter (CFU/cm^2) (or CFU/ml of rinse fluid for whole-bird rinse). CSIs are also to verify that the

establishment records the results on a process control chart or table that shows at least the most recent 13 test results.

B. One or more of the following findings evidence that the establishment does not comply with 310.25(a)(4) or 381.94(a)(4):

1. The establishment does not record the generic *E. coli* test results on a process control chart or table in terms of CFU/cm^2 of surface area sponged or excised or CFU/ml of fluid.

2. The establishment's process control chart or table does not show at least the most recent 13 *E. coli* results.

3. The establishment does not retain records of test results for 12 months.

C. CSIs are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

VI. EVALUATION OF RESULTS

REGULATORY TABLE FOR THE EVALUATION OF RESULTS

Table 1 – Evaluation of *E. coli* Test Result

Type of Livestock	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of samples tested (n)	Maximum number permitted in marginal range (c)
Cattle	Negative	100 CFU/cm^2	13	3
Swine	10 CFU/cm^2	10,000CFU/cm^2	13	3
*Chickens	100 CFL/ml	1,000 CFU/ml	13	3
*Turkeys	N.A.[a]	N.A.	N.A.	N.A.

[a] Not available; values for turkeys will be added upon completion of data collection program for turkeys.
* This portion of the Table 1 was extracted from Table 1of § 381.94(a)(5).

A. CSIs are to review the establishment's records to verify that it is evaluating the generic *E. coli* test results to assess slaughter process control. CSIs are to verify that the results meet the criteria in the table above in establishments that excise tissue samples from cattle or swine or in establishments that sample chickens. In all other establishments, CSIs are to verify that the establishment is evaluating the test results using statistical process control techniques.

B. In this context, CSIs are to verify that an establishment that uses statistical process control has assessed the historical "normal" performance of the slaughter process when it was in control and developed criteria that will indicate when the process may not be in control. CSIs are to verify that the establishment uses generic *E. coli* testing results to identify times when the slaughter process is trending toward a loss of control and takes necessary actions to reestablish control. CSIs are not to focus on the particular method the establishment uses to set process control criteria. Instead, they are to review the generic *E. coli* testing results and verify that the establishment has set generic *E. coli* criteria to define process control and responds to results outside those criteria.

C. One or more of the following findings evidence that the establishment does not comply with 9 CFR 310.25(a)(5) or 381.94(a)(5):

1. The establishment does not evaluate generic *E. coli* testing results to assess slaughter process control, either by using the applicable M/m criteria in Table 1, or by using statistical process control techniques.

2. The establishment does not take necessary actions to re-establish control of the slaughter process when the testing results indicate a loss of process control.

NOTE: The establishment's generic *E. coli* testing results cannot, by themselves, support a finding of noncompliance with 9 CFR 310.25(a) or 381.94(a). However, if an establishment's testing results indicate a failure of process control, CSIs are to verify the establishment's sanitary dressing procedures.

D. CSIs are to document the results of their verification, including any noncompliance, in a manner that accords with Chapter V of this document.

CHAPTER V – DOCUMENTATION AND ENFORCEMENT

I. DOCUMENTING VERIFICATION RESULTS IN PHIS

A. IPP are to use PHIS to document the results of their verification procedures, including findings of regulatory compliance and regulatory noncompliance. For additional instructions in how to use PHIS to document inspection results, please refer to the PHIS User Guide.

B. FSIS intends to use the results of inspection procedures and information about establishment operations to guide policy development and target Agency resources to those activities that will best protect public health. To assist with these types of decisions PHIS is designed to capture information about inspection procedures such as:

1. Which regulatory requirements IPP verified, and whether they observed compliance or noncompliance;

2. For HACCP procedures, which HACCP plans, prerequisite programs, and CCPs IPP included in their verification;

3. How IPP verify regulatory requirements (e.g. recordkeeping or review and observation);

C. After IPP have completed a verification procedure, they are to record the results of the procedure by selecting the procedure and recording the results in the task results page. They are to make the appropriate entries regarding the procedure and their findings of regulatory compliance or noncompliance by checking appropriate boxes, making appropriate selections from lists, or typing in text as prompted by the PHIS system.

D. PHIS will prompt the IPP to select the specific regulatory requirements that they verified during the inspection procedure from a list. IPP are to select the regulations they verified during the procedure and record a finding of compliance or noncompliance for each one.

E. When IPP find noncompliance, they are to:

1. Notify a representative of establishment management as soon as possible (before documenting the findings).

2. Document the noncompliance in PHIS, mark the noncompliance as “final” (see section II below), print the NR, and present it to establishment management. Note that PHIS will allow IPP to document one or more noncompliances as separate documents within a single NR. IPP are to finalize each individual noncompliance and present it to establishment management as soon as practical, even if they have not finished the inspection task. If they find

subsequent noncompliances during the remainder of the inspection task, those may be documented separately.

3. Verify that the establishment takes necessary actions to return to compliance with the applicable regulation(s) found noncompliant. When the regulations require specific corrective actions, the IPP is to verify that the establishment meets those regulatory requirements (see 9 CFR 417.3, 416.15).

4. When the establishment has returned to compliance with all regulations found noncompliant in the NR, IPP are to mark the NR and the associated inspection task as "completed." Record the establishment's return to compliance in PHIS. PHIS will not consider the inspection task complete until the inspector documents that the establishment returns to compliance.

5. Perform a directed inspection procedure to follow up and verify that the establishment continues to comply with the applicable regulatory requirements. PHIS will automatically direct that a follow-up procedure be performed. When they perform this directed inspection procedure, IPP are to verify the same regulatory requirements for the same type of product that they did when they detected the noncompliance.

6. When IPP enter inspection results in PHIS, the system will allow IPP to enter information by selecting from appropriate choices wherever possible. The possible selections for these data fields will reflect the information in the PHIS establishment profile.

7. If IPP observe that the available selections do not match the establishment's operations, they are to review the plant profile and make any necessary updates. IPP are to refer to FSIS PHIS Directive 5300.1 for information about the establishment profile and instructions on how to update the profile.

II. DOCUMENTING NONCOMPLIANCE

A. When IPP find noncompliance with one or more regulatory requirements, PHIS will allow the IPP to complete a NR(NR, FSIS Form 5400-4). The IPP is to complete the NR in the PHIS electronic format following the instructions here and in the PHIS User Guide.

