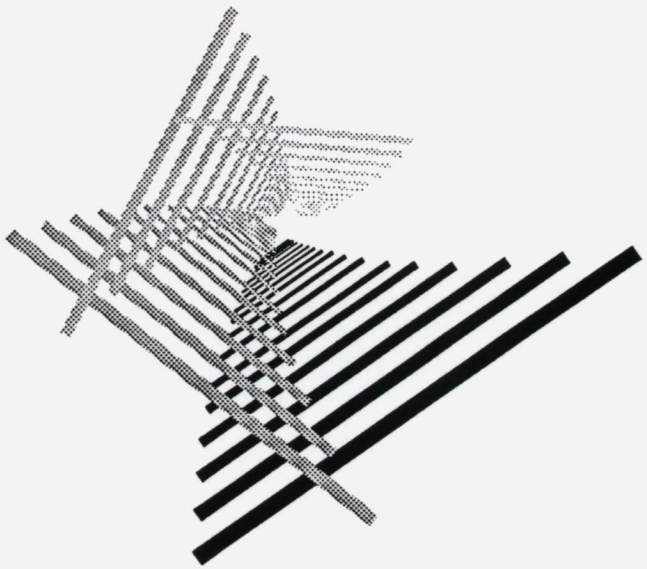
FSIS PRE-HACCP

Sanitation Standard Operating Procedures (SSOP)

Reference Guide

July 1996



U.S. Department of Agriculture • Food Safety and Inspection Service • Human Resource Development Division

FSIS PRE-HACCP

Sanitation Standard Operating Procedures (SSOP)

Reference Guide
July 1996

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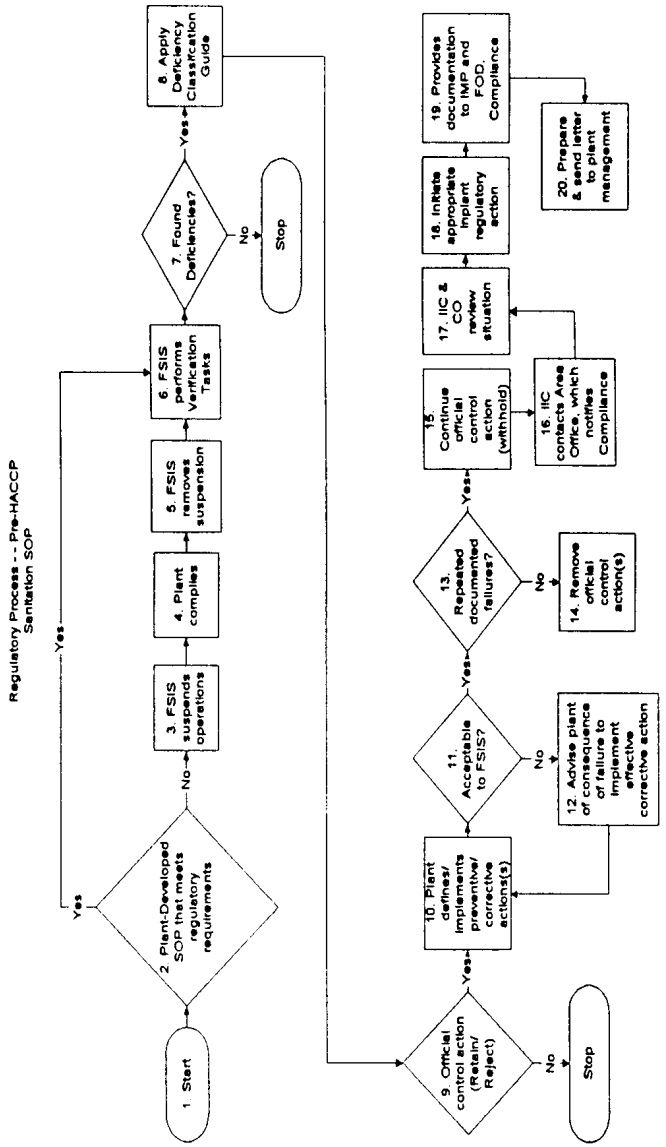

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NOTE: The "blocks" listed below and illustrated in the flow diagram on the preceding page represent steps in the regulatory process. Each "block" discussion addresses the decisions and actions required by the FSIS inspector at that step of the process. When applicable, sections from the regulatory Preamble are quoted and/or other regulatory references are listed.

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PREAMBLE

Plant Responsibilities

The proposed requirements for Sanitation SOP's were the result of many years of observations by FSIS of establishment sanitation and management practices. The persistence of insanitary conditions within some meat and poultry establishments was documented in the "1,000 Plant Review," conducted by FSIS between September 1993 and February 1995. This project involved unannounced visits to 1,014 inspected establishments during which operations were observed and deficiencies noted. More than 60 percent of all deficiencies documented by the review involved establishment sanitation. The distribution of sanitation problems was not, however, uniform in the establishments sampled. Fewer than half those establishments visited accounted for 90 percent of the sanitation deficiencies. Data collected through FSIS's Performance Based Inspection System similarly documents that sanitation is the most frequent deficiency noted by inspection personnel in routine establishment visits.

Through analysis of this information, FSIS determined that the difference between establishments with consistently sanitary conditions and those with chronic sanitation deficiencies is often that the better performing establishments have effective quality control and sanitation programs, including written Sanitation SOP's, while the marginal establishments do not.

Substantial evidence exists that insanitary facilities or equipment, poor food handling, improper personal hygiene, and similar insanitary conditions create an environment in which products become contaminated with microorganisms, including pathogens. While sanitation has improved greatly throughout the industry over the years, some individual establishments still have difficulty getting their facilities and equipment ready to start operations each day and keeping conditions sanitary during establishment operations. FSIS affirms that proper sanitation is an important and integral part of every food process and a fundamental requirement of the inspection laws that the Agency enforces.

In the past, FSIS has enforced the sanitation requirements primarily through a combination of prescriptive sanitation regulations, detailed guidance materials, and direct, hands-on involvement by inspectors in day-to-day pre-operational and operational sanitation procedures in inspected establishments. This system achieved sanitation goals on a

daily basis in individual establishments, but at a relatively large public cost because it encouraged establishments to shift accountability for sanitation to the FSIS inspector. For example, in the past, FSIS inspectors have taken responsibility for checking sanitation in every slaughter establishment before it begins daily processing. In extreme cases, inspectors have led daily "bucket brigades" of slaughter establishment employees through pre-operational establishment cleanup. In these circumstances, FSIS has, in effect, taken responsibility for establishment sanitation conditions.

Although the majority of meat and poultry establishments maintain adequate sanitary conditions, some establishments have significant sanitation problems that can be resolved only through more clearly defining establishment responsibility and accountability for the daily observance of sound sanitation practices. Sanitation SOP's make it clear that responsibility for identifying and conducting procedures needed to maintain sanitary conditions rests with the establishment, not with FSIS.

Finally, the Sanitation SOP's requirements of this final rule are set out in a new Part 416, Sanitation. These provisions are formatted differently from the proposal to comport with FSIS's announced project to reform, reorganize, and recodify the meat and poultry regulations. This regulatory reform project is well underway, and will, among other things, eliminate unneeded regulations by combining, to the extent possible, the currently separate meat and poultry regulations.

Role of Inspectors

A related concern of many commenters was the role FSIS inspectors will play in the development and enforcement of Sanitation SOP's. Some commenters expressed concern that during inspection inspectors would rely solely on record reviews instead of actually observing establishment conditions. Other commenters expressed concerns that Sanitation SOP's would merely provide FSIS inspectors with more latitude to make intrusive and arbitrary decisions. FSIS strongly disagrees with this characterization of Sanitation SOP's and the role of the Agency's inspection personnel. Industry's responsibility for producing safe meat and poultry and FSIS responsibility for regulatory oversight are fundamentally different.
Sanitation SOP's are the establishment's commitment to FSIS that they will consistently provide a sanitary environment for food production. FSIS inspectors will not be tasked with directing an establishment's sanitation procedures, nor with ``approving" the establishment's Sanitation SOP's. They will, however, verify that the Sanitation SOP's

are being implemented and that they are effective in preventing direct product contamination and adulteration.

Oversight of Sanitation SOP's will become an increasingly important part of daily inspection activity, while the directing of sanitation activities will occur less frequently. Periodic inspection tasks will include verifying that Sanitation SOP's meet the regulation's requirements, are being implemented and maintained, and are effective in producing sanitary conditions. FSIS inspectors' oversight will include review of the Sanitation SOP's and required records, direct observation of the implementation and monitoring of the Sanitation SOP's, and visual observation of sanitary conditions in the production areas of the establishment.

FSIS expects that establishments will rely less on inspectors to direct them in maintaining sanitary conditions as establishments rely more on adherence to their own Sanitation SOP's. The mix of inspector tasks that comprise sanitation inspection also will change. As establishments adopt and successfully implement Sanitation SOP's, and consistently achieve good sanitation results, FSIS inspectors can spend less time ensuring that basic sanitation requirements are being met. Conversely, to the extent some establishments do not implement effective Sanitation SOP's and consistently achieve good sanitation, FSIS inspectors will be obliged to intensify their focus on actual establishment conditions and initiate appropriate enforcement actions. Ensuring establishments operate under sanitary conditions should be made easier for inspectors, and ultimately permit inspectors to spend more time on other tasks. One purpose of the Sanitation SOP's regulations is to help inspectors, as well as establishments, focus their attention on those aspects of establishment sanitation that pose the most risk of causing product contamination or adulteration. Under the current inspection system, inspectors look at all aspects of establishment sanitation, including many that have a relatively low probability of causing product contamination. In the future, normal oversight activities will focus more on whether an establishment is following its Sanitation SOP's and thereby consistently preventing, or as appropriate, correcting, conditions that cause direct product contamination or adulteration. Some commenters were concerned about the effect on establishment operations if inspection personnel, when enforcing the Sanitation SOP's requirements, reject one piece of equipment, utensil, room or compartment as insanitary. As previously stated, inspectors will take prompt action in cases where there is a finding of insanitation or the likelihood of product contamination or adulteration. The type and intensity of this response will vary. For example, establishment operations may be allowed to continue if inspection personnel determine

that a rejected item, compartment or room is not related to other processes or products being produced. However, inspection would be withheld in rooms, departments, or facilities associated with the production of contaminated or adulterated products where the establishment can not show FSIS that they have isolated the cause of the contamination or adulteration and have taken appropriate action to prevent further contamination or adulteration. In a similar vein, commenters also stated that establishments should not be penalized for the occurrence of a sanitation problem that is effectively abated. These commenters suggested that "U.S. Rejected" tags should be used only if an establishment fails to identify and correct insanitary conditions. If the establishment takes proper corrective action, they argued, it should be viewed as evidence that the Sanitation SOP's is being adequately implemented. FSIS agrees. Establishments that identify and correct insanitary conditions in a timely manner and make proper disposition of any affected product will be considered to be in compliance with the Sanitation SOP's regulations.

Although FSIS fully expects that the clarification of establishments' sanitation responsibilities will lead to better and more consistent compliance with sanitation requirements, the Agency recognizes that this will not be the case in all establishments. Establishments that fail to comply with the requirements in this final rule for Sanitation SOP's will be subject to appropriate compliance and regulatory action that will, when necessary, include suspension or withdrawal of inspection. Further, as noted in the proposal, anyone who intentionally falsifies records will be subject to criminal prosecution.

ACTIONS

BLOCK 1

Preparation is essential for success. Before performing *any* task for regulatory enforcement of Sanitation SOPs, FSIS inspection personnel will be sure they:

- know the regulatory requirements for Sanitation SOPs;
- have the equipment, supplies, and references needed to perform and document inspection findings; and
- have access to pertinent plant records or documentation.

BLOCK 1 - Start

DECISIONS

Once prepared, FSIS inspection personnel will proceed to:

BLOCK 2	if the task is *evaluation* of a Sanitation SOP.
BLOCK 6	if the task is *verification* of a Sanitation SOP.

BLOCK 2 - Plant Develops Sanitation SOP

PREAMBLE

All inspected establishments shall develop, implement, and maintain written Sanitation SOP's. The Sanitation SOP's shall describe all procedures an establishment conducts daily to prevent direct contamination or adulteration of product(s). FSIS has clarified that Sanitation SOP's also shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s). While the employee responsible for implementation and maintenance of procedures in the Sanitation SOP's may be the employee who actually performs such activities, s/he instead may be the employee in charge of ensuring that the sanitation procedures are carried out. All that is required is that the Sanitation SOP's identify the employee(s) responsible for implementation and maintenance of the procedures in the Sanitation SOP's. The establishment does not need to necessarily identify the employee(s) who will actually perform the sanitation procedures. Also, an establishment's Sanitation SOP's may have more than one employee responsible for implementation and maintenance of sanitation procedures. For example, one employee may be responsible for pre-operational procedures and another may be responsible for operational procedures. The rule provides such flexibility.

Further, FSIS is clarifying in this final rule that establishments must explicitly identify pre-operational sanitation procedures in their written Sanitation SOP's, distinguishing them from sanitation activities to be carried out during operations. This will assist both the establishment and FSIS in identifying which sanitation procedures are to be carried out each day prior to start-up of operations.

FSIS is also requiring that Sanitation SOP's be signed and dated by "the individual with overall authority on-site or a higher level official of the establishment," and that the signature shall signify that the establishment will implement the Sanitation SOP's. This new language grants establishments greater flexibility than did the proposed requirement that ``the establishment owner or operator" be responsible for implementation of Sanitation SOP's. Additionally, this final rule specifies that Sanitation SOP's must be signed upon initiation and upon any modification.

As in the proposal, the format and content of Sanitation SOP's are not

specified in the final regulations. Because there are many types of inspected establishments that will achieve the required sanitary conditions in different ways, this rule gives establishments flexibility to customize their sanitation plans. Each meat and poultry establishment must analyze its own operations and identify possible sources of direct contamination that must be addressed in its Sanitation SOP's.

