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

# FSIS DIRECTIVE	5000.4 Rev. 1	09/28/11

NOTE: DO NOT IMPLEMENT THIS DIRECTIVE UNTIL NOVEMBER 12, 2011.

PERFORMING THE REVIEW COMPONENT OF PBIS 01B02 PROCEDURE AND PHIS PRE-OP SANITATION SOP REVIEW AND OBSERVATION TASK IN FEDERALLY INSPECTED PROCESSING, SLAUGHTER AND IMPORT ESTABLISHMENTS

CHAPTER I – GENERAL

I. PURPOSE

This directive provides instructions to FSIS inspection program personnel (IPP) on how to perform the review component of Performance-Based Inspection System (PBIS) procedure 01B02 Pre-operational (pre-op) Sanitation Verification and Public Health Information System (PHIS) Pre-Op Sanitation Standard Operating Procedures (Sanitation SOP) Review and Observation task in most slaughter and import establishments and those processing establishments that do daily clean-up. IPP are to focus inspection efforts on those production areas and equipment that present the highest risk of becoming insanitary or of being the site of, or causing, product contamination. This directive instructs IPP how to select equipment and areas to inspect, and how to determine to what extent (i.e. how in-depth) to perform pre-op verification. If IPP are in processing establishments, or in limited circumstances, slaughter establishments that maintain less than daily (LTD) sanitation procedures, they are to follow the instructions in FSIS Directive 5000.5**.**

II. CANCELLATION

FSIS Directive 5000.4, Performing the Review Portion of 01B02 (Pre-Operational Sanitation Verification) in Raw and Ready-to-Eat Product Processing Operations (Nov 17, 2008)

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to address the following:

A. This directive consolidates and updates instructions to IPP regarding how to select equipment and areas of an establishment for inspection as part of the review component of pre-op sanitation verification (PBIS procedure 01B02 and PHIS task Pre-Op SANITATION SOP Review and Observation).

B. The directive clarifies FSIS' expectations regarding the pre-op sanitation standards that IPP are to apply in performing pre-op sanitation verification in slaughter operations, and in processing operations that conduct daily sanitation operations.

C. A section addressing Supervisory Responsibility has been added to this directive