NOTE: If PHIS is not operational, IPP may complete and issue a paper copy of the NR (FSIS Form 5400-5). However, once PHIS becomes operational again, IPP are to record the applicable procedure and results and document the NR in PHIS.

B. The date, NR number, procedure code, and establishment number are automatically completed by PHIS.

C. *Relevant Regulations*—Select one or more of the regulatory citations offered on the noncompliance page in PHIS. PHIS will offer the regulatory citations based on the earlier recording of the regulations verified on the task results page. IPP are to verify that the regulatory citation includes all the specific regulations whose requirements the establishment did not meet. If a particular noncompliant regulatory citation is not available in PHIS, IPP are to type it in the description text block. If IPP believe the regulatory citation should be available for a particular inspection task, they are to submit the suggestion to PDD through askFSIS.

D. *Description of Noncompliance*—IPP are to include the following elements in their description:

1. A description of each noncompliance in clear, concise terms, including the problem, time of occurrence, location, and effect on the product, if any. The description should clearly explain how the IPP's findings support the determination that the establishment did not meet regulatory requirements.

2. An explanation of how the IPP notified establishment management of the noncompliance.

3. When there is a developing trend of noncompliance, the number of the previous NRs with the same cause and a description of how the NR derived from the same cause. PHIS allows IPP to review recent similar NRs and select one or more NRs associated to the new NR. In addition, IPP are to describe any unsuccessful further planned actions taken by the establishment to address the noncompliances. Additionally, IPP are to state whether they have discussed the developing trend of noncompliance with establishment management IPP are also to document the identified trend in the meeting notes feature of PHIS for discussion at the next meeting with establishment management (refer to the PHIS User Guide for additional instructions on the meeting notes and MOI features of PHIS).

E. *Affected Product Information* – IPP are to record approximate weight and any product name, lot number, or other information available to identify the specific amount of product affected by the noncompliance, if any.

F. P*roduct adulteration* -- IPP are to use the product adulteration check box on the noncompliance page to indicate if the documented noncompliance resulted in any adulterated or misbranded product being produced.

G. *Retain Tags/Rejected Tags* -- If IPP took a regulatory control action (US Retain/Reject tag) as a result of the noncompliance, they are to enter the number on the tag(s).

NOTE: In most cases, it is not necessary to include references to the Acts or to quote the applicable regulation in full in the description of noncompliance.

H. Examples of information to be included in the description of noncompliance:

1. At approximately 0410 hours, after the establishment's pre-operational inspection and before the start of production, I performed a pre-operational Sanitation SOP verification procedure. I observed the following noncompliances: Rust on the auger and auger throat of the #2 grinder; rust on the auger and blender arms of the small Hobart grinder; rust on the crossbar on top of the hopper to the stuffer; and dried residue on the blade guides and the bottom of the pulley on both band saws. Because these surfaces are all actual or potential product contact surfaces, rust and product residue in these areas would cause product to become contaminated at the start of operations. I applied U.S. "Reject" tags # B 1469277, B 1469278, B 1469279, B 1469280, and B 1469281 to the #2 grinder, the small Hobart grinder, the stuffer, and both band saws, respectively. I informed the foreman who immediately had the equipment appropriately cleaned to restore sanitary conditions. Verbally the foreman provided the following preventive measure: increasing the amount of time spent conducting pre-op monitoring and giving instructions to the cleaning crew to be more observant. A similar noncompliance was documented on NR 05 -11, dated February 13, 2011. The preventive measures of modifying the Sanitation SOPs to include a procedure for cleaning the grinder parts and saw blades in a manner that will prevent rust formation were not implemented or were ineffective in preventing recurrence.

2. At approximately 1425 hours, I observed condensation dripping from pipes in the ceiling onto chicken parts on belt #1 in the processing boning room. Belt #1 was U.S. "Rejected" with tag #578688. Approximately 30# of product was U.S. "Retained" with tag #578689. Ms. Jane Doe was notified of the direct contamination of product and the insanitary condition of belt #1. She was informed that the regulatory control actions would remain in effect until the establishment meets the requirements of 9 CFR 416.15 and 416.2.

3. I was reviewing the HACCP records for cooked chicken, lot 1287, and observed a note "see sampling results date 07/05/10" in the margin of the cooking log. I asked the HACCP coordinator, Sam Billings, about this note and was told there is a new customer who requires copy of a negative sample report for each shipment of product purchased. I asked to see the sampling reports and at first Mr. Billings replied that since this sampling is being done for a customer and is not included in the HACCP plan the records could not be shared. I explained that the establishment must make the sampling reports available and referred him to Directive 5000.2 for more information. After obtaining the sampling reports, I observed negative Salmonella results recorded for all lots sampled, except lot 1287. For lot 1287 there is a positive sample result for Salmonella, and a notation "lot resampled, pending further results". I examined the HACCP records and observed that pre-shipment review has been completed for this lot. I asked Mr. Billings to demonstrate where the product is being stored. After

determining that the entire lot was still present and that the establishment had apparently not recognized the hazard represented by the positive result, nor taken any action to prevent the shipment of the product, I took regulatory control action over the product by applying U.S. Retained tag # 687423 to 37 cases of cooked chicken, approximately 3,700 pounds of product. I informed the establishment that the positive Salmonella result would indicate a hazard and that corrective actions per 417.3 would be required. I called my Frontline Supervisor to discuss whether to allow the establishment to continue operating with this HACCP plan.

I. *To (Name and Title)* -- PHIS will provide a list of names from the PHIS Establishment profile Contact tab information to select from or enter the name and title of the responsible establishment official if not listed. For a HACCP system noncompliance, always enter the name of the person who signed the HACCP plan. For a Sanitation SOP noncompliance, always enter the name of the person who signed the Sanitation SOP. For SPS noncompliance, IPP are to enter the name of the establishment official responsible for responding to the NRs.

*J. Personnel Notified -- E*nter the names of the establishment management personnel who were notified about the noncompliance. Select one or more names from the list offered in PHIS. If IPP notified someone other than one of the listed contacts, enter that name in the fields.

K. *Signature of Inspection Program Employee*-- IPP sign the paper NR form after the noncompliance has been finalized and printed.

L. *Plant Management Response* -- On the printed NR, the "immediate action" and "further planned action" blocks may be completed by the establishment. When the establishment elects to respond, the "immediate action" is the action the establishment is taking to correct the noncompliance including appropriate product disposition. The "further planned action" is the action to prevent recurrence. If the establishment elects to respond to the NR orally, IPP are to document the response by plant management.