ACTIONS

BLOCK 2

Although there is no formal approval process for Sanitation SOPs, FSIS inspection personnel will perform an initial evaluation task to determine if the plant has met the following Sanitation SOP regulatory requirements.

1. The plant has a written Sanitation SOP describing daily procedures they will conduct before and during operations to prevent direct product contamination or adulteration. The Sanitation SOP also includes the frequency at which each procedure will be done.

2. The Sanitation SOP is signed and dated by an official with overall authority on-site or a higher level official of the plant. Sanitation SOPs must be signed upon initiation or modification.

3. The Sanitation SOP identifies the procedures the plant will conduct prior to the start of operations. At a minimum, these procedures must address the cleaning of food contact surfaces, equipment, and utensils.

4. The plant has identified individuals who will be responsible for implementing and maintaining daily sanitation activities.

5. The plant has identified records they will maintain on a daily basis to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken.

BLOCK 2 - Plant Develops Sanitation SOP

DECISIONS

Following initial evaluation of the Sanitation SOP, FSIS inspection personnel will proceed to:

BLOCK 6 if all the regulatory requirements have been met.

BLOCK 3 if one or more regulatory requirements have *not* been met.

REFERENCES

FSIS Directive 11,100.3, Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure (Evaluation of Regulatory Requirements)
Regulation 416.11
Regulation 416.12

PREAMBLE

Oversight of Sanitation SOP's will become an increasingly important part of daily inspection activity, while the directing of sanitation activities will occur less frequently. Periodic inspection tasks will include verifying that Sanitation SOP's meet the regulation's requirements, are being implemented and maintained, and are effective in producing sanitary conditions. FSIS inspectors' oversight will include review of the Sanitation SOP's and required records, direct observation of the implementation and monitoring of the Sanitation SOP's, and visual observation of sanitary conditions in the production areas of the establishment.

Enforcement Actions When Compliance with Regulatory Requirements Cannot be Verified

FSIS inspection personnel may find that the establishment's SSOP's fail to include procedures to prevent direct contamination or adulteration of product, fail to contain signature of an official with overall authority on-site or a higher level official of the establishment, and/or fail to identify required records. Such a finding alone supports the withholding of inspection to prevent use of the facilities and equipment in the production of products until the failure is remedied.

a. If at any time after the required implementation date FSIS personnel determine that an establishment has failed to meet the regulatory requirements for development or maintenance of a SSOP, the following immediate steps will be taken:

   1. The Inspector-in-Charge (IIC) will refuse to allow any meat and poultry products produced under the above conditions to be labeled, marked, stamped, or tagged as "inspected and passed" or "inspected for wholesomeness".

   2. The IIC will attach a "U.S. Retained" to all alleged adulterated meat or poultry products produced under such conditions or procedures.

   3. The IIC will attach a "U.S. Rejected" tag to the applicable equipment, utensil, room or compartment.

b. The IIC will immediately orally advise establishment management that the above steps have been taken and document the reasons for taking such action on FSIS Form 8820-2, Process Deficiency

Record (PDR). The IIC will subsequently notify the Inspection Operations Area Office (AO) of the action initiated.

c. If an establishment fails to render immediate corrective action, the AO will contact the appropriate Compliance Program Area Officer-In-Charge (OIC) to request that a Compliance Officer (CO) assist with documentation of the alleged non-regulatory compliance. When necessary, a CO will visit the establishment at the earliest possible date to assist the IIC. The AO will subsequently notify the Circuit Supervisor (CS) of the action initiated.

d. The CO will initiate, develop and document an investigative case file. All documented findings will be handled by assigned inspectors and compliance officers in accordance with this issuance.

ACTIONS

BLOCK 3

If initial evaluation by FSIS inspection personnel reveals that one or more Sanitation SOP regulatory requirements have not been met, FSIS will suspend operations. For example, the plant's Sanitation SOP may not include procedures to prevent direct product contamination or adulteration; *or* the SOP may not be signed appropriately; *or* required daily monitoring records may not be identified. *Any* of these findings support the withholding of inspection to prevent the use of the facilities and equipment for food production until the failure is corrected.

If a plant fails to meet the regulatory requirements for the development or maintenance of a Sanitation SOP, FSIS will take action. The sequence of regulatory enforcement is outlined below.

1. Immediate steps will be taken to withhold inspection. The Inspector-in-Charge (IIC) will:

   a. refuse to allow any meat and poultry products produced under the above conditions to be labeled, marked, stamped, or tagged as *"inspected and passed"* or *"inspected for wholesomeness"*;

   b. attach a "U.S. Retained" tag to all alleged contaminated or

adulterated meat or poultry products; and

c. attach a "U.S. Rejected" tag to the applicable equipment, utensils, rooms, or areas.

2. Immediate notification and documentation action will be taken. The IIC will:

a. immediately advise plant management orally that the steps (a-c) in "1" above have been taken;

b. document the actions and the justifying rationale on FSIS Form 8820-2, Process Deficiency Record (PDR); and

c. subsequently notify the Inspection Operations Area Office (AO) of the actions initiated.

3. Once notified, if a plant fails to immediately correct the deficiency, the AO and Compliance will become involved.

a. The AO will contact the appropriate Compliance Program Area Officer-in-Charge (OIC) to request a Compliance Officer (CO) to assist with documentation of the alleged regulatory non-compliance.

b. When necessary, the CO will visit the plant at the earliest possible date to assist the IIC.

c. The AO will subsequently notify the Circuit Supervisor (CS) of the action initiated.

d. The CO will initiate and develop an investigative case file. All documented findings will be handled by assigned inspectors and compliance officers in accordance with the MPI regulations and FSIS directives.

DECISIONS

FSIS will continue to suspend operations until the plant meets the Sanitation SOP regulatory requirements. FSIS inspection personnel must determine when requirements have been met.

Go to BLOCK 4

BLOCK 3 - FSIS Suspends Operations

REFERENCES

FSIS Directive 11,100.3, Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure (Enforcement Actions when Compliance with Regulatory Requirements Cannot be Verified)

BLOCK 4 - Plant Complies

ACTIONS

BLOCK 4

No further action is required by FSIS in this block. The suspension imposed in block 3 remains in effect until the plant complies with the Sanitation SOP regulatory requirements.

DECISIONS

As soon as the non-compliance is corrected, FSIS inspection personnel will proceed to:

BLOCK 5

PREAMBLE

Each establishment is required to conduct pre-operational and operational procedures as specified in the SOP's, monitor the conduct of the procedures, and routinely evaluate the content and effectiveness of the SOP's and modify the SOP's accordingly. The Sanitation SOP's must be kept current. The establishment must evaluate and modify Sanitation SOP's as needed in light of changes to establishment facilities, personnel, or operations to ensure they remain effective in preventing direct product contamination and adulteration. As upon initial implementation, Sanitation SOP's must be dated and signed by the individual with overall authority on-site or a higher level official of the establishment following any modification.

Establishment is allowed to resume operation.

The FSIS inspector will perform an evaluation task to ascertain that the establishment has met the following SSOP regulatory requirements:

a. The establishment has a written SSOP describing daily procedures the establishment will conduct before and during operations and the frequency at which they will be conducted, to prevent direct contamination or adulteration of product(s).

b. The SSOP is signed and dated by an official with overall authority on-site or a higher level official of the establishment. SSOP's must be signed upon initiation and any modifications.

c. The SSOP identifies procedures the establishment will conduct prior to the start of operations. These procedures at a minimum must address the cleaning of food contact surfaces of facilities, equipment, and utensils.

d. The establishment has identified individuals who have responsibility for implementing and maintaining daily sanitation activities.

e. The establishment has identified records to be maintained that on a daily basis document the implementation and monitoring of SSOP's and any corrective actions taken.

This evaluation will be performed as an each occasion (EO) through the Performance Based Inspection System (PBIS). Establishments must routinely assess the effectiveness of SSOP's and adjust SSOP's in light of changes to establishment facilities, personnel, or operations.

Modifications to SSOP's will be evaluated by inspection personnel as they occur.

ACTIONS

BLOCK 5

As soon as the plant is in compliance with Sanitation SOP regulatory requirements, FSIS will remove the suspension and allow the plant to resume operations.

NOTE: **Any time the plant changes its Sanitation SOP after the initial evaluation, FSIS will re-evaluate the Sanitation SOP as an "each occurrence" task generated through the Performance Based Inspection System.**

FSIS actions will be the same as those used in the *initial* evaluation of a Sanitation SOP. FSIS inspection personnel will determine if the plant has met the following Sanitation SOP regulatory requirements.

1. The plant has a written Sanitation SOP describing daily procedures they will conduct before and during operations to prevent direct product contamination or adulteration. The Sanitation SOP also includes the frequency at which each procedure will be done.

2. The Sanitation SOP is signed and dated by an official with overall authority on-site or a higher level official of the plant. Sanitation SOPs must be signed upon initiation or modification.

3. The Sanitation SOP identifies the procedures the plant will conduct prior to the start of operations. At a minimum, these procedures must address the cleaning of food contact surfaces, equipment, and utensils.

4. The plant has identified individuals who will be responsible for implementing and maintaining daily sanitation activities.

5. The plant has identified records they will maintain on a daily basis to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken.

BLOCK 5 - FSIS Removes Suspension

As stated earlier, re-evaluation of a Sanitation SOP will be performed as an "each occurrence" (EO) task generated through the Performance Based Inspection System (PBIS). In other words, modifications to Sanitation SOPs will be evaluated by FSIS "as they occur". This type of evaluation will not be unusual. Plants must routinely assess the effectiveness of their Sanitation SOP and make modifications as necessary to reflect changes in plant facilities, personnel, or operations.

DECISIONS

After the plant complies with Sanitation SOP regulatory requirements and FSIS removes suspension, FSIS inspection personnel will proceed to:

BLOCK 6 — to perform tasks to verify that the plant's Sanitation SOP has been implemented and is effective.

Following *re-evaluation* of a plant's "modified" Sanitation SOP, the FSIS inspector will proceed to:

BLOCK 6 — if all the regulatory requirements have been met.

BLOCK 3 — if one or more regulatory requirements have *not* been met.

REFERENCES

FSIS Directive 11,100.3, Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure (Evaluation for Compliance with Regulatory Requirements)

BLOCK 6 - FSIS Performs Verification Tasks

PREAMBLE

In this final rule, FSIS is clarifying that it will verify that the Sanitation SOP's are being implemented and maintained, and that they are effective. FSIS inspectors will ensure not only that an establishment is complying with the requirement to develop, implement, and maintain Sanitation SOP's, and to maintain daily records for them, but also that the Sanitation SOP's are in fact working. Inspectors will review the Sanitation SOP's, the daily records, the conduct of procedures specified in the Sanitation SOP's, and the sanitary conditions themselves.

The failure by an establishment to comply with the Sanitation SOP's regulations may initiate regulatory action. The full array of compliance tools includes process deficiency reports, tagging of equipment or areas, retention of product, letters of warning, and suspension and withdrawal of inspection. The nature of FSIS's response will depend on the circumstances. Minor omissions or errors in Sanitation SOP's documentation, not symptomatic of larger "system" problems, will result in regulatory action commensurate with the severity of the violation. For example, process deficiency reports might be issued to direct corrective action. However, a pattern of violations of the Sanitation SOP's provisions would lead to additional responses, with persistent and serious failures resulting in suspension or withdrawal of inspection from the establishment. Suspensions and withdrawals would be made in accordance with applicable rules of practice for those proceedings.

If FSIS determines that an establishment's Sanitation SOP's fail to include procedures to prevent direct product contamination or adulteration or that required records are not being kept, the Agency may tag affected facilities and equipment and suspend inspection until the failure is remedied. Because the tagging of insanitary facilities and equipment is based on current statutory authority, the specific regulatory provisions for tagging in the proposal are not retained in this final rule.

Verification and compliance activities under the Sanitation SOP's provisions are distinguishable from actions taken as a consequence of a finding of product adulteration under the sanitation requirements elsewhere in the regulations. As a practical matter, however, such findings are likely to be connected. A finding of deficient Sanitation SOP's or Sanitation SOP's records may prompt additional inspection activity directed at determining whether or not product contamination or adulteration has occurred. If it has, FSIS will take appropriate action to prevent adulterated product from entering commerce and, where necessary, seek recall of product that has already entered commerce.

Records verification

FSIS inspection personnel will perform pre-operational records verification PBIS task _____ and operational record verification PBIS task _____ to verify:

a. Establishments are maintaining daily records which document:

1. the effectiveness of the pre-operational activities of the SSOP.

2. the monitoring of the pre-operational activities of the SSOP.

3. initiation of corrective actions to prevent direct product contamination or adulteration. Corrective actions must include:

(I) procedures to ensure the appropriate disposition of products that may be contaminated or adulterated.

(ii) restoration of sanitary conditions.

(iii) prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the SSOP.

b. Establishments are maintaining daily records which document:

1. The effectiveness of operational activities of the SSOP; and any corrective actions.

2. The monitoring of operational activities of the SSOP.

3. Initiation of corrective actions to prevent direct product contamination or adulteration. Corrective actions must include:

(i) procedures to ensure the appropriate disposition of products that may be contaminated or adulterated.

(ii) restoration of sanitary conditions.

(iii) prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the SSOP.

Process Verification

FSIS inspection personnel will perform pre-operational process verification PBIS task _____ and operational process verification PBIS task _____ to verify:

a. Establishments are:

1. implementing the pre-operational activities of the SSOP.

2. monitoring of the pre-operational activities of the SSOP.

3. initiating corrective actions to prevent direct product contamination or adulteration. Corrective actions must include:

(i) procedures to ensure the appropriate disposition of products that may be contaminated or adulterated.