M. *Signature of Plant Management and Date* -- If establishment management responds in writing on block 12 or block 13, an establishment official should sign and date the NR.

N. *Verification Signature of Inspection Program Employee and Date* – Once an establishment has returned to compliance for all the regulatory noncompliances documented in the NR, IPP are to navigate to that NR in PHIS and designate it as completed.

NOTE: The NR can only be marked completed after IPP have verified that the establishment has brought itself into compliance with the regulatory requirement that was not met and resulted in the issuance of the NR. If the non-compliance necessitates the establishment to take actions as required by 9 CFR 416.15 or 417.3, the NR can only be closed after IPP have verified that the establishment has met the requirements

of 9 CFR 416.15 and 417.3. Once the NR has been marked completed, IPP are also to mark the associated inspection task as completed.

O. The establishment is not required to indicate its corrective and preventive measures on the NR, and IPP may need to verify corrective actions by reviewing establishment records.

III. DOCUMENTATION OF SPS VERIFICATION RESULTS

A. IPP perform the generic sanitation verification procedure to verify compliance with the SPS regulations. Noncompliance is the failure of an establishment to meet one or more regulatory requirements in 9 CFR 416.1 – 416.5. Every time IPP find that the establishment is not meeting the SPS requirements, they are to document the noncompliance on the NR. Noncompliance with one or more of the SPS regulatory requirements will be designated as a food safety noncompliance by PHIS.

B. If IPP determine that there is regulatory noncompliance, they are to enter the noncompliance finding and complete a NR in PHIS.

C. If an establishment has not complied with a sanitation performance standard, but product is not directly contaminated, IPP need to determine whether the noncompliance requires a regulatory control action to prevent contamination or adulteration of product.

D. If there is an imminent probability that the noncompliance will result in product adulteration if not addressed immediately, IPP are to take a regulatory control action such as retaining product or rejecting equipment and complete a NR.

E. If the noncompliance does not need immediate attention, IPP are to notify the establishment management of the noncompliance and document the finding on a NR.

F. If an establishment has not complied with a sanitation performance standard, and product is directly contaminated, IPP are to verify that the establishment addresses the noncompliance by meeting the requirements of 9 CFR 416 or 9 CFR 417 as described below. IPP are to document the noncompliance using the appropriate Sanitation SOP or HACCP procedure code as described in the following sections. IPP are to record the results of the original SPS procedure without a NR and indicate the regulations that were verified. IPP are also to note that a HACCP or Sanitation SOP noncompliance was detected and refer to the subsequent HACCP or Sanitation SOP NR.

G. If direct product contamination occurs, IPP are to verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 416.15. The establishment may need to re-evaluate the effectiveness of its Sanitation SOPs and modify them if they are no longer effective in preventing direct contamination or adulteration of product.

H. the direct product contamination poses a food safety hazard, IPP are to verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 417.3(b). These corrective actions include a reassessment to determine whether the unforeseen hazard should be incorporated into the HACCP plan.

I. If IPP determine that a SPS noncompliance is because of the establishment's systematic or repetitive failure to maintain sanitary conditions, they are to document noncompliance with 9 CFR 416.1 in addition to the specific applicable SPS regulation.

IV. DOCUMENTATION OF SANITATION SOP VERIFICATION RESULTS

A. IPP perform the Sanitation SOP verification procedures to verify that the establishment is meeting the regulatory requirements of 9 CFR 416.12 – 416.16 as described in Chapter II of this document. IPP select in PHIS the regulatory requirements they have verified and indicate compliance or noncompliance for each. If the establishment does not meet one or more regulatory requirements, IPP document the noncompliance on a NR.

B. When IPP document compliance with SSOP corrective action requirements, they are to include a brief description of their observations that support a finding of compliance. IPP are to record these affirmative findings in the text box in the inspection task results page of PHIS.

C. When IPP determine that there is noncompliance with the Sanitation SOP regulatory requirements as described in Chapter I of this document, they are to document that noncompliance on a NR in PHIS. IPP are to clearly describe on the NR their findings that support the determination of Sanitation SOP noncompliance. When IPP observe Sanitation SOP noncompliance that does not result in contamination of product or product contact surfaces (e.g. failure to initial records), they are not to take a regulatory control action.

D. When IPP observe contamination of product or direct product contact surfaces during an Operational Sanitation SOP verification procedure, they are to take a regulatory control action on the affected equipment or product. IPP are to remove the regulatory control action only after the establishment has proposed corrective actions that 1) ensure appropriate disposition of products, 2) restore sanitary conditions, and 3) prevent recurrence of direct contamination or adulteration of products.

E. When IPP observe contamination of direct product contact surfaces during a Pre-Operational Sanitation SOP verification procedure, they are to take a regulatory control action on the affected equipment. During pre-operational sanitation there should be no affected product. IPP are to remove the regulatory control action only after the establishment has restored sanitary conditions.

F. the establishment has found the contaminated contact surface or product and taken

the corrective actions required, there is no noncompliance. IPP are to verify that the establishment is implementing the corrective actions specified in 9 CFR 416.15 when the establishment finds direct contamination or adulteration of products or contact surfaces.

G. If IPP determine that a Sanitation SOP noncompliance evidences a systematic or repetitive failure by the establishment to prevent product contamination or maintain sanitary conditions, they are to document noncompliance with 9 CFR 416.1 in addition to the applicable Sanitation SOP regulation.

H. If IPP observe Sanitation SOP and SPS noncompliance while performing a Sanitation SOP verification procedure, they are to document both of the noncompliances on a single Sanitation SOP NR by recording a result of noncompliance for each applicable regulatory citation. If IPP observe only SPS noncompliance while performing a Sanitation SOP verification procedure, they are to record the Sanitation SOP procedure results of regulatory compliance and record the SPS noncompliance under a separate SPS verification procedure. IPP are to initiate a directed SPS verification procedure even if they had not planned to perform a routine SPS procedure that day.

V. DOCUMENTING HACCP VERIFICATION RESULTS

A. IPP may observe HACCP noncompliance when they perform the HACCP implementation verification procedure or the Hazard Analysis Verification procedure as described in Chapter III of this document. When IPP perform a HACCP implementation or HAV procedure, they are to record a determination of compliance or noncompliance for each specific regulatory requirement verified. If IPP record a determination of noncompliance for one or more regulatory requirements, they are to document a NR in PHIS. In the NR, IPP are to clearly describe the findings and how the findings support a determination of HACCP noncompliance.