(ii) restoration of sanitary conditions.

(iii) prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the SSOP.

b. Establishments are:

1. implementing operational activities of the SSOP.

2. monitoring of operational activities of the SSOP.

3. initiating corrective actions to prevent direct product contamination or adulteration. Corrective actions must include:

(i) procedures to ensure the appropriate disposition of products that may be contaminated or adulterated.

(ii) restoration of sanitary conditions.

(iii) prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the SSOP.

Process verification involves observation and comparison of results to

what is recorded by the establishment. Record comparison can be performed before or after the observation process.

ACTIONS

BLOCK 6

FSIS inspectors will perform both records and process verification tasks to determine the effectiveness of a plant's Sanitation SOP. Verification tasks for Sanitation SOPs will be generated through PBIS.

Records Verification

1. FSIS inspectors will perform ***pre-operational record verification PBIS task*** _____ to verify that a plant is maintaining daily records which document:

   a. effectiveness of the *pre-operational* activities of the Sanitation SOP;

   b. monitoring of the *pre-operational* activities of the Sanitation SOP; and

   c. initiation of corrective actions as needed *before* operations to prevent direct product contamination or adulteration. **NOTE:** Corrective actions must include:

      (1) procedures to ensure appropriate disposition of products that may be contaminated or adulterated;

      (2) restoration of sanitary conditions; and

      (3) prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the Sanitation SOP.

2. FSIS inspectors will perform ***operational record verification PBIS task*** _____ to verify that a plant is maintaining daily records

which document:

   a. effectiveness of the *operational* activities of the Sanitation SOP;

   b. monitoring of the *operational* activities of the Sanitation SOP; and

   c. initiation of corrective actions as needed *during* operations to prevent direct product contamination or adulteration. **NOTE:** Corrective actions must include:

      (1) procedures to ensure appropriate disposition of products that may be contaminated or adulterated;

      (2) restoration of sanitary conditions; and

      (3) prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the Sanitation SOP.

Process Verification

NOTE: Process verification involves observation or "hands-on" inspection and comparison of results to plant records. FSIS inspectors may review the plant's records *before* or *after* performing the "hands-on" inspection.

1. FSIS inspectors will perform ***pre-operational process verification PBIS task*** _____ to verify that a plant is:

   a. implementing the *pre-operational* activities of the Sanitation SOP;

   b. monitoring the *pre-operational* activities of the Sanitation SOP; and

   c. initiating corrective actions as needed *before* operations to prevent direct product contamination or adulteration. **NOTE:** Corrective actions must include:

      (1) procedures to ensure appropriate disposition of products that may be contaminated or adulterated;

      (2) restoration of sanitary conditions; and

(3) prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the Sanitation SOP.

2. FSIS inspectors will perform ***operational process verification PBIS task*** _____ to verify that a plant is:

   a. implementing the *operational* activities of the Sanitation SOP;

   b. monitoring the *operational* activities of the Sanitation SOP; and

   c. initiating corrective actions as needed *during* operations to prevent direct product contamination or adulteration. **NOTE:** Corrective actions must include:

      (1) procedures to ensure appropriate disposition of products that may be contaminated or adulterated;

      (2) restoration of sanitary conditions; and

      (3) prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the Sanitation SOP.

DECISIONS

Upon completion of a records or process verification task, FSIS inspectors will proceed to:

BLOCK 7 to determine if deficiencies exist.

REFERENCES

FSIS Directive 11,100.3, Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure (Verification of Compliance with Regulatory Requirements)

ACTIONS

BLOCK 7

Records Verification

To determine if records deficiencies exist, FSIS inspection personnel will answer the following questions:

- Do the records document the effectiveness of the activities of the Sanitation SOP?
- Do the records document monitoring the activities of the Sanitation SOP?
- Do the records document corrective actions taken to include all the actions required by regulation?
- Are the records requirements of the Sanitation SOP met?

If the answer to any of these questions is "no", one or more deficiencies exist. Each deficiency is identified as the specific requirement which was not met.

Process Verification

With process or "hands-on" verification tasks, FSIS inspection personnel will identify deficiencies through actual inspection and comparison with corresponding plant records. The following questions will be answered:

- Do actual conditions and corresponding plant records reflect implementation and effectiveness of the activities of the Sanitation SOP?
- Is there evidence that the plant is monitoring activities of the Sanitation SOP appropriately?
- Are corrective actions taken and documented as required?

If the answer to any of these questions is "no", one or more deficiencies

BLOCK 7 -FSIS Determines if Deficiencies Exist

exist. Each deficiency is identified as the specific requirement which was not met. **NOTE:** If the plant has identified a deficiency and is taking appropriate action, FSIS inspection personnel will *not* identify the problem as a *regulatory* deficiency.

DECISIONS

After evaluating the results of a records or process verification task, FSIS inspection personnel will:

Go to BLOCK 8 if one or more deficiencies exist.

STOP if there are no deficiencies.

BLOCK 8 - FSIS Uses the Deficiency Classification Guide

RECORDS VERIFICATION

Pre-Op Sanitation and/or Operational Sanitation

Focus on whether the record requirements and plant inspection activities meet the Sanitation SOP plan.

Failure to complete a daily record(s) may be presumptive evidence that the plant is producing product that poses a health and safety risk.

PROCESS VERIFICATION

Pre-Op Sanitation and/or Operational Sanitation

Focus of verification task is on equipment, facilities, and employee practices which cause direct product contamination or adulteration.

When a deficiency is identified, FSIS inspection personnel will implement actions outlined in FSIS Directive 8820.1. Deficiencies must be classified using the Deficiency Classification Guide (DCG).

ACTIONS

BLOCK 8

When a deficiency is identified, FSIS inspection personnel will implement actions outlined in FSIS Directive 8820.1. Deficiencies must be classified using the Deficiency Classification Guide (DCG).

Records Deficiencies

When classifying record deficiencies, FSIS inspection personnel will remember that failure to complete a daily record(s) may be presumptive evidence that the plant is producing product that poses a food safety risk. Consequently, further inquiries may be required to determine the full extent of such failures.

BLOCK 8 - FSIS Uses the Deficiency Classification Guide

Process Deficiencies

When classifying process deficiencies, FSIS inspection personnel will remember that the primary focus or emphasis is on deficiencies in equipment, facilities, or employee practices which result in direct product contamination or adulteration.

General Guidelines

As FSIS inspection personnel use the DCG, they will consider each deficiency within the context of what is known for a *fact* (i.e., the inspection findings) and what is *reasonable to assume* based on immediate observations and available information.

DECISIONS

After FSIS inspection personnel classify a deficiency using the DCG, they will proceed to:

BLOCK 9 to determine if official control action is warranted.

REFERENCES

FSIS Directive 11,100.3, Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure (Instructions to Inspectors Regarding Deficiencies and Enforcement Actions)

BLOCK 9 - FSIS Takes Official Control Action Taken as Warranted

PREAMBLE

However, the final rule itself remains nonprescriptive in that it requires each establishment to determine for itself what procedures are necessary to prevent insanitary conditions that will cause direct product contamination or adulteration. Overall, the comments confirmed that, while proper sanitation is a common need in every food production facility, the means to achieve it are diverse and establishment-specific. Establishments that now have good sanitation and effective process controls are expected to continue using techniques that work in their establishment. Other establishments will need to analyze and select effective abatement procedures among various alternatives for attaining a sanitary processing environment. What works in one establishment may or may not work in another.

The proposed rule also solicited comments as to whether FSIS should mandate Good Manufacturing Practices (GMP's) for all or certain Sanitation SOP's. FSIS listed illustrations in the proposal of elements that might be mandatory elements of Sanitation SOP's. Although some commenters expressed support for making GMP's or other practices mandatory, many objected to such specific requirements on the basis that they would be infeasible. FSIS agrees with those commenters who stated that detailed GMP regulations are infeasible because of the difficulty in making them specific enough to be useful. FSIS also was concerned that such specificity could result in lost flexibility.

For these reasons, this final rule will not prescribe a single format for individual establishment Sanitation SOP's or mandate specific GMP's. It will be the responsibility of each establishment to consider existing FSIS regulations and guidelines; evaluate its facilities, processes, and sanitation conditions; determine what sanitation procedures must be implemented to prevent direct product contamination or adulteration; and describe these procedures in Sanitation SOP's.

Sanitation SOP's

Sanitation SOP's require the establishment to implement procedures designed to prevent direct product contamination or adulteration. Therefore, deficiencies classified as "critical", in addition to requiring official action, will be considered SSOP failures. Official control action consists of retention of products, and rejecting equipment, rooms, and/or areas: thereby withholding inspection as required, to prevent the use of facilities and equipment in the production of products until a

failure is remedied. Deficiencies classified as "minors" will not require official control action. FSIS inspection personnel will determine whether official control action is necessary for deficiencies classified as "major." Minor deficiencies and major deficiencies do not constitute a Sanitation SOP failure. However, minor and major deficiencies do require corrective and preventive actions. Documentation of minor and major deficiencies are important when the Agency seeks further regulatory or administrative actions.

If there is a situation involving a SSOP failure and a misrepresentation of records is suspected, the direct product contamination or adulteration situation must be dealt with first and then the misrepresentation issue. Public health and safety always takes precedence over any other activities.

ACTIONS

BLOCK 9

After FSIS inspection personnel classify a deficiency using the DCG, they will determine if official control action is needed.

Critical Deficiencies

Critical deficiencies always require official control action. This action consists of retaining products and rejecting equipment, rooms, and/or areas. By taking these actions, FSIS inspectors effectively "withhold" inspection and prevent the use of facilities and equipment for production until the failure is corrected.

Critical deficiencies are also considered Sanitation SOP failures. To meet the regulatory requirements for a Sanitation SOP, the plant must implement procedures to prevent direct product contamination or adulteration. Since a critical deficiency is one which is "certain" to result in direct product contamination or adulteration, it represents a failure of the Sanitation SOP.

BLOCK 9 - FSIS Takes Official Control Action Taken as Warranted

Major Deficiencies

Major deficiencies *may* require official control action. Using the DCG and professional judgment, FSIS inspectors will decide if official control action is necessary or warranted.

Major deficiencies do *not* constitute immediate Sanitation SOP failure. They *do* require corrective and preventive actions by the plant, however, and FSIS inspectors must also adequately document them. Documentation is critical to the Agency's ability to successfully seek further regulatory or administrative actions.

Minor Deficiencies

Minor deficiencies do *not* require official control action. Like major deficiencies, however, they *do* require corrective and preventive actions by the plant and adequate documentation by FSIS. The importance of documentation to the Agency's ability to take regulatory or administrative action against noncomplying plants cannot be over emphasized.

Other

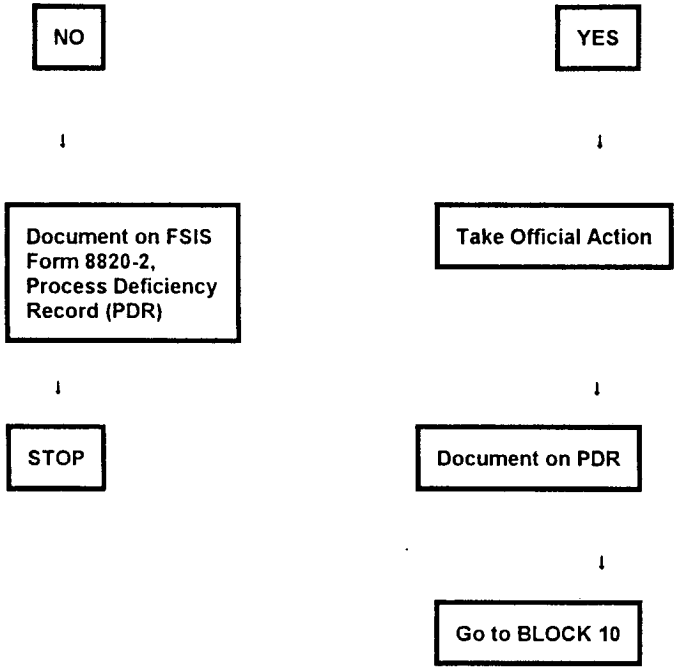
In a situation involving a Sanitation SOP failure and possible misrepresentation of records, FSIS inspectors will take action *first* on the critical deficiency. Direct product contamination or adulteration is a public health risk which *always* has priority over any other issues.

NOTE: If, at any time, FSIS inspection personnel suspect that a plant has engaged in any illegal activity (e.g., falsified required records; offered for sale, sold, or transported adulterated or misbranded meat or poultry products in commerce), they will report the alleged violations to the appropriate Compliance Program OIC.

DECISIONS

Depending on the answer to the question "Is official control action needed or warranted?", FSIS inspectors will proceed in one of two ways.

BLOCK 9 - FSIS Takes Official Control Action Taken as Warranted



REFERENCES

FSIS Directive 11,100.3, Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure (Instructions to Inspectors Regarding Deficiencies and Enforcement Actions)

BLOCK 10 - Plant Defines/Implements Corrective/Preventive Actions

PREAMBLE

Establishments should not be penalized for the occurrence of a sanitation problem that is effectively abated. "U.S. Rejected" tags should be used only if an establishment fails to identify and correct insanitary conditions. If the establishment takes proper corrective action, it should be viewed as evidence that the Sanitation SOP's is being adequately implemented. Establishments that identify and correct insanitary conditions in a timely manner and make proper disposition of any affected product will be considered to be in compliance with the Sanitation SOP's regulations.

ACTIONS

BLOCK 10

No action is required by FSIS inspection personnel in this step of the process. The *plant* must define and implement effective corrective action to include *preventive* measures. Additionally, If the deficiency warranting official control action is a Sanitation SOP failure, the plant must re-evaluate their Sanitation SOP and modify it as necessary.

NOTE: Although the plant must define their corrective/preventive actions, FSIS inspection personnel may document the plant actions on the PDR.

DECISIONS

Once the plant has defined and implemented corrective actions and preventive measures, FSIS inspection personnel will proceed to:

BLOCK 11 to determine if the plant's actions are acceptable.

BLOCK 11 - FSIS Determines if Plant Actions are Acceptable

ACTIONS

BLOCK 11

After the plant defines and implements corrective actions and preventive measures, FSIS inspection personnel will determine if plant actions are acceptable to FSIS. A plant's proposed *corrective* action will *not* be accepted unless it is accompanied by effective *preventive* measures. The plant's actions and proposed prevention measures must *correct* the problem and provide reasonable assurance that the problem will not recur.

Effective corrective action must include:

1. procedures to ensure appropriate disposition of products that may be contaminated or adulterated;

2. restoration of sanitary conditions; and

3. prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the Sanitation SOP.

NOTE: FSIS inspection personnel will continue official control action (e.g., rejection of equipment, utensils, or rooms) until the plant has implemented acceptable corrective actions and preventive measures.

DECISIONS

After reviewing the plant's actions, FSIS inspection personnel will proceed to:

BLOCK 12 if the plant's actions are *not* acceptable.

BLOCK 13 if the plant's actions *are* acceptable.

BLOCK 12 - FSIS Advises Plant of Potential Consequences for not Implementing Effective Corrective Action

ACTIONS

If the plant's corrective actions or preventive measures are not acceptable, FSIS inspection personnel will advise the plant of possible consequences.

- Official control action (e.g., rejection of equipment, utensils, or rooms; retention of product) will continue until acceptable corrective actions and preventive measures are implemented.

- Additional regulatory and/or administrative actions may be taken.

DECISIONS

After FSIS inspection personnel advise the plant of possible consequences for not implementing effective corrective actions and preventive measures, the next step of the process is to:

Return to BLOCK 10

BLOCK 13 - FSIS Determines if there are Repeated Documented Failures

PREAMBLE

If it is determined that contamination or adulteration may have occurred, FSIS will take appropriate action to prevent adulterated product from entering commerce and, where necessary, seek recall of adulterated product that has already entered commerce.

Repeated Documented Failures?

There is no magic number to determine what constitutes repetitive critical deficiencies for the same root cause. An extremely important part of this determination is the failure of previously implemented corrective and preventive actions by the establishment to prevent the recurrence of direct product contamination or adulteration. Professional judgement must be used when making this determination. Notify the Area Office of the implementation of any withholding action.

ACTIONS

BLOCK 13

When FSIS inspection personnel document a Sanitation SOP failure (i.e., a critical deficiency), they will determine if it is an isolated incident or if the failure is a repetitive (i.e., repeatedly documented) deficiency with the same root cause. "Same root cause" refers to the negligence, ineffective method, or incomplete execution by the plant which results in the same or similar deficiencies occurring repeatedly. To decide if the Sanitation SOP failure is repetitive, FSIS inspectors will review previous PDRs for the plant.

No magic number exists to define a critical deficiency as *repetitive*. A very important part of this determination is the *failure* of the plant's *previously* implemented corrective and preventive actions to prevent the recurrence of direct product contamination or adulteration. FSIS inspection personnel will use professional judgment when making this determination.

DECISIONS

After determining if the deficiency for which the plant has proposed

BLOCK 13 - FSIS Determines if there are Repeated Documented Failures

corrective actions represents a "repetitive" Sanitation SOP failure, FSIS inspectors will proceed to:

BLOCK 14 — if the deficiency is *not* a repetitive Sanitation SOP failure.

BLOCK 15 — if the deficiency *is* a repetitive Sanitation SOP failure.

BLOCK 14 - FSIS Removes Official Control Action If Failure is Not Repetitive

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ACTIONS

BLOCK 14

If the identified deficiency is *not* a repetitive Sanitation SOP failure, and the plant's proposed corrective actions and preventive measures are acceptable (determined in Block 11), FSIS inspection personnel will remove the official control action. Official control action is no longer needed at this point because the plant has corrected the deficiency and adopted reasonable prevention measures. Since the identified deficiency was not repetitive, the effectiveness of the plant's preventive measures will be proven (or disproved) as the plant resumes normal operations.

DECISIONS

No further action is required by FSIS inspectors. So they will:

STOP

BLOCK 15 - FSIS Continues Official Control Action (Withholds Inspection) for Repetitive Failures

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ACTIONS

BLOCK 15

If FSIS inspection personnel determine that the records (i.e., PDRs) show a pattern of repetitive Sanitation SOP failures with the same root cause, they will *continue* official control action or institute action to withhold inspection services.

To withhold inspection due to repetitive Sanitation SOP failures, the IIC will:

1. refuse to allow any meat or poultry products produced under these unacceptable conditions to be labeled, marked, stamped, or tagged as *"inspected and passed"* or *"inspected for wholesomeness"*;

2. attach a "U.S. Retained" tag to all alleged contaminated or adulterated meat or poultry products; and

3. attach a "U.S. Rejected" tag to the applicable equipment, utensils, rooms, or areas.

The IIC will withhold inspection pending an assessment of the plant's compliance history.

DECISIONS

After withholding inspection, the IIC will proceed to:

BLOCK 16 and contact the Area Office.

REFERENCES

FSIS Directive 11,100.3, Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure (Instructions for Action to be

BLOCK 15 - FSIS Continues Official Control Action (Withholds Inspection) for Repetitive Failures

Taken by Inspectors for Repeated Plant Failures Documented Through Verification Activities)

BLOCK 16 - IIC Contacts Area Office

ACTIONS

BLOCK 16

After the IIC withholds inspection (continues official control action) due to repetitive Sanitation SOP failures, the following sequential events will occur.

1. The IIC will immediately contact the Area Office to notify them of the actions taken and to request assistance.

2. The Area Office will contact the appropriate Compliance Program Area Office OIC, inform him/her of the situation, and request that a Compliance Officer visit the plant at the earliest possible date to assist the IIC in assessing the plant's compliance history.

3. The Area Office will notify the Circuit Supervisor (CS) of the action initiated.

NOTE: If, at any time, FSIS inspection personnel suspect that a plant has engaged in any illegal activity (e.g., falsified required records; offered for sale, sold, or transported adulterated or misbranded meat or poultry products in commerce), they will report the alleged violations to the appropriate Compliance Program OIC.

DECISIONS

After a Compliance Officer contacts the IIC, the IIC and CO will proceed to:

BLOCK 17 to review the plant situation.

REFERENCES

FSIS Directive 11,100.3, Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure (Reporting of Alleged Violations by Inspectors)

BLOCK 17 - IIC and CO Review Situation

ACTIONS

BLOCK 17

When deemed necessary, a Compliance Officer (CO) will visit the plant to help the IIC assess the plant's compliance history and if warranted, initiate and develop an administrative case file.

The IIC and CO will determine if inspection records (PDRs or other documentation):

1. accurately describe plant conditions.

2. show that plant management has received adequate oral and written notice of:

   a. inspection findings;

   b. failure of previous plant corrective actions;

   c. any applicable deadlines;

   d. consequences of failure to implement effective corrective and preventive action; and

   e. any applicable appeal rights regarding inspection findings.

3. accurately reflect plant management response (both performance and nonperformance) to any notice of inspection findings.

4. accurately reflect that FSIS inspection personnel have used program authority (e.g., rejection/retention; denying use of processes <down time>; denying use of marks of inspection and/or labels).

DECISIONS

If further action is justified, but the conditions at the plant do not warrant regulatory enforcement action under "other applicable rules of practice", the IIC will proceed to:

BLOCK 17 - IIC and CO Review Situation

BLOCK 18 to initiate appropriate "in-plant" regulatory action.

NOTE: The decision to pursue a case under "other applicable rules of practice" will not be made at the plant level.

BLOCK 18 - IIC Initiates Appropriate In-Plant Regulatory Action

ACTIONS

BLOCK 18

If the IIC and CO assessment shows a pattern of recurring deficiencies and noncompliance, the IIC, in consultation with the Area Office, will initiate appropriate in-plant regulatory action. **NOTE:** This action does not preclude suspension of inspection services, when applicable.

The IIC requesting assistance with the compliance history review will be responsible for leading the process. The CO assisting with the review will serve in an advisory capacity. The CO will:

- initiate an investigative file;
- assess the adequacy of documentation to support in-plant regulatory action and/or any administrative procedures which may be recommended; and
- with the IIC, consult with the Area Office to decide what additional regulatory or administrative actions will be taken.

DECISIONS

Once the review is completed and FSIS personnel decide on an appropriate course of action, the IIC and CO will proceed to:

BLOCK 19 to complete the documentation requirements.

BLOCK 19 - IIC Provides Documentation to IMP and FOD, Compliance

ACTIONS

BLOCK 19

The IIC and CO will forward all documented findings to the headquarters, Inspection Management Program (IMP) and Compliance Program, Field Operations Division (FOD). Staff specialists from these Program areas will review the documentation.

DECISIONS

Following a comprehensive review of the documentation, the staff specialists from IMP and FOD will proceed to:

BLOCK 20 to produce written notification for the plant.

REFERENCES

FSIS Directive 11,100.3, Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure (Administrative Procedures to be Followed by Inspectors)

BLOCK 20 - IMP and FOD Prepare and Provide Letter to Plant Management

ACTIONS

BLOCK 20

The staff specialists from IMP and FOD assigned to the case will collectively work to produce a written notification to the plant at the earliest possible date.

Written notification to the plant should include:

1. a description of the alleged violations of the Acts and/or the regulations issued thereunder.
2. a description of the actions considered necessary to be taken by each recipient or operator of the plant to:
   a. effect a permanent correction of the unacceptable conditions;
   b. comply with the requirements of the Acts and/or the regulations promulgated thereunder; and
   c. eliminate the need to commence an action to withdraw inspection services.
3. a statement indicating:
   a. the suspension of inspection operations will remain in effect until permanent corrections of the unacceptable practices or conditions described have been achieved; and
   b. if the applicant or operator of the plant fails to eliminate the unacceptable practices or conditions described, FSIS intends to commence an action to withdraw inspection in accordance with appropriate rules of practice set forth in 9 CFR Part 335 and Part 381, Subpart W.

BLOCK 20 - IMP and FOD Prepare and Provide Letter to Plant Management

REFERENCES

FSIS Directive 11,100.3, Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure (Administrative Procedures to be Followed by Inspectors)

APPENDIX A

Guidelines for Developing a Standard Operating Procedure for Sanitation (Sanitation SOP's) in Federally Inspected Meat and Poultry Establishments

I. Introduction

Foodborne illness is a significant public health problem in the United States. While data on illness associated with meat and poultry products are limited, data from various sources suggest that foodborne microbial pathogens may cause up to 7 million cases of illness each year, and 7,000 deaths. Of these, nearly 5 million cases of illness and more than 4,000 deaths may be associated with meat and poultry products.

FSIS is pursuing a broad and long-term science-based strategy to improve the safety of meat and poultry products to better protect public health. FSIS is undertaking steps to improve the safety of meat and poultry throughout the food production, processing, distribution, and marketing chain. The Agency's goal is to reduce the risk to public health of consuming meat and poultry products by reducing pathogenic microbial contamination. The FSIS strategy relies heavily on building the principle of prevention into production processes.

Sections 308.7, 381.57 and 381.58 of the Meat and Poultry Inspection Regulations require that rooms, compartments, equipment, and utensils used for processing or handling meat or poultry in a federally inspected establishment must be kept clean and in a sanitary condition. Establishments are responsible for sanitation of facilities, equipment and utensils.

Sanitation maintains or restores a state of cleanliness, and promotes hygiene for the prevention of foodborne illness. Sanitation encompasses many areas and functions of an establishment, even when not in production. However, there are certain sanitary procedures that must be addressed and maintained on a daily basis to prevent direct product contamination or adulteration. Good sanitation is essential in these areas to maintaining a safe food production process.

FSIS is requiring meat and poultry establishments to develop and implement a written Standard Operating Procedure for sanitation (Sanitation SOP's) which addresses these areas. An establishment's adherence to its written Sanitation SOP will demonstrate knowledge of and commitment to sanitation and

production of safe meat and poultry products.

New part 416 to the Meat and Poultry Inspection Regulations requires that a written Sanitation SOP contain established procedures to be followed routinely to maintain a sanitary environment for producing safe and unadulterated food products. Plant management must develop a Sanitation SOP that describes daily sanitation procedures to be performed by the establishment. A designated establishment employee(s) must monitor the Sanitation SOP and document adherence to the SOP and any corrective actions taken to prevent direct product contamination or adulteration. This written documentation must be available to FSIS program employees.

These FSIS guidelines should help federally inspected meat or poultry establishments develop, implement and monitor written Sanitation SOPs.

The Sanitation SOP developed by the establishment must detail daily sanitation procedures it will use before (pre-operational sanitation) and during (operational sanitation) operation to prevent direct product contamination or adulteration. FSIS program employees will verify an establishment's adherence to its Sanitation SOP and will take appropriate action when there is noncompliance.

These guidelines, where applicable, are for:

- Livestock Slaughter and/or Processing Establishments
- Poultry Slaughter and/or Processing Establishments
- Import Inspection Establishments
- Identification Warehouses

The establishment should update the Sanitation SOP to reflect changes in equipment and facilities, processes, new technology, or designated establishment employees.

Pre-operational Sanitation

Established procedures of pre-operational sanitation must result in clean facilities, equipment and utensils prior to starting production. Clean facilities, equipment, and utensils are free of any soil, tissue debris, chemical or other injurious substance that could contaminate a meat or poultry food product. Pre-operational sanitation established procedures shall describe the daily, routine sanitary procedures to prevent direct product contamination or

adulteration. The sanitary procedures must include the cleaning of product contact surfaces of facilities, equipment and utensils to prevent direct product contamination or adulteration. The following additional sanitary procedures for pre-operational sanitation might include:

- Descriptions of equipment disassembly, reassembly after cleaning, use of acceptable chemicals according to label directions, and cleaning techniques.
- The application of sanitizers to product contact surfaces after cleaning. Sanitizers are used to reduce or destroy bacteria that may have survived the cleaning process.