B. IPP perform the HACCP verification procedure to verify that the establishment is meeting the regulatory requirements of 9 CFR 417.2 – 417.7 for a particular production. The four requirements that the IPP verify when performing these procedures are monitoring, verification, corrective actions, and recordkeeping. IPP perform the HAV procedure to verify that the establishment has met the regulatory requirements for hazard analysis (9 CFR 417.2(a)), supporting documentation (9 CFR 417.5(a)), and validation (9 CFR 417.4(a)).

C. When IPP document compliance with HACCP corrective action requirements, they are to include a brief description of their observations that support a finding of compliance. IPP are to record these affirmative findings in the text box in the inspection task results page of PHIS.

D. A deviation from a critical limit is the failure to meet the applicable value determined by the establishment for a CCP. If a deviation from a critical limit occurs, an establishment is required to take actions in accordance with 9 CFR 417.3.

E. A HACCP noncompliance is the failure to meet any of the regulatory requirements of 9 CFR Part 417, monitoring, verification, recordkeeping, reassessment, and corrective action. If a HACCP noncompliance occurs, an establishment is expected to take immediate and further planned actions to correct the noncompliance.

F. Before making a determination that there has been noncompliance, consider the following questions:

1. Has the establishment identified the failure to meet the regulatory requirements or deviations from critical limits?

2. If product is involved, has the establishment ensured product safety?

3. Has the establishment taken immediate and further planned actions to correct the failure to meet regulatory requirements, or has it taken corrective actions to address the deviations in accordance with 9 CFR 417.3?

4. Is a trend developing (i.e., has the establishment repetitively carried out the actions in 1.a through 1.c above for similar situations)?

NOTE: In answering these questions, it may be necessary to consider additional records.

G. If the answer is no to questions F 1. through F 3., or yes to question 4, then a noncompliance exists. IPP are to document noncompliance in PHIS and generate an NR.

H. If the answer is yes to F 1. through F 3. and no to question 4, then there is no noncompliance because the establishment has already identified and addressed the situation. IPP are to document compliance with the applicable regulations in PHIS, and no other action is necessary. Because the establishment's response provides the further planned actions and preventive measures for the noncompliance or deviation, not writing an NR does not adversely affect an inspection program employee's ability to track developing trends. However, an establishment's failure to follow through on further planned actions and preventive measures could lead to recurring noncompliances and would warrant NRs in recurring situations.

I. For purposes of consistency, all the examples below use monitoring. The methodology applies to problems with verification, recordkeeping, reassessment, and corrective actions as well.

EXAMPLE 1*:* While reviewing records during a HACCP verification procedure, a IPP finds that an establishment employee missed a 9:00 a.m. monitoring check. The IPP then finds that the establishment found the error during its records verification, demonstrated product safety with other records, and took immediate and further planned actions for the noncompliance by re-training the employee. In addition, the IPP looked at previous NRs and determined that the establishment had not missed a monitoring check in over three months. In this situation no NR is necessary even though there was a missed monitoring check, and the IPP documents compliance with the monitoring requirement for the HACCP verification procedure in PHIS. However, if the IPP had found that adequate immediate and further planned actions were not in place, and that the missed monitoring check and correction had occurred several times within the month, he or she may determine that a trend for monitoring noncompliance is developing. In this case he or she is to document the noncompliance in PHIS, issue an NR, and discuss this trend with establishment management during the weekly meeting.

EXAMPLE 2: While reviewing records during a HACCP verification procedure, a IPP finds that an establishment employee missed a 9:00 a.m. monitoring check and finds no indication that the establishment identified the missed monitoring check. The IPP then determines that the product was shipped without a pre-shipment review. He or she documents noncompliance with the monitoring requirement and the pre-shipment review requirement in PHIS and writes an NR for the HACCP procedure. Next he or she determines whether the establishment can provide other documentation that establishes product safety. If the establishment cannot demonstrate product safety, IPP is to take action under the Rules of Practice, 9 CFR part 500.

EXAMPLE 3: While reviewing records during a HACCP verification procedure, a IPP observes that an establishment employee recorded a deviation from a critical limit on the monitoring record. The IPP verifies that the corrective actions taken by the establishment met the requirements of 9 CFR 417.3(a). There is no regulatory noncompliance, and an NR is not necessary. The IPP documents his or her findings of regulatory compliance in PHIS.

EXAMPLE 4: While reviewing records during a HACCP verification procedure for a single lot of product, a IPP sees in the records that an establishment employee missed a monitoring check at 10:00 a.m., and that at 11:00 a.m. the establishment had a deviation from a critical limit. The IPP continues to review the records and finds that at pre-shipment review, the establishment identified the deviation and took the proper 9 CFR 417.3 corrective and preventive measures but failed to address the monitoring error. In this situation the IPP documents noncompliance with the monitoring requirement because of the monitoring error and determines whether the establishment can demonstrate product safety relevant to the missed monitoring check. If so, no other action is necessary. If the establishment cannot support product safety, the IPP is to take action in accordance with the Rules of Practice, 9 CFR part 500.

J. When IPP observe a HACCP noncompliance that includes a deviation from a critical limit or an unforeseen hazard, they are to verify that the establishment implements

corrective actions required by 9 CFR 417.3 as described in Chapter II of this document. IPP are to verify that the establishment controls the affected product and ensures that no adulterated product will enter commerce. IPP are not to take a regulatory control action unless they determine that the establishment has failed to identify all the affected product or that the establishment's corrective action will allow adulterated product to enter commerce.

VI. DOCUMENTING GENERIC *E. coli* VERIFICATION RESULTS

A. IPP perform the Generic *E. coli* verification procedures to verify that the establishment is meeting the regulatory requirements of 9 CFR 310.25(a) or 381.94(a) as described in Chapter IV of this document. When IPP enter their verification results in PHIS, they are to select the regulatory requirements they verified and indicate compliance or noncompliance for each. If the establishment does not meet one or more regulatory requirements, IPP document the noncompliance on a NR.

B. The establishment's generic *E. coli* testing results cannot, by themselves, support a finding of noncompliance with 9 CFR 310.25(a) or 381.94(a). However, if an establishment's testing results indicate a failure of process control, IPP are to verify the establishment's sanitary dressing procedures.

C. When IPP make a determination that one or more of the above requirements are not met, IPP are to document the noncompliance on an NR as described in Section II, above.