III. Operational Sanitation

All federally inspected establishments must describe daily, routine sanitary procedures that the establishment will conduct during operations to prevent direct product contamination or adulteration. Established procedures for operational sanitation must result in a sanitary environment for preparing, storing, or handling any meat or poultry food product in accordance with sections 308/381 of the Meat and Poultry Inspection Regulations. Established procedures during operations might include, where applicable:

- Equipment and utensil cleaning--sanitizing--disinfecting during production, as appropriate, at breaks, between shifts, and at midshift cleanup.
- Employee hygiene: includes personal hygiene, cleanliness of outer garments and gloves, hair restraints, hand washing, health, etc.
- Product handling in raw and in cooked product areas.

The established sanitary procedures for operational sanitation will vary with the establishment. Establishments with complex processing need additional sanitary procedures to ensure a sanitary environment and to prevent cross contamination. Establishments that do not slaughter or process (such as an Import Inspection facility) should develop established sanitary procedures specific to that facility.

IV. Implementing and Monitoring of the Sanitation SOP

The Sanitation SOP shall identify establishment employee(s) (positions rather than specific names of employees) responsible for the implementation and maintenance of the Sanitation SOP. Employee(s) are to be identified to monitor and evaluate the effectiveness of the Sanitation SOP and make corrections when

needed. The evaluation can be performed by using one or more of the following methods: (1) organoleptic (sensory--e.g., sight, feel, smell); (2) chemical (e.g., checking the chlorine level); (3) microbiological (e.g., microbial swabbing and culturing of product contact surfaces of equipment or utensils).

Establishments might specify the method, frequency, and recordkeeping processes associated with monitoring. Pre-operational sanitation monitoring should, at a minimum, evaluate and document the effective cleaning of all direct product contact facilities, equipment, and/or utensils that are to be used at the start of production. Operational sanitation monitoring should, at a minimum, document adherence to the SOP, including actions that identify and correct instances or circumstances of direct product contamination which occur from environmental sources (facilities, equipment, pests, etc.) or employee practices (personal hygiene, product handling, etc.). All establishment records of pre-operational and operational sanitation monitoring, including corrective actions to prevent direct product contamination or adulteration, must be maintained by the establishment for at least six months, and be made available to FSIS program employees. After 48 hours, they may be maintained off-site.

V. Corrective Actions

When deviations occur from the established sanitary procedures within the Sanitation SOP, the establishment must take corrective and preventive actions to prevent direct product contamination or adulteration. Instructions should be provided to employees and management officials for documenting corrective actions. The actions must be recorded.

Appendix B

Model of a Standard Operating Procedure for Sanitation

Hill-Top Meats has prepared a written Standard Operating Procedure (SOP) for Sanitation. Let's look at the Sanitation SOP and discuss its attributes (guidance and advice are inside the boxes).

Hill-Top Meats, Est. 38, Anytown, U.S.A. is a slaughter and medium processing establishment. This plant receives live cattle for slaughter and dressing and processes the carcasses into chubs of ground beef, roast beef, and ready to eat beef products.

This introductory information is not a regulatory requirement but identifies the type of establishment and its production. The information will help FSIS personnel, who are not familiar with the establishment, review the Sanitation SOP.

Management structure is as follows:

President--Joe Doe
Slaughter Manager--Ken Smith
Processing Manager--Susan Jones
Quality Control (QC) Manager--Gwen Summers
Sanitation Manager--Carl Anderson

The QC Manager is responsible for implementing and daily monitoring of the Sanitation SOP and recording the findings and any corrective actions. The Slaughter, Processing and Sanitation Managers are responsible for training and assigning specific duties to other employees and monitoring their performance within the Sanitation SOP.

All records, data, checklists and other information pertaining to the Sanitation SOP will be maintained on file and made available to FSIS program employees.

The identification of establishment personnel (positions rather than specific names of employees) responsible for implementing, maintaining, monitoring and records associated with the Sanitation SOP is a regulatory requirement. All records pertaining to the Sanitation SOP must be kept on file and made available to FSIS personnel, but it is not necessary to make that statement.
Sanitation SOP for EST. 38

I. Preoperational Sanitation--Equipment and Facility Cleaning
Objective

All equipment will be cleaned and sanitized prior to starting production.

A. General Equipment Cleaning. (Simple equipment and hand tools are cleaned and sanitized in the same manner but they do not require disassembly and reassembly.)

1. Established Sanitary Procedures for Cleaning and Sanitizing Equipment:
   a. The equipment is disassembled. Parts are placed in the designated tubs, racks, etc.
   b. Product debris is removed.
   c. Equipment parts are rinsed with water to remove remaining debris.
   d. An approved cleaner is applied to parts and they are cleaned according to manufacturers' directions.
   e. Equipment parts are rinsed with potable water.
   f. Equipment is sanitized with an approved sanitizer, and rinsed with potable water if required.
   g. The equipment is reassembled.
   h. The equipment is resanitized with an approved sanitizer, and rinsed with potable water if required.

The established sanitary procedures are daily routine sanitary procedures to prevent direct product contamination or adulteration. Daily routine sanitary procedures to prevent direct product contamination or adulteration are required in the Sanitation SOP; FSIS personnel use them to verify compliance with the Sanitation SOP. The procedures shall be specific for each establishment; however, they can be as detailed as the establishment wants to make them.

2. Implementing, Monitoring and Recordkeeping. The QC Manager performs daily organoleptic sanitation inspection after preoperational equipment cleaning and sanitizing. The results of the inspection are recorded on Establishment Form E-1. If everything is acceptable, the appropriate box is initialed. If corrective actions are needed, such actions are to be documented (see below).

   The QC Manager performs daily microbial monitoring for Total Plate Counts (TPCs) after preoperational equipment cleaning and sanitizing. The QC Manager swabs one square inch of a food contact surface on a piece of equipment or hand tool within one hour prior to production. The samples are plated and incubated at

35 deg. C for 48 hours. Colonies are counted and recorded as number of colony forming units (CFU) per square inch of surface swabbed. Daily microbial counts are documented on Establishment Form M-1.

3. Corrective Actions.
   a. When the QC Manager determines that the equipment or hand tools do not pass organoleptic examination, the cleaning procedure and reinspection are repeated. The Sanitation Manager monitors the cleaning of the equipment or hand tools and retrains sanitation crew employees, if necessary. Corrective actions are recorded on Establishment Form E-1.
   b. If microbial counts exceed ____ CFUs/sq. in., the QC Manager notifies the Sanitation Manager and attempts to determine the cause of the high count (for example, cleaning procedures varied, new people cleaned the equipment, sanitizer not applied). If microbial counts remain high for several days, the QC Manager will confer with the Sanitation Manager. The Sanitation Manager notifies sanitation crew employees and reviews all cleaning and sanitizing procedures and personal hygiene. Microbial counts are recorded on Establishment Form M-1. Corrective actions to prevent direct product contamination or adulteration are documented on Establishment Form E-1.

The establishment is required to monitor daily routine sanitation activities as described in the Sanitation SOP, the establishment determines the methods and frequency of monitoring. Microbiological sampling is not required, but Hill-Top Meats wants to monitor the effectiveness of the cleaning by daily microbial sampling, in addition to organoleptic monitoring, and has set limits to enable them to take appropriate action when those limits are exceeded. Establishment Forms E-1 and M-1 are used only as examples; no specific forms or form numbers are required. However, establishments must record the daily completion or adherence to the established procedures in the Sanitation SOP, any deviations from regulatory requirements, and corrective actions.

B. Cleaning of Facilities--including floors, walls and ceilings.
   1. Cleaning Procedures.

a. Debris is swept up and discarded.
b. Facilities are rinsed with potable water.
c. Facilities are cleaned with an approved cleaner, according to manufacturer's directions.
d. Facilities are rinsed with potable water.

2. Cleaning Frequency. Floors and walls are cleaned at the end of each production day. Ceilings are cleaned as needed, but at least once a week.

There is no specific requirement to include facility cleaning in the Sanitation SOP, unless part of the facility could directly contaminate or adulterate product.

3. Establishment Monitoring.
The QC Manager performs daily organoleptic inspection prior to the start of operations. Results are recorded on Establishment Form E-1.

4. Corrective Actions.
When the QC Manager determines that the facilities do not pass organoleptic inspection, the cleaning procedure and reinspection are repeated. The Sanitation Manager monitors the cleaning of facilities and retrains sanitation crew employees if necessary. Corrective actions to prevent direct product contamination or adulteration are recorded on Establishment Form E-1.

II. Operational Sanitation

Objective: Carcass dressing will be performed under sanitary conditions and in a manner to prevent contamination of the carcass.

A. Slaughter Operations.

1. Established Methods for Carcass Dressing--

a. Employees will clean hands, arms, gloves, aprons, boots, etc., as often as necessary during the dressing procedures.
b. Employees will clean and then sanitize with 180 deg. F water, knives and other hand tools, saws and other equipment, as often as necessary during the dressing procedures to prevent contamination of the skinned carcass.
c. The brisket saw is sanitized between carcasses using 180 deg. F water.

d. Eviscerating employees will maintain clean hands, arms, clothes, aprons, boots and knives during the evisceration process. If contamination occurs, the employee is required to step away from the evisceration table onto a side platform to clean and sanitize apron, boots and knives. It may be necessary to clean hands and arms with soap and water. In cases of contamination from an abscess or other extensive contamination, the employee may need to shower and change clothes before resuming work.
e. The carcass splitting saw is sanitized with 180 deg. F water after each carcass.

The above methods for carcass dressing are specific for Hill-Top Meats. The establishment considers them to be Good Manufacturing Practices for their type of operation, to prevent direct contamination or adulteration of carcasses. Each establishment determines the sanitary procedures and any requirements they want to detail in their Sanitation SOP.

2. Monitoring and Recordkeeping.
a. The Slaughter Manager is responsible for ensuring that employee hygiene practices, sanitary conditions and cleaning procedures are maintained during a production shift. The QC Manager monitors the sanitation procedures twice during a production shift. Results are recorded on Establishment Form E-1.
b. A Microbiological Control and Monitoring Program is used to determine the level of bacteria on product contact surfaces of equipment (e.g., knives, hand tools, evisceration table, etc.) and outer garments (such as aprons and gloves) during production. The QC Manager performs daily microbial monitoring for Total Plate Counts (TPCs). The samples are plated and incubated at 35 deg.C for 48 hours.
Colonies are counted and recorded as number of colony forming units (CFU) per square inch of surface swabbed. Daily microbial counts are documented on Establishment Form M-1.

3. Corrective Actions.
a. When equipment is visibly contaminated, contaminants are removed by cleaning and sanitizing equipment prior to resuming

production. The Slaughter Manager attempts to determine the cause of the contamination and takes corrective action. This may require adjusting equipment, retraining employees, temporarily stopping or slowing the line speed, etc. Corrective actions are recorded on Establishment Form E-1.

b. If microbial counts from equipment swabbing exceed the action level set, the QC Manager notifies the Slaughter Manager. The Slaughter Manager attempts to determine the cause (for example, new people not adequately trained, equipment not adjusted properly) and takes corrective action. If microbial counts remain above established limits for several days, the QC Manager confers with the Slaughter Manager and all slaughter operations are reviewed. The Slaughter Manager notifies the slaughter employees and reviews personal hygiene, equipment adjustment, and sanitary handling procedures. Corrective actions to prevent direct product contamination or adulteration are recorded on Establishment Form E-1.

The establishment is required to monitor the regulatory daily sanitation activities as described in its Sanitation SOP, but each establishment determines its own methods for monitoring, the frequency of monitoring, and the corrective actions to include in the Sanitation SOP. Records must be kept on daily completion of the established procedures, deviations, and corrective actions.

B. Processing Operations.

Objective: Processing is performed under sanitary conditions to prevent direct and cross contamination of food products.

1. Established Sanitary Procedures for Processing–
   a. Employees clean and sanitize hands, gloves, knives, wizard knives, other hand tools, cutting boards, etc., as necessary during processing to prevent contamination of food products.
   b. All equipment, belt conveyors, tables, and other product contact surfaces are cleaned and sanitized throughout the day as needed.
   c. Employees take appropriate precautions when going from a raw product area to a cooked product area, to prevent cross contamination of

cooked products. Employees change outer garments, wash hands and sanitize hands with an approved hand sanitizer (sanitizer is equivalent to 50 ppm chlorine), put on clean gloves for that room and step into a boot sanitizing bath on leaving and entering the respective rooms.

   d. Raw and cooked processing areas are separate. There is no cross utilization of equipment between raw and cooked products.
   e. Outer garments, such as aprons, smocks and gloves, are identified and designated specifically for either the raw processing rooms or the cooked processing rooms. Blue is designated for raw processing rooms and orange for cooked processing rooms. The outer garments are hung in designated locations when an employee leaves each room. Outer garments are maintained in a clean and sanitary manner and are changed at least daily and, if necessary, more often.

Establishments with processing will determine their own established sanitary procedures in the Sanitation SOP and any establishment requirements. Hill-Top Meats considers its established procedures for processing to be Good Manufacturing Practices.

2. Monitoring and Recordkeeping.
   a. The Processing Manager is responsible for ensuring that employee hygiene practices, employee and product traffic patterns, sanitary product handling procedures, and cleaning procedures are maintained during a production shift. The QC Manager monitors the sanitation procedures twice during a production shift. Results are recorded on Establishment Form P-1.
   b. A Microbiological Control and Monitoring Program is used to determine and control the level of bacteria on both raw and cooked product contact surfaces during production. Once a day, the QC Manager performs Microbial Monitoring for Total Plate Counts (TPCs). The QC Manager swabs one square inch on a product contact surface from each of three randomly selected pieces of equipment in each raw product room and cooked

product room.