VII. TRENDS OF NONCOMPLIANCE

A. After IPP document a noncompliance, they are to consider whether the noncompliance is associated with previous noncompliances at that establishment. For each NR, IPP are to use the NR reporting tools in PHIS to identify previous NRs that might be associated with the current NR. IPP are to refer to the PHIS User Guide for instructions on how to use the PHIS tools for this purpose.

B. IPP are to associate two or more NRs when they indicate an ongoing trend of related noncompliances or systemic problems with the establishment's food safety system. The following characteristics may help IPP to identify NRs that may be associated, but these factors, in themselves do not justify associating the NRs:

1. Two or more NRs have the same regulatory citation,

2. Two or more NRs resulted from the same type of inspection procedure, or

3. Two or more NRs occurred within a reasonably close period of time..

C. IPP are to associate NRs when they demonstrate one or more of the following trends:

1. One NR indicates that the establishment's corrective actions for a previous NR were not implemented or did not prevent recurrence of the same noncompliance,

EXAMPLE: IPP documented noncompliance with 9 CFR 416.13(a) this week at Establishment A when they observed condensation dripping from the ceiling onto product in the processing room. Upon reviewing the NR history prior to the weekly meeting, IPP noted another noncompliance with 416.13(a) last week that also documented condensation dripping onto product in the same area. After reviewing the establishment's proposed preventive measures from the previous noncompliance, IPP find that the establishment did not implement their proposal to add another ventilation fan in the area. IPP concluded that the establishment failed to implement the preventive measures resulting in the recurrence so they associate the two NRs.

2. Two or more NRs demonstrate repetitive failures of the same aspect of the establishment food safety system.

EXAMPLE: IPP documented noncompliance with 9 CFR 417.2(c)(4) this week at Establishment C when they observed a deviation from a critical limit that was not detected by the establishment monitoring employee. The establishment determined that the monitoring employee was new and had not been thoroughly trained in the correct monitoring procedure. The preventive measure was to retrain the employee. Upon reviewing the NR history in preparation for the weekly meeting, IPP noted a noncompliance with 417.2(c)(4) from last month involving a different employee at a different CCP who also failed to detect a deviation from a critical limit. In that case, the establishment had also determined that the employee was improperly trained in the monitoring procedure and re-trained the employee as a preventive measure. Even though these two monitoring noncompliances involved different employees at different CCPs, IPP decide to associate them because they both indicate a problem with the establishment's training program for employees assigned to monitor CCPs.

D. When IPP determine that an NR is associated with one or more previous NRs, they are to record the association and briefly describe why they determined that the NRs were associated in the inspector notes feature of PHIS. IPP are to record the reason for their decision to associate the noncompliances in the inspector notes. If IPP are uncertain whether particular noncompliances are associated, they are to request assistance from their supervisor.

E. Before the weekly meeting with establishment management, IPP are to use the tools in PHIS to develop the agenda for the weekly meeting. IPP are to refer to the PHIS User Guide for instructions on developing the meeting agenda in PHIS. One feature of PHIS will allow IPP to include appropriate entries from the PHIS inspector notes tool in the agenda for the weekly meeting. Once IPP determine that one or more previous noncompliances are associated with a current NR, they are to add it to the discussion points in the weekly meeting agenda in PHIS.

F. During the weekly meeting, IPP are to discuss any identified associations between current and past noncompliances and describe to plant management why the associated NRs indicate a trend of noncompliance.

G. After the weekly meeting, IPP are to prepare a MOI from the meeting agenda in PHIS to document the items covered in the weekly meeting and document any outcomes. IPP are to document any discussion of noncompliance trends and NR associations in the MOI.

H. FLS or RIFS are to adsk the following questions regarding trends of noncompliance:

1. Do the NRs indicate a trend of ongoing related noncompliances or systematic problems with the establishment's food safety system?

2. How much time has elapsed between associated NRs?

3. Are there NRs over the past three months that should have been associated with other NRs?

4. Do the NRs establish that there is a persistent problem in the plant's approach to addressing noncompliances (e.g., the establishment's procedures led to repeated noncompliances)?

I. Based on the answers to these questions, the FLS or RIFS and IPP are to determine whether IPP are correctly identifying and documenting any trends of noncompliance and whether a Food Safety Assessment should be recommended.

CHAPTER VI - RULES OF PRACTICE

I. ENFORCEMENT ACTIONS

9 CFR 500.1 defines three types of enforcement actions. They are:

(a) A "regulatory control action," is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product;

(b) A "withholding action," is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process; and

(c) A "suspension," is an interruption in the assignment of program employees to all or part of an establishment."

A. Withholding actions affect whether the mark of inspection may be applied, while suspensions affect whether inspection verification activities will be performed.

B. Both withholding and suspension actions are different from a withdrawal of a Federal grant of inspection or a refusal to grant inspection. Withdrawal actions are initiated by the FSIS Administrator according to the Department of Agriculture's Uniform Rules of Practice, a different set of procedures, found at 7 CFR Subtitle A, Part 1, Subpart H.

II. REGULATORY CONTROL ACTION

9 CFR 500.2 lists the reasons for which FSIS may decide to take a regulatory control action. They are:

(1) insanitary conditions or practices;

(2) product adulteration or misbranding;

(3) conditions that preclude FSIS from determining that product is not adulterated or not misbranded; or

(4). inhumane handling or slaughtering of livestock.

A. A regulatory control action covers a wide variety of inspection procedures.

B. A regulatory control action is a limited focus action that is to be used to address specific problems that IPP come upon in the course of their activities.

C. A regulatory control action permits IPP to identify regulatory noncompliance and prevent the movement of the product involved or use of the equipment or facility

involved until the noncompliance has been corrected. IPP are not required to give the establishment prior notification that they are about to execute a regulatory control action.

D. Examples of regulatory control actions:

1. A regulatory control action may be warranted for direct product contamination with a contaminant that does not result in a food safety hazard.

2. A regulatory control action may be warranted with respect to product that is economically adulterated.

3. A regulatory control action may also be warranted as a result of regulatory noncompliance even when there is no product contamination or adulteration.

4. A regulatory control action should be taken when IPP are assessing sanitary conditions of the establishment prior to operation and observe product residue from the previous day's production on a product contact surface.

5. A regulatory control action would be warranted if IPP determine that packaged product does not meet the net weight requirements.

6. IPP could initiate a regulatory control action when there is noncompliance with the SPS regulations, if control is needed to prevent contamination of product.

NOTE: Regulatory control actions typically are not used for HACCP regulatory noncompliance unless control is necessary to prevent shipment of contaminated or adulterated product.

E. After determining that a regulatory control action needs to be taken, IPP will notify, as specified in 9 CFR 500.2(b), the establishment orally or in writing of the action and the basis for it. The written notification will be a NR.

F. As specified in 9 CFR 500.2(c), an establishment may appeal a regulatory control action by following the procedures described in 9 CFR 306.5 and 381.35. These simple procedures direct establishments that want to appeal to bring the appeal to the next level of supervision.

G. When an establishment violates a regulatory control action by removing a reject or retain tag, they are in violation of 9 CFR 500.3(a)(5). The existing policy for a situation where a U.S. retain or reject tag is removed by someone other than a program employee is for the IPP to immediately meet with the establishment management to discuss this issue, documenting the conversation in an MOI in PHIS.

H. IPP are to provide a copy of the MOI to the establishment, put a copy in the government file and e-mail a copy through the supervisory channels to the DO.

I. The DM or Director of IID or their designee will then decide whether this violation requires the initiation of a suspension under 9 CFR 500.3(a)(5).

J. If the DM or Director of IID or designee makes that determination, the establishment will be notified as per 9 CFR 500.5(a). The establishment is then afforded an opportunity to provide adequate statements as to what happened to the tag, who removed it, and what its proposed actions are to prevent it from occurring in the future.

K. If the DM or Director of IID or designee decides not to initiate a suspension, a letter will be provided to the establishment regarding the serious nature of a U.S. reject or retain tag violation. The DM or Director of IID or designee is to consider the public health significance of the original noncompliance that resulted in the inspection program employee using a regulatory control action (U.S. reject or U.S. retain tag) when deciding not to take a suspension or withholding action.

III. WITHHOLDING ACTIONS AND SUSPENSIONS (PRIOR NOTIFICATION NOT NECESSARY)

9 CFR 500.3, states that *"FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:*

(1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602;

(2) The establishment does not have a HACCP plan as specified in §417.2 of this chapter;

(3) The establishment does not have Sanitation Standard Operating Procedures as specified in §§416.11-416.12 of this chapter;

(4) Sanitary conditions are such that products in the establishment are or would be rendered adulterated;

(5) The establishment violated the terms of a regulatory control action;

(6) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or

(7)The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof in accordance with part 314 or part 381, subpart L of this chapter, within three days of notification.

NOTE: As a suspension only under 9 CFR 500.3(b), the establishment is handling or slaughtering animals inhumanely.

A. The situations in paragraph III A necessitate prompt action to protect the public health or the safety of FSIS personnel. When this is the case, but only in such cases, a withholding action or suspension action may be taken without prior notification.

B. IPP taking withholding actions without prior notification need to be able to document the imminent threat to public health or to the safety of IPP that made prior notification infeasible.

C. Multiple instances of economic adulteration do not justify taking a withholding action without prior notification to the establishment and the opportunity to achieve compliance.

IV. WITHHOLDING ACTION OR A SUSPENSION ACTION (PRIOR NOTIFICATION GIVEN)

9 CFR 500.4 states that *FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:*

(a) The HACCP system is inadequate under §417.6 of this chapter, due to multiple or recurring noncompliances;

(b) The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in §§416.13 through 416.16 of this chapter;

(c) The establishment has not maintained sanitary conditions as prescribed in §§416.2 – 416.8 of this chapter due to multiple or recurring noncompliances;

(d) The establishment did not collect and analyze samples for Escherichia. coli Biotype I, and record results in accordance with §310.25(a) or §381.94(a) of this chapter; or

(e) The establishment did not meet the Salmonella performance standard requirements prescribed in §310.25(b) or §381.94(b) of this chapter.

A. The purpose of prior notification, with an opportunity for the establishment to respond, is to provide the establishment with due process procedures.

B. For paragraph IV above, the determinations require that the Agency compile extensive information and analyze it with care and good judgment. This makes it reasonable to provide the establishment with this information in advance. The establishment will have an opportunity to point out any factual errors made by the Agency, identify scientific or technical disagreements, and articulate differing interpretations of regulatory requirements. All this information is useful to FSIS in determining how to proceed. The establishment also has an opportunity to present corrective actions.

V. NOIE

A. An NOIE is a notice of intended enforcement action. It provides notification to an establishment that there is a basis for FSIS to withhold the marks of inspection or to suspend inspection as specified in 9 CFR 500.4. The information in the NOIE meets the notification requirements of 9 CFR 500.5 that states: *If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:*

(1) State the effective date of the action(s);

(2). Describe the reasons for the action(s)

(3) Identify the products or processes affected by the action(s)

(4) Provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and

(5) Advise the establishment that it may appeal the action as provided in section 306.5 and section 381.35 of this chapter.

B. A DM or the Director of IID issues an NOIE to an establishment for noncompliances that do not pose an imminent threat to public health but that may warrant the withholding of the mark of inspection or suspension of inspection if not corrected. In addition to informing an establishment about noncompliances warranting a withholding or suspension, the NOIE provides an establishment three business days to contest the basis for the proposed enforcement action or to demonstrate how compliance has been or will be achieved. Based on discussion with the establishment, the DM or Director of IID may extend the three business days if he or she believes this is necessary.

C. The DM or Director of IID should assess and evaluate the establishment's response and decide whether inspection should be withheld or suspended. The DM or Director of IID determines whether the establishment's proposed action plan addresses the problem and, if implemented, is likely to provide an acceptable solution. The DM or Director of IID should consider any decisionmaking documents as required by the appropriate regulations. Also, the DM or Director of IID should consider the establishment's history of implementing its operating procedures and its planned corrective and preventive actions and determine whether the establishment is likely to implement its proposed actions effectively. DM or Director of IID are encouraged to contact staff members from the Policy Development Division (PDD), the Office of Public Health and Science, and the Office of Policy and Program Development for assistance in making decisions.

D. Upon assessing and evaluating the establishment's response, the DM or Director of

IID may decide to accept the establishment's plan, implement the appropriate enforcement action, or defer his or her decision. The following provides the DM or Director of IID guidance on what procedures to follow:

1. Under what circumstances should a DM or Director of IID accept the establishment's response?

    a. If the establishment responds within the specified time frame, has demonstrated that compliance has already been achieved, or provides a description of acceptable corrective and preventive actions from which the DM or Director of IID can find that compliance will be achieved upon implementation, the DM or Director of IID can accept the response, notify the establishment of the decision, ensure that the establishment implements the corrective and preventive actions in a timely manner, and close the matter with a letter to the establishment.