Note: The samples are taken from the cooked product rooms first and then from the raw product rooms. The samples are plated and incubated at 35 deg. C. for 48 hours. Colonies are counted and recorded as number of colony forming units (CFU) per square inch of surface swabbed. Microbial counts are documented on Establishment Form M-1.

3. Corrective Actions.
   a. When the QC Manager identifies sanitation problems, the QC Manager notifies the Processing Manager. The Processing Manager stops production, if necessary, and notifies processing employees to take appropriate action to correct the sanitation problems. If necessary, processing employees are retrained. Corrective actions are recorded on Establishment Form P-1.

      If microbial counts exceed the action level set for each piece of equipment for the specific product in that production line, the QC Manager notifies the Processing Manager. The Processing Manager attempts to determine the cause (for example, new people going back and forth between the raw and cooked rooms, gloves not being changed regularly) and takes corrective action. Additional daily microbial sampling is done on any equipment that showed high microbial counts, until the counts fall below the action level. If microbial counts remain high for several days, the QC Manager confers with the Processing Manager and Sanitation Manager to review all operations that impact that equipment. The Processing Manager notifies the processing employees and reviews personal hygiene and sanitary product handling procedures. Corrective actions are recorded on Establishment Form P-1.

      The monitoring and corrective actions are specific for Hill-Top Meats only. Microbial sampling and monitoring are not required for product contact surfaces. Each establishment determines its own procedures for monitoring and the frequency of monitoring to include in its Sanitation SOP.

Sec. 416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

Sec. 416.12 Development of Sanitation SOP's.

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).
(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.
(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.
(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

Sec. 416.13 Implementation of SOP's.

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.
(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.
(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

Sec. 416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's 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.

Sec. 416.15 Corrective Actions.

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, 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 SOP's and the procedures specified therein.

Sec. 416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's 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 accesable 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.

Sec. 416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:
(a) Reviewing the Sanitation SOP's;
(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;
(c) Direct observation of the implementation of the Sanitation SOP's

and the procedures specified therein and any corrective actions taken or required to be taken; and
(d) Direct observation or testing to assess the sanitary conditions in the establishment.

11,100.3

EVALUATING, VERIFYING, AND ENFORCING A SANITATION STANDARD OPERATING PROCEDURE

I. PURPOSE

This directive provides instructions to inspectors for evaluating, verifying, and enforcing an establishment's Sanitation Standard Operating Procedure (SOP).

II. CANCELLATION

FSIS Directive 11,040.1, Revision 2, dated 00-00-96
FSIS Directive 11,040.2, Revision 1, dated 00-00-96

III. RESERVED

IV. RESERVED

V. EVALUATION PROCESS

The FSIS Inspector-in-Charge (IIC) or designee will perform an evaluation task (PBIS task 02D01a2, see Attachment 1, page 13) to ascertain that the establishment has met the following Sanitation SOP regulatory requirements:

A. The establishment has a written Sanitation SOP describing daily procedures the establishment will conduct before and during operations and the frequency at which they will be conducted, to prevent direct contamination or adulteration of product(s).

B. The Sanitation SOP is signed and dated by an official with overall authority on-site or a higher level official of the establishment. Sanitation SOPs must be signed upon initiation and any modifications.

C. The Sanitation SOP identifies procedures the establishment will conduct prior to the start of operations. These procedures at a minimum must address the cleaning of food contact surfaces of facilities, equipment, and utensils.

D. The establishment has identified individuals who have responsibility for implementing and maintaining daily sanitation activities.

E. The establishment has identified records to be maintained that on a daily basis document the implementation and monitoring of Sanitation SOPs and any corrective actions taken.

This evaluation will be performed as an each occasion (EO) task through the Performance Based Inspection System (PBIS). Establishments must routinely assess the effectiveness of Sanitation SOPs and adjust Sanitation SOPs in light of changes to establishment facilities, personnel, or operations. Modifications to Sanitation SOPs will be evaluated by inspection personnel as they occur. Initial evaluation of Sanitation SOPs will occur on January 27, 1997.

VI. ENFORCEMENT ACTIONS FOR THE EVALUATION PROCESS

The IIC or designee may find that the establishment's Sanitation SOPs fail to include procedures to prevent direct contamination or adulteration of product, fail to contain the signature of an official with overall authority on-site or a higher level official of the establishment, and/or fail to identify required records. Such a finding alone supports the withholding of inspection to prevent use of the facilities and equipment in the production of products until the failure is remedied.

A. If at any time after the required implementation date the IIC or designee determines that an establishment has failed to meet the regulatory requirements for development or maintenance of a Sanitation SOP, the following immediate steps will be taken:

1. The IIC or designee will refuse to allow any meat and poultry products produced under the above conditions to be labeled, marked, stamped, or tagged as "inspected and passed" or "inspected for wholesomeness."

2. The IIC or designee will "U.S. Retain" all alleged adulterated meat or poultry products produced under such conditions or procedures.

3. The IIC or designee will attach a "U.S. Rejected" tag to the applicable equipment, utensil, room or

compartment.

B. The IIC or designee will immediately orally advise establishment management that the above steps have been taken and document the reasons for taking such action on FSIS Form 8820-2, Process Deficiency Record (PDR). The IIC or designee will subsequently notify the Inspection Operations Area Office (AO) of the action initiated.

C. If an establishment fails to render immediate corrective action, the AO will contact the appropriate Compliance Program OIC to request that a Compliance Officer (CO) assist with documentation of the alleged non-regulatory compliance. A CO will visit the establishment at the earliest possible date to assist the IIC. The AO will subsequently notify the Circuit Supervisor (CS) of the action initiated.

D. The CO will initiate, develop and document an investigative case file. All documented findings will be handled by assigned inspectors and compliance officers in accordance with this directive.

VII. VERIFICATION PROCESS

FSIS inspection personnel shall perform PBIS record and process verification tasks to determine the implementation, effectiveness, and maintenance of the Sanitation SOP and procedures specified therein. PBIS will schedule daily pre-op sanitation activities in both slaughter and processing operations. PBIS will randomly select either records verification or hands-on verification tasks to be performed daily.

There will be one verification task for slaughter and processing in combination establishments.

A. Records Verification

FSIS inspection personnel will perform pre-operational record verification PBIS task 02E01a2 and operational record verification PBIS task 02F01a2 (see Attachment 1, pages 14-17) to verify:

1. Establishments are maintaining daily records which document:

   a. The effectiveness of the pre-operational activities of the Sanitation SOP.

   b. The monitoring of the pre-operational activities of the Sanitation SOP.

   c. Initiation of corrective actions to prevent direct product contamination or adulteration. Corrective actions must include:

      (1) Procedures to ensure the appropriate disposition of products that may be contaminated or adulterated.

      (2) Restoration of sanitary conditions.

      (3) Prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the Sanitation SOP.

2. Establishments are maintaining daily records which document:

   a. The effectiveness of operational activities of the Sanitation SOP; and any corrective actions.

   b. The monitoring of operational activities of the Sanitation SOP.

   c. Initiation of corrective actions to prevent direct product contamination or adulteration. Corrective actions must include:

      (1) Procedures to ensure the appropriate disposition of products that may be contaminated or adulterated.

      (2) Restoration of sanitary conditions.

      (3) Prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the Sanitation SOP.

B. Process Verification

FSIS inspection personnel will perform pre-operational process

verification PBIS task 02E02a2 and operational process verification PBIS task 02F02a2 (see Attachment 1, pages 14-17) to verify:

1. Establishments are:

   a. Implementing the pre-operational activities of the Sanitation SOP.

   b. Monitoring the pre-operational activities of the Sanitation SOP.

   c. Initiating corrective actions to prevent direct product contamination or adulteration. Corrective actions must include:

      (1) Procedures to ensure the appropriate disposition of products that may be contaminated or adulterated.

      (2) Restoration of sanitary conditions.

      (3) Prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the Sanitation SOP.

2. Establishments are:

   a. Implementing operational activities of the Sanitation SOP.

   b. Monitoring the operational activities of the Sanitation SOP.

   c. Initiating corrective actions to prevent direct product contamination or adulteration. Corrective actions must include:

      (1) Procedures to ensure the appropriate disposition of products that may be contaminated or adulterated.

      (2) Restoration of sanitary conditions.

      (3) Prevention of recurrence of direct product contamination or adulteration including appropriate re-evaluation or modification of the Sanitation SOP.

Process verification involves observation and comparison of results to what is recorded by the establishment. Record comparison can be performed before or after the observation process.

C. Slaughter Process Verification Methodology

Hands-on verification of the pre-operational sanitation component of a slaughter establishment's Sanitation SOP will include utilization of a Pre-Operational Sanitation Inspection Plan. The development of a plan is necessary to provide uniformity in conducting pre-operational sanitation inspection by identifying areas and units for random sample monitoring. Plans will differ with the size of the establishment: Establishments that have 15 or more units will be subdivided into areas and have a certain time allotment as compared to smaller establishments that have 14 or less units which will not be divided into areas and thus a shorter time allotment.

D. Pre-Op Sanitation Inspection Plans for Slaughter Establishments Having 15 Units or More

A Pre-Op Sanitation Inspection Plan consists of two sections:

1. Section One identifies the inspection assignments, sets the time allotted for pre-op inspection, including lockout/tagout procedures, and sets the pre-op start time for each assignment:

   a. The pre-op start time will be determined by the IIC based on the Inspection Units (IUs) selected, establishment pre-op record availability, and the amount of time the establishment will need to perform lockout/tagout on the selected equipment. (The task time is independent of the lockout/tagout verification time.)

   b. The inspector's tour of duty may not always begin at the same time as the scheduled pre-op start time. The inspector's tour of duty should not be confused with the pre-op start time.

2. Section Two contains schematics that designate areas and identify units in each area:

   a. An area is a major portion of an establishment designated in the Pre-Op Sanitation Inspection Plan for hands-on pre-op sanitation inspection. Examples of an area include the picking area, the eviscerating area, or major equipment groupings or systems. The IIC will determine the boundaries of each area. One to five areas will be covered during a pre-op inspection assignment.

   b. Each area is divided into units. The size of an area may vary from 15 to 50 units. A unit is a numbered three-dimensional section within an area. Each unit must be sufficiently identified so that inspectors who rotate into a pre-op sanitation inspection assignment can easily identify each unit. A unit may have irregular boundaries that are usually identified by landmarks such as an individual piece of equipment, utensils, associated floors, walls, drains, or other vertical structures and overhead structures. A hand-drawn schematic of the area will be used to identify units. The schematic will include major landmarks in the area such as walls, doors, and posts, and an outline of the principal equipment. The boundaries of the units will be drawn on the schematic and the units numbered. To the extent practical, units should be numbered in the order of product flow for each area. Large, complex equipment may be divided into smaller units. For example, a designated unit might be an individual piece of equipment, such as a picker, and the floor, gutter drain, posts, walls, and overhead structures in the vicinity of that piece of equipment. The picker may also be divided down the middle and each half included in a different unit. Other examples of units include portions of the area with identifiable boundaries, such as the hide puller, including the floors, drains, walls, and overhead structures and a traffic lane through which products and personnel move.

   c. Portable equipment and other equipment that is

displaced during cleaning may not always be located entirely within a unit at the time of inspection. Such equipment will be inspected when it is within the boundaries of a unit.

   d. A unit takes approximately 1 minute to physically observe. If a section identified as a unit takes longer than 1 minute to observe, it is too large to be a unit and must be divided into 1 minute units. Physical boundaries must be specified for each unit in the Pre-Op Sanitation Inspection Plan.

   e. Inspection Units (IUs) will be randomly selected from units in an area:

      (1) Upon receipt of the Inspection Assignment Schedule (i.e., the week before) the IIC or designee should select the random IUs for those days a hands-on verification task is scheduled to be performed. This can be done the week before, but **must** be completed at least the day before hands-on verification is scheduled. This will allow determination of the lockout/tagout verification time based on the IUs selected. The selected IUs should remain under security. The amount of time for lockout/tagout verification should be communicated to the inspector(s) responsible for performing preoperational sanitation.

The number of IUs to be selected for area sampling is according to the following schedule:

Units Per Area	Number of IUs
15 to 30	3
31 to 40	4
41 to 50	5

      (2) The CS will authorize a method of randomly selecting IUs for inspection. The following method may be used:

         (a) Number cardboard chips to

correspond with the inspection unit numbers and place them in a container large enough to permit thorough mixing of the chips.

(b) Before each inspection, mix and then select the specified number of chips from the container.

(c) Write the IU numbers that have been selected for inspection on a piece of paper.

(d) Return the chips to the containers.

E. Pre-Op Sanitation Inspection Plans in Small Establishments Having 14 Units or Less

Pre-op sanitation inspection in small establishments will differ from pre-op sanitation inspection in larger facilities. The Pre-Op Inspection Plan consists of two sections:

1. Section One identifies the inspection assignment, sets the time allotted for pre-op inspection, including lockout/tagout procedures, and sets the pre-op start time:

   a. The IIC will create a Pre-Op Sanitation Inspection Plan. The plan will be filed in the inspector's office or in a file designated for the inspector's use in those establishments that are not required to maintain an inspection office.

   b. The pre-op start time will be determined by the IIC based on the IUs selected, establishment pre-op record availability, and the amount of time the establishment will need to perform lockout/tagout on the selected equipment. (The task time is independent of the lockout/tagout verification time.)

   c. The inspector's tour of duty may not always begin at the same time as the scheduled pre-op start time. The inspector's tour of duty should not be confused with the pre-op start time.