2. Under what circumstances could a DM or Director of IID implement an enforcement action?

    a. If the establishment does not respond or, based on the DM or Director of IID assessment and evaluation of all pertinent information, the DM or Director of IID finds that compliance cannot or will not be achieved upon implementation, the DM or Director of IID will implement the enforcement action. In those instances involving:

        i. withholding actions, the DM or Director of IID instructs the IPP to impose the withholding action and notifies the establishment as specified in 9 CFR 500.5(a). The DM or Director of IID notification is to include the basis for his or her decision.

        ii. suspension actions, the DM or Director of IID instructs the IPP to suspen inspection and notifies the establishment as specified in 9 CFR 500.5(a). The DM or Director of IID's notification is to include the basis for his or her decision.

E. A DM or Director of IID may defer an enforcement decision when he or she has substantial reason to believe that the establishment's proposed corrective and preventive actions are adequate to eliminate the noncompliance but lacks the substantive and supporting evidence that he or she needs to make a definite decision. For example, a plant may submit an apparently adequate proposed plan and have a good history of executing its HACCP plan, but not include sufficient documentation to enable the DM or Director of IID to find that the proposed plan, once executed, will prevent recurrence. In this situation, a DM or Director of IID may choose to defer his or her enforcement decision and allow the establishment to implement the plan until the DM or Director of IID can determine whether the plan is effective. The DM or Director of IID is expected to make a decision on the adequacy of the preventive action as soon as

sufficient information becomes available. The DM or Director of IID should not defer a decision for more than 90 days without cause. The DM or Director of IID is to notify the establishment in writing as to why he or she deferred a decision.

F. If, at any time during a period of deferral, the establishment fails to adhere to the proposed action plan, and the DM or Director of IID determines that an enforcement action is warranted, the DM or Director of IID will instruct the IPP to either impose a withholding action or effect the suspension in accordance with 9 CFR 500.4. The DM or Director of IID will immediately notify the establishment management of this decision and the basis for it in accordance with 9 CFR 500.5.

VI. ABEYANCE

9 CFR 500.5(e) states that *FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.*

A. When a DM or Director of IID has suspended inspection, he or she may subsequently decide to hold that suspension in abeyance as specified in 9 CFR 500.5 if:

1. The establishment presents a plan that demonstrates to the satisfaction of the DM or Director of IID that the establishment has designed corrective and preventive actions that are appropriate to meet the regulatory requirement and ensure that it will not recur; and

2. It is necessary to allow the establishment to operate after implementing these corrective and preventive actions so the DM or Director of IID can determine whether the establishment is able to adequately execute the plan. The DM or Director of IID should not hold a suspension in abeyance until the corrective and preventive actions are implemented, and the abeyance should not be for more than 90 days without cause.

B. If the establishment has a history of failing to meet the criteria discussed above, the DM or Director of IID may decide not to accept the establishment's plan.

C. If the DM or Director of IID decides to put the suspension in abeyance, and the establishment fails to either meet regulatory requirements or maintain regulatory compliance, during the abeyance period, the DM or Director of IID may lift the abeyance and put the suspension back in effect. If this occurs, the DM or Director of IID will instruct the IPP to suspend inspection in accordance with 9 CFR 500.4 and immediately notify the establishment management in accordance with 9 CFR 500.5(a). The DM or Director of IID will also contact the Acting Regional Investigation Manager.

VII. VERIFICATION PLANS

A. The EIAO will develop a verification plan in conjunction with the in-plant inspection team when the DM 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 for a food safety related issue. The VP provides a systematic means for IPP to verify that an establishment is effectively implementing the corrective measures that were proffered to FSIS. The EIAO has the primary responsibility for preparing the written verification plan. However, the EIAO is to work with the in-plant inspection team, including the FLS or RIFS, in the development of the VP.

B. The VP is to:

1. Describe the verification activities that will be performed by IPP based on the establishment's corrective measures.

2. List the PHIS procedures associated with each verification activity that will be carried out by the inspection team.

3. List the regulatory provisions associated with each verification activity.

4. Be developed so that the verification activities identified in the VP are performed by in-plant IPP as part of routine and directed PHIS procedures.

C. The EIAO has primary responsibility for communicating and discussing the final verification plan to the IPP. The FLS or RIFS and appropriate district or regional office personnel should also participate in the discussion. If a new IPP is assigned to the facility at any time during the deferral or abeyance period (e.g., due to a scheduled rotation), the EIAO and FLS or RIFS are to ensure that the IPP understands how to implement the verification plan.

D. The in-plant inspection team is to carry out the verification plan developed in conjunction with the EIAO. IPP are to schedule directed versions of their routine inspection tasks to specifically verify the items in the verification plan.

E. On at least a bi-weekly basis, the in-plant team is to report via e-mail to the FLS or RIFS, and the DO, the results of the activities it has conducted under the VP.

F. The in-plant inspection team has the flexibility to increase the frequency of the verification activities based on its findings, and are to notify the FLS or RIFS if they do so. The in-plant team, through the FLS or RIFS, may request that the EIAO conduct a follow-up visit to an establishment that has had an enforcement action deferred or is under a suspension action that is held in abeyance to determine the overall effectiveness of the establishment's corrective measures.

G. The EIAO is to revisit an establishment operating under a verification plan at 30, 60, and 90-day intervals as long as the verification plan is in place. The EIAO is to assess the adequacy of the plant's corrective and preventive actions that resulted in the deferral or abeyance and provide a recommendation to the DO as to the appropriate next steps. Recommendations made by the EIAO could include continuing to hold the

action in abeyance, close the action, or to initiate further enforcement in the event that the establishment's corrective and preventive actions are found not to be effective.

H. When the in-plant inspection team believes it appropriate that a deferral or abeyance action be closed, the in-plant team may request that an EIAO visit the establishment to review the effectiveness of the corrective and preventive measures implemented by the establishment. When such requests are made and throughout the course of the EIAO visit, the in-plant inspection team is to continue with their daily verification responsibilities.

VIII. ANALYSIS OF DATA

PHIS tracks inspection activities that are used to verify an establishment's food safety system. The Office of Data Integration and Food Protection (ODIFP), Data Analysis and Integration Group will analyze PHIS data on a monthly basis to track whether inspection activities have been completed. The analyses will include identifying trends in noncompliance by the type of activity.

Refer questions regarding this directive to the Policy Development Division through *askFSIS* at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development

Attachment 1

USE OF MICROBIAL PATHOGEN COMPUTER MODELING (MPCM) IN HACCP PLANS

1. What is an MPCM program?

An MPCM program is computer-based software that, based on such factors as growth, lethality, and survival in culture broth and food products, estimates the growth or decline of food-borne microbes in food samples in production.

2. How can the MPCM programs be used?

MPCM programs can be valuable tools for establishments to use in supporting hazard analyses, developing critical limits, and evaluating the relative severity of problems caused by process deviations. They can also be used to help predict the expected effectiveness of corrective actions.

3. What are the limitations of MPCM programs?

It is not possible or appropriate to rely solely upon a predictive modeling program to determine the safety of foods and processing systems. Determining pathogen growth or survival and controlling it in food products requires complete and thorough analysis by an independent microbiology laboratory, challenge studies, and surveys of the literature. MPCM programs do not replace these types of activities or the judgment of a trained and experienced microbiologist.

4. How should IPP verify the use of MPCM programs?

A. Establishments are responsible for validating their HACCP plans and must justify the use of the conclusions reached by the use of MPCM programs. IPP should verify that establishments document the use of MPCM programs as specified in 9 CFR 417.5. Generally, an MPCM program would not be the only documentation relied upon to support an element of a HACCP plan. However, in certain circumstances, a microbiologist or other trained process authority professional may determine the MPCM program is the most appropriate source of data to support HACCP decision making. For example, the control of *Clostridium botulinum* in low acid canning technology has long been established and documented in scientific and other technical reference literature. Provided that the control parameters for *C. botulinum* are incorporated into an MPCM program and accurately reflect the process under review, then the MPCM program may be relied upon as the sole source for decision making for a HACCP element. In such cases, the microbiologist or other trained professional on the HACCP Team is to document their decision to use the MPCM as part of the HACCP records.

B. IPP should verify that the parameters used in the predictive model match the ones used by the establishment in its process, and that the data produced by the MPCM program were taken into account by the establishment in its decision making process during the HACCP plan development or implementation.

NOTE: IPP should not use or place on Agency computers an establishment's MPCM program. In the future, IPP may have access to an Agency issued MPCM program.

C. If IPP have questions regarding an establishment's use of an MPCM program, they should contact PDD. If necessary, an EIAO may respond to the concerns about the establishment's use of the MPCM programs.

Attachment 2

Import Establishment

A. Good sanitation practices are essential to prevent contamination of edible products, and control rodents and pests. An import establishments SSOP demonstrate the commitment of management to consistently control operations in the interest of public health. When Federal inspection is granted to an establishment, the applicant agrees to maintain the sanitary practices necessary to preserve the wholesomeness of imported product.

B. When FSIS personnel inspect the grounds, facilities, and equipment at an import establishment they observe these areas for insanitary conditions before and during operations..

C. To determine whether conditions in or around an establishment are insanitary, inspection program personnel must ask the question posed by the Acts:

1. Could these conditions cause product to be contaminated with filth or cause product to become adulterated?

2. Could these conditions cause product stored in the import establishment to become adulterated?

D. Import establishments must meet two sets of regulations concerning sanitation that Import Inspection Personnel must verify:

1. The Sanitation Standard Operating Procedures (Sanitation SOP). Sanitation SOP requirements require that each import establishment must develop, implement, and maintain written procedures for the actions it takes daily, before and during operations, to prevent product from being directly contaminated and adulterated. An establishment's Sanitation SOP typically covers the scheduled, daily pre-operational and operational cleaning and sanitation of equipment and surfaces that may contact product directly. Import inspection personnel are to verify the pre-operational and operational Saniatation SOP is being met daily.

2. Sanitation Performance Standards (SPS). The SPS regulations cover all of the other aspects of plant sanitation that can affect food safety, e.g., pest control, adequate ventilation and lighting, and plumbing systems. Keep in mind that these two sets of regulations overlap somewhat in the plant activities they cover and should be monitored simultaneously, if possible.

E. Hands-on verification of the pre-operational (pre-op) procedures and operational component in areas of an import establishments where product is exposed will take place daily.

F. As scheduled by the PHIS, Import Iinspection Personnel verify that establishments are complying with the SPS (9 CFR 416.2 – 416.5) and the Sanitation SOPs (9 CFR 416.11 – 416.16). FSIS inspection personnel may directly observe conditions in the establishment or review records to verify that the establishment is complying with the sanitation regulatory requirements.

G. If an establishment's procedures or the prerequisite programs that it uses to meet the SPS, referenced in the Sanitation SOP, the records associated with the procedures are required to be available to FSIS.

H. Most of the time Import Inspection Personnel will verify compliance with the SPS regulatory requirements by directly observing the conditions in the establishment.

I. Import Inspection Personnel must use professional knowledge and good judgment in making the determination whether the SPS requirements are met. FSIS inspection personnel must assess the situation in the establishment and then determine whether the situation creates insanitary conditions, causes adulteration of product, or prevents FSIS from performing import inspection.

J. This means that there can be conditions in the facility that are less than perfect but that would not represent noncompliance with the SPS regulatory requirements because they are not creating insanitary conditions, adulterating product, or preventing FSIS personnel from performing inspection activities. If the establishment is not meeting the regulatory requirements, it is FSIS inspection personnel responsibility to initiate the appropriate regulatory control actions to gain regulatory compliance.

K. When noncompliance with regulatory requirement(s) is found, Import Inspection Personnel will take the appropriate action consistent with applicable regulations (including identification of violative equipment, utensils, rooms, or compartments as "U.S. Rejected" in the import inspection room).

NOTE: Hands-on verification includes a records review component. Prior to performing the hands-on verification, the inspector will review the establishment's records for that day, if available at that time. Import Inspection Personnel will document findings on an NR. When determining if noncompliance exists, Import Inspection Personnel are to take into account what is known for a fact.

L. The regulations on Sanitation SOP's require the establishment to implement procedures sufficient to prevent direct contamination or adulteration of product(s), and pre-op procedures in the Sanitation SOP's are to address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils. Therefore, contaminated product and violative facilities, equipment, and utensils, in addition to requiring official

control actions, will be considered Sanitation SOP failures. Official control action consists of retention of products and rejecting equipment, utensils, and rooms and/or areas to prevent their use in the inspection of exposed imported products until the failure is remedied.

M. Import Inspection Personnel will determine whether official control action is appropriate. When the Agency seeks to take further regulatory or administrative action, it is to be able to rely on NR information. Therefore, documenting failure to comply with regulatory requirements as specified above is essential (whether or not official control action was taken).