2. Section Two contains schematics that designate units:

   a. A unit takes approximately 1 minute to physically observe. If a section identified as a unit takes longer than 1 minute to observe, it is too large to be a unit and must be divided into 1 minute units. Physical boundaries must be specified for each unit in the Pre-Op Sanitation Inspection Plan.

   b. Small establishments will not be subdivided into areas.

   c. The IIC or designee will select 3 IUs at random for pre-op sanitation inspection as scheduled by the PBIS.

   d. The IIC or designee should select the random IUs upon receipt of the Inspection Assignment Schedule (i.e., the week before) for those days a hands-on verification task is scheduled to be performed. This can be done the week before, but must be completed at least the day before hands-on verification is scheduled.

F. Completing FSIS Form 8820.2, Process Deficiency Record, in Large Slaughter/Processing Establishments Where Sanitation Tasks are Performed by More Than One Inspector (Slaughter by Assigned Slaughter Inspector and Processing by Assigned Processing Inspector)

The IIC will ensure inspection personnel assigned to slaughter and processing operations respectively, will verify pre-operational and operational sanitation components of the Sanitation SOP independent of each other. A PDR Continuation Sheet will be utilized for documenting findings on individual inspection tasks performed by multiple inspectors. However, as the purpose of these PBIS generated tasks is to verify the effectiveness of the establishment's Sanitation SOP (procedures to prevent direct product contamination throughout the entire establishment), Sanitation SOP failures and sanitation deficiencies identified by either inspector in either the slaughter or processing departments will be combined and reported on one FSIS Form 8800-2, Process Deficiency Record (PDR), and the appropriate PDR Continuation Sheet(s) would be attached. Only one inspection result block on FSIS Form 8800-2, Inspector Assignment Schedule, will

be checked. The one block checked will always be the deficiency having the most serious classification as determined through the use of the Deficiency Classification Guide (DCG).

For example: If the processing inspector identified a critical deficiency and a minor deficiency while performing pre-op sanitation inspection, and the slaughter inspector identified a separate critical deficiency while performing pre-op sanitation inspection, all three "findings" would be combined and documented in the narrative description on one PDR and the appropriate PDR Continuation Sheets would be attached. Only one block (critical block) would be checked on FSIS Form 8820-2. Because documentation will play such a critical part in the enforcement process for Sanitation SOPs, it is imperative that inspection personnel responsible for sanitation activities in both slaughter and processing operations correlate their results to facilitate the documentation process. IICs will be responsible, or may empower either of the inspectors performing the sanitation tasks, to complete the PDR from beginning to closure, including attachment of PDR Continuation Sheet(s) as appropriate.

G. **Instructions to Inspectors Regarding Deficiencies and Enforcement Actions**

When a deficiency is identified, FSIS inspection personnel will implement actions outlined in FSIS Directive 8820.1. Deficiencies must be classified using the Deficiency Classification Guide (DCG).

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. The inspector will classify deficiencies according to the Deficiency Classification Guide (DCG) and document findings on FSIS Form 8820-2, Process Deficiency Record (PDR). However, when determining if a deficiency exists, you must take into account what is known for a fact. Therefore, if an establishment's records for that day are available, there may be something in the records that would make a difference in the deficiency classification. If the establishment's records for that day are not available, findings written on the establishment's records later will not be known as a fact when a deficiency is classified by the inspector during the hands-on verification.

Sanitation SOPs require the establishment to implement procedures designed to prevent direct product contamination or adulteration.

Therefore, deficiencies classified as "critical", in addition to requiring official control action, will be considered Sanitation SOP failures. Official control action consists of retention of products, and rejecting equipment, rooms, and/or areas: thereby withholding inspection as required, to prevent the use of facilities and equipment in the production of products until a failure is remedied. Deficiencies classified as "minors" will not require official control action. FSIS inspection personnel will determine whether official control action is necessary for deficiencies classified as "major." Minor deficiencies and major deficiencies do not constitute a Sanitation SOP failure. However, minor and major deficiencies do require corrective and preventive actions. Documentation of minor and major deficiencies are important when the Agency seeks further regulatory or administrative actions.

H. **Instructions for Action to be Taken by Inspectors for Repeated Establishment Failures Documented Through Verification Activities**

Upon determining that the records reflect repeated establishment Sanitation SOP failures for the same root cause, FSIS inspection personnel will:

1. Institute action to withhold inspection services as follows:

   a. Attach a "U.S. Rejected" tag to the applicable equipment, utensil, room, or area.

   b. Attach a "U.S. Retained" tag to all alleged contaminated or adulterated products produced under such conditions.

   c. Refuse to allow any meat and/or poultry products produced under such conditions to be labeled, marked, stamped, or tagged as "inspected and passed" or "inspected for wholesomeness."

   d. Maintain the withholding action pending a joint Compliance Program/Inspection Operations assessment of the establishment's compliance history.

2. Notify the Area Office.

I. **Administrative Procedures to be Followed by**

APPENDIX D

Inspectors

1. All documented findings will be forwarded to the headquarters Inspection Management Program (IMP) and Compliance Program, Field Operations Division (FOD) for assignment to staff specialists for review. The IMP and FOD personnel assigned to review the matter should collectively work to produce a written notification to the establishment at the earliest possible date.

2. Written notification to the establishment should include:

   a. A description of the alleged violations of the Acts and/or the regulations issued thereunder.

   b. A description of the actions considered necessary to be taken by each recipient or operator of the establishment to (1) effect a permanent correction of the unacceptable conditions, (2) comply with the requirements of the Acts and/or regulations promulgated thereunder, and (3) eliminate the need to commence an action to withdraw inspection services.

   c. A statement indicating that (1) the suspension of inspection operations will remain in effect until permanent corrections of the unacceptable practices or conditions described have been achieved, and (2) if the applicant or operator of the establishment fails to eliminate the unacceptable practices or conditions described, FSIS intends to commence an action to withdraw inspection, in accordance with appropriate rules of practice set forth in 9 CFR Part 335 and Part 381, Subpart W.

J. Reporting of Alleged Violations by Inspectors

If, at any time, FSIS personnel have reason to believe that an establishment has engaged in any violation of law, for example, falsified required regulatory records, or offered for sale, sold or transported, adulterated or misbranded meat or poultry products in commerce, they will immediately contact and report the alleged violation to the appropriate Compliance Program OIC.

Deputy Administrator
Inspection Operations

Attachment 1 -- Evaluation and Verification Tasks
Attachment 2 -- OIC Phone Numbers

02D01a2
Evaluation Task for Sanitation SOPs

Each occurrence; initially and after any modifications by establishment; one task for pre-op and operation.

Compliance Standard

The establishment has written Sanitation SOP that is signed and dated by an establishment official. The Sanitation SOP describes pre-operational procedures the establishment will conduct daily to prevent direct contamination or adulteration of product(s). The Sanitation SOP describes daily operational procedures the establishment will conduct, and the frequency at which they will be conducted, to prevent direct contamination or adulteration of product(s). The establishment has identified individuals who have responsibility for implementing and maintaining daily sanitation activities. The establishment has identified records to be maintained.

References

§416.1 - §416.7
FSIS Directive 11,100.3

Task

Determine that the establishment has met the regulatory requirements for the development and maintenance of a Sanitation SOP.

If results do not meet compliance standards, initiate appropriate action.

Pre-Operational Verification

02E01a2 - pre-op records check
02E02a2 - pre-op hands-on

Compliance Standard

A written Standard Operating Procedure for sanitation which describe all procedures the establishment will conduct daily, before operations, sufficient to prevent direct product contamination or adulteration has been implemented and is being maintained.

Pre-operational procedures in the Sanitation SOP are conducted before the start of operations. The implementation of procedures in the Sanitation SOP are monitored daily. The establishment evaluates the effectiveness of the Sanitation SOP and revises as necessary.

Corrective actions are taken by the establishment when either the establishment or FSIS determines the Sanitation SOP or procedures therein may have failed to prevent direct contamination or adulteration of product(s).

Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restoration of sanitary conditions, prevention of the recurrence of direct contamination or adulteration of product(s).

Daily records are maintained which document the implementation and monitoring of pre-operational activities, as well as initiation of corrective actions. The records are authenticated by the initials and date of responsible establishment employee.

References

416.1-416.7
FSIS Dir. 11,100.3
308.8
381.57
381.58
FSIS Dir. 11,000.2

Task (Records)

Verify appropriate records generated from the establishment's Sanitation SOP to determine the implementation and effectiveness of the pre-

operational activities of the Sanitation SOP; the monitoring of the pre-operational activities of the Sanitation SOP; and the initiation of corrective actions to prevent direct product contamination or adulteration.

If results do not meet compliance standards, initiate appropriate action.

Task (Hands-On)

Review the Sanitation SOP including the pre-op records for that day, if available, review conduct of procedures specified in the Sanitation SOP, and observe sanitary conditions themselves. For processing check one or more areas or departments to determine if plant conditions are acceptably clean. For slaughter use Slaughter Process Verification Methodology, FSIS Dir. 11,100.3.

Verification activities should determine the implementation and effectiveness of the pre-op activities of the Sanitation SOP; the monitoring of the pre-op activities of the Sanitation SOP; and the initiation of corrective actions to prevent direct product contamination or adulteration.

If results do not meet compliance standards, initiate appropriate action.

Operational Verification

02F01a2 - operational records check
02F02a2 - operational hands-on

Compliance Standard

A written Standard Operating Procedure for sanitation which describe all procedures an establishment will conduct daily, during operations, sufficient to prevent direct product contamination or adulteration of product(s) is implemented and is being maintained. The Sanitation SOP identifies the frequency with which each procedure is to be conducted and identifies the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

All procedures in the Sanitation SOP are conducted at the frequency specified in the Sanitation SOP. The implementation of procedures in the Sanitation SOP are monitored daily. The establishment evaluates the effectiveness of the Sanitation SOP and revises as necessary.

Corrective actions are taken by the establishment when either the establishment or FSIS determines the Sanitation SOP or procedures therein may have failed to prevent direct contamination or adulteration of product(s).

Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restoration of sanitary conditions, prevention of the recurrence of direct contamination or adulteration of product(s).

Daily records are maintained which document the implementation and monitoring of operational activities, as well as initiation of corrective actions. The records are authenticated by the initials and date of responsible establishment employee.

References
308.3
308.8
318.17
381.57
381.61
416.1-416.7
FSIS Dir. 11,100.3
FSIS Dir. 11,000.2

Task (Records)

Verify appropriate records generated from the establishment's Sanitation SOP to determine the implementation and effectiveness of the operational activities of the Sanitation SOP; the monitoring of the operational activities of the Sanitation SOP; and the initiation of corrective actions to prevent direct product contamination or adulteration.

If results do not meet compliance standards, initiate appropriate action.

Task (Hands-On)

Review the Sanitation SOP including the operational records for that day, review conduct of procedures specified in the Sanitation SOP, and observe sanitary conditions themselves by checking one or more areas or departments to determine if establishment conditions are acceptably clean.

Verification activities should determine the implementation and effectiveness of the operational activities of the Sanitation SOP; the monitoring of the operational activities of the Sanitation SOP; and the initiation of corrective actions to prevent direct product contamination or adulteration.

If results do not meet compliance standards, initiate appropriate action.

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APPENDIX E

SELECTION AND VERIFICATION OF ESTABLISHMENT RECORDS & DOCUMENTATION OF DEFICIENCIES

I. INTRODUCTION

This document outlines the selection and examination protocol to be employed by FSIS personnel when performing records review/verification tasks and documenting record deficiencies. For purposes of this document, records are written or other recorded information - such as information stored electronically or on imaging media - created by the establishment to document their activities, conditions, test results, etc. Such records shall be generated under the establishment's required prerequisite programs.

A thorough record examination by FSIS personnel is critical to the overall effectiveness of FSIS inspection activities. Record examination allows an assessment of plant conditions and employee activities that the inspector may not witness directly. Record examination also allows FSIS to audit processing and control measures as defined in the establishment's prerequisite programs.

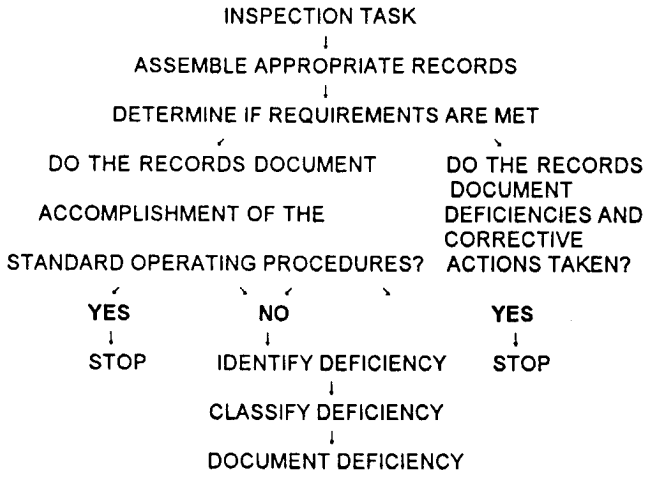
Records may be used to show that a plant is not meeting the requirements of a prerequisite program and to support additional regulatory action. As such, records should be treated as official documents.

II. STATUTORY AUTHORITY

FSIS has statutory authority under the Federal Meat Inspection Act and the Poultry Products Inspection Act to enter and inspect regulated establishments, review records, and collect copies of appropriate records when deemed necessary.

III. RECORD REVIEW MECHANICS

Inspectors will review records in a methodical and organized manner as depicted in the following flow chart.



A. Record Selection

Record verification tasks will be assigned by PBIS. Inspection personnel should select records which have not been previously examined. This means that only records generated by the establishment since the last FSIS verification of the activity (hands-on or record exam) should be selected. In some instances (e.g., suspect process and/or product), the FSIS inspector may determine that additional record verification tasks are necessary. For these unscheduled tasks, the inspector is expected to use professional judgment in deciding on the type and number of records to review.

B. Record Review/Examination

Establishments must meet regulatory requirements and any specific requirements defined in their prerequisite programs.

1. ***Compare record to procedure.***

   Compare the record to the section of the prerequisite program which requires that record. Review the record for compliance with program and/or regulatory requirements. Is the structure of the record such that it accomplishes its

intended purpose? Is it understandable? Does it reflect the necessary data?

2. ***Look for common record keeping deficiencies.***

As you review the records, attempt to answer the following questions. Is there any evidence of alterations, interlineation, interpolation, or substitution? Was the document prepared on the date it bears? Is there evidence of erasure, deletion, or removal of any part? Do the folds, tears, staple holes, etc. have any significance? Was the same writing instrument used throughout? Is there any reason to suspect that the record was prepared to deliberately misrepresent the facts? NOTE: This is a serious observation since it may involve criminal intent to defraud the government. If you suspect this practice, document the deficiency and request that the Area Office contact the appropriate Compliance Program Officer-in-Charge.

3. ***Look for common problems associated with record keeping.***

a. *There is no record.* This is the easiest record keeping deficiency to uncover but often the hardest to document. If you determine that there is no record when one is required, check with the responsible plant employee and document his/her response in the Process Deficiency Record (PDR). Always reference in the PDR the section of the program/procedure which calls for the record.

b. *A record exists, but it does not document the intended activity, condition, or result.* You may be given a record to review that does not clearly document the activity, condition, or result for which the record was to be generated. You can determine this by comparing the record entry to the record requirement.

c. *The record documents that an activity was performed incorrectly or is out of compliance, and there is no documentation of corrective action.* The record may document non-compliance without any indication that corrective action was taken. For example, the record may show an inadequate thermal cycle with no documentation of corrective action.

d. *The record is illegible.* The information on the record may not be clear or understandable or the penmanship of the plant employee may be so poor that the record is partially or totally unreadable.

e. *The record is not initialed and/or dated.* At a minimum, the responsible individual must initial and date the record.

f. *The record is altered with white-out or erasures.* Erasures and evidence of white-out will always require further investigation.

IV. RECORDS REVIEW ROLE IN VERIFICATION TASKS

When reviewing records as part of a hands-on verification task, compare the record to what is actually being done. Attempt to witness the production or testing operation and compare it to the record. Compare the results of any hands-on tests you do to previous results listed in the record. Records should be accurate and not contain misleading or erroneous information.

V. DEFICIENCY CLASSIFICATION

Deficiencies are classified using the Deficiency Classification Guide. Despite the use of a "guide", inspectors are expected to be as methodical, organized, and consistent in classifying deficiencies as they are in reviewing records.

Classification of deficiencies involves what is "known for a fact" and what is "reasonable to conclude" based on immediate observations and information available. The Deficiency Classification Guide must be used to determine the relative significance of inspection findings, including those associated with record keeping requirements.

Each situation will have its own set of circumstances and facts. Consider the difference between unintentional errors or isolated cases of sloppy record keeping and those that reveal a pattern of non-compliance with plan requirements, willful errors or omissions, or intentional misinformation. Always keep in mind the difference between records that indicate a prerequisite program breakdown, such as failure to clean and sanitize equipment which contacts cooked product, and those that are record keeping errors, such as calculations for determining sanitizer strength, that

were incorrectly transcribed from a laboratory work sheet. Although neither condition is acceptable, the former, which is a failure to meet regulatory and/or plan requirements, may be far more serious than the latter.

Using the Deficiency Classification Guide requires you to ask and answer three crucial questions. You must consider the "facts" and "reasonable conclusions" as well as the circumstances in answering the questions. The answers to these questions will determine if the deficiency is minor, major, or critical. The Deficiency Classification Guide is shown below.

DEFICIENCY CLASSIFICATION GUIDE

A.	Will the deficiency result in adulterated or misbranded/mislabeled product?	_____Certain _____Likely _____Potential
B.	Will the adulterated or misbranded/ mislabeled product reach consumers?	_____Certain _____Likely _____Potential
C.	Will the product have a detrimental effect upon consumers?	_____Certain _____Likely _____Potential

A ***critical*** deficiency must show "certain" in A, B, and C.

A ***major*** deficiency must show no less than "likely" in A, B, and C.

A ***minor*** deficiency exists when "potential" is shown in A, B, *or* C.

DEFINITIONS

CERTAIN: Inevitable or seems inevitable

LIKELY: Reasonable to assume, but not certain

POTENTIAL: Low probability

DETRIMENTAL: Injurious to health or significant departure from consumer expectations

Once a deficiency has been classified, it must be documented. Minor, major, and critical deficiencies are documented in the PDR. The entry

in the PDR should reference the applicable establishment record (see VI below).

VI. DEFICIENCY DOCUMENTATION

Be alert for serious, continuing problems in records. If persistent problems exist, attempt to document the continuing nature of the problems as well as the root cause. A much more compelling case can be made if the inspector can show that the problem is a persistent, recurring one rather than an isolated, one time occurrence. The information you document on PDRs will form the basis of Agency administrative or legal actions.

A. Recording Deficiencies

All deficiencies identified while performing a specific task will be combined and documented/described on one PDR with PDR Continuation Sheet(s) attached as appropriate.

B. Describing the Deficiencies

Deficiencies must be accurately described in block 8 of the PDR. The PDR is an official record used by the inspector to document deficiencies. All information related to the deficiency must be included when describing the deficiency. Since PDRs may be used to support an enforcement action, they must be written in a manner that will allow anyone reading the narrative to accurately "visualize" the deficiency. If additional space is needed to describe a deficiency, the back side of the form should be used, and a notation to that effect should be made in block 8. PDR Continuation sheet(s) should be attached, as appropriate

C. Supporting Information

When documenting deficiencies, it's important to include supporting documentation. Always cite the regulation (e.g., 308.7) which was violated. Include the page and/or part number of the establishment's prerequisite program when those program requirements are not met. Always cite the date and the name and/or number of the plant form when describing any deficiency connected with plant records. From an enforcement perspective, it's vital that previous deficiencies which have the same "root cause" be included in the documentation. This can be accomplished by

referencing the PDR numbers and dates. When citing these repetitive deficiencies, also record the failure of the establishment's corrective/preventive action as documented on the previous PDRs.

D. Establishment Corrective and Preventive Actions

When completing a PDR, establishment corrective and preventive actions must be documented in blocks 13 and 13a respectively. In most cases, the corrective and preventive actions to be taken should already be addressed in the establishment's prerequisite plan. However, inspection personnel must evaluate the proposed action to make sure it is adequate. If inspection personnel determine that the corrective or preventive actions called for in the establishment's prerequisite program are inadequate, the establishment must propose acceptable alternate or additional actions. If the deficiency represents a program failure, the plant will need to reevaluate and possibly modify their program.

Sanitation Regulatory References

This table may not be all inclusive, and should be used as a reference only.

	Meat	Poultry	Sanitation
Agency Verification			416.1
Backflow prevention	308.3(d)(1)	381.50(a)	
Belts/Conveyors		381.58(g)	
Boiler room		381.47(g)	
Burlap	308.11		
Catch basins	308.13		
Cats	308.3(i)	381.59	
Ceilings	308.3(e) 308.8(b)	381.48(c)	
Chilling tanks		381.53(h)	
Cleaning Equip/Utensils Rooms/Compart.		 381.58 381.57	
Coolers/Freezers		381.47(d)	
Condemned carcass receptacle		381.53(m)	
Condensation	308.8(b)	381.52(c)	
Containers Condemned Inedible Offal	308.12	 381.53(m) 381.53(a)(1) 381.53(l)	
Conveyors		381.53(g) 381.58(g)	
Corrective Actions			416.15

Sanitation Regulatory References

This table may not be all inclusive, and should be used as a reference only.

	Meat	Poultry	Sanitation
Dated records			416.12(b)
Deboning room		381.47(e)	
Development, SOP			416.11 416.12
Docks	308.13		
Doors/Doorways	308.3(e)	381.48(b)	
Diseased persons	308.14		
Disinfectants	308.8(c)		
Dogs	308.3(i)	381.59	
Drainage	308.3(c)(d) 308.4(c) 308.13	381.49 (b)(c)	
Drawings & Specs.	308.2		
Driveways	308.13		
Dust	308.3(g)		
Employees			
Clothing	308.8(d)		
Facilities	308.4(a)(b)	381.51(c)-((j)	
Equipment	308.8(d)	381.61 (b)(c)	
Health	308.14	381.61(a)	
Sanitary practices	308.8(e)	381.61(c)(d)	
Equipment/Utensils	308.5	381.53	
Accessibility		381.54	
Cleaning		381.58	
Restrictions		381.55	

Sanitation Regulatory References

This table may not be all inclusive, and should be used as a reference only.

	Meat	Poultry	Sanitation
Establishment			
Procedures			
Daily			416.12(a)
Prior to op.			416.12(c)
Frequency			416.12(d)
Responsibilities			416.11
Corrective Act.			416.15
Development			416.12
Implementation			416.13
Maintenance			416.14
Recordkeeping			416.16
Evaluations			
Establishment			416.14 416.15(b)
FSIS			416.17(a)) & (b)
Flies	308.3(h) 308.13	381.59	
Floors	308.3(e)	381.48(a)	
Freezers		381.47(d)	
FSIS			
Evaluations			416.17
Responsibilities			416.17
Verifications			416.17
Germicides		381.60	
Handwashing Fac.		381.51(f)	
Holding room		381.47(c)	
Ice shovels		381.53(f)	
Implement., SOP			416.11 416.13

Sanitation Regulatory References

This table may not be all inclusive, and should be used as a reference only.

	Meat	Poultry	Sanitation
Inedle			
Facility	308.13		
Receptacles		381.53(a)(1)	
Insects/Rodents			
Prevention	308.3(h)	381.59	
Control	308.3(h)	381.60	
Insecticides	308.3(h)		
Interceptor traps		381.49(c)(2)	
Lavatories	308.4	381.51	
Lighting	308.3(b) 308.4(a)	381.36(c)(1) 381.52(a)(b) 381.76(b)(1)	
Lockers		381.51(c)	
Lunch facilities		381.47(i)	
Maintenance			
Sanitary cond		381.56	416.11
SOP			416.14
Mech. debon. rm.		381.47(e)	
bservations			416.17(c) 416.17(d)
Odors	308.3(g) 308.8(f)	381.52(c)	
Operational sanitation			416.12 416.13
Outside			
Openings		381.46(b)	
Premises	308.13	381.49(b) 381.56(a)	

Sanitation Regulatory References

This table may not be all inclusive, and should be used as a reference only.

	Meat	Poultry	Sanitation
Overflow		381.53(d)	
Pen construction	308.13		
Pest Control	308.3(h)	381.59	
Pre-Op sanitation			416.12(a) (c) & (d) 416.13(a)
Preventive Actions			416.15(b)
Proprietary Sub. &			
Nonfood Comp.	318.1(c)(e) 318.7 318.15	381.60 381.147	
Procedures, Est.			
Daily			416.12(a)
Pre-Op			416.12(c)
Frequency			416.12(d)
Rats/Mice		381.59	
Receptacle			
Condemned		381.53(m)	
Inedible		381.53(a)(1)	
Offal		381.53(l)	
Records			
/Recordkeeping			416.16
Authentication			416.16(a)
Daily			416.16(a)
Requirements			416.16
Retention			416.16(c)
SOP's			416.11 416.12
Refuse			
Containers		381.52(c)	
Room		381.47(b)	

Sanitation Regulatory References

This table may not be all inclusive, and should be used as a reference only.

	Meat	Poultry	Sanitation
Responsibilities			
Establishment			416.11
Corrective Act.			416.15
Develop SOP			416.12
Implementation			416.13
Maintenance			416.14
Recordkeeping			416.16
FSIS			416.17
Retain room		381.47(c)	
Reviews			
SOP's			416.17(a)
Daily Records			416.17(b)
Revisions, SOP			416.14
			416.15(b)
Rooms/Compart.		381.47	
Cleaning		381.57	
Sanitation	Part 308	Subpart H	Part 416
Building		381.46	
Employee pract.	308.8		
Equipment		381.53 - .55	
Est. (General)	308.3		
Floors, Walls, Ceilings		381.48	
Inedible Op. & storage rm.	308.12		
Inspection	308.8(b)		
Pre-Op			416.12
			416.13(a)
Operational			416.12
			416.13(b)
Outer premises	308.13	381.49(b)	
Rooms		381.47	
Utensils		381.53	
Sanitary facilities		381.51	

Sanitation Regulatory References

This table may not be all inclusive, and should be used as a reference only.

	Meat	Poultry	Sanitation
Sanitizers/Steril.	307.2 (f)(g)		
Scalding Equip.		381.53(d)	
		381.58(c)	
Overflow		381.53	
Sewers		381.49(c)	
Shovels, ice		381.53(f)	
Signature			416.12(b)
Initials			416.16(a)
Signs, toilet room		381.51(h)	
SOP's			
Development			416.12
Implementation			416.13
Maintenance			416.14
Storage & Supply		381.47(f)	
Tanks		381.53(h)	
Thawing tanks		381.53(h)	
Toilet rooms	308.4	381.47(h)	
		381.51	
Trash containers		381.51(e)	
Utensils		381.53	
Vermin		381.53	
Ventilation	308.3	381.52(a) & (c)	
Waste containers		381.51(e)	

Sanitation Regulatory References

This table may not be all inclusive, and should be used as a reference only.

	Meat	Poultry	Sanitation
Water			
Cleaning	308.3(d)		
Nonpotable	308.3(d)	381.50(e)	
Potable	308.3(d)	381.50(a)	
Reuse	308.3(d)	381.50(e)(f)	
Supply	308.3(d)	381.50	
Wax finishing		381.53(e)	
Wetting agents		381.60	
Wrappings, burlap	308.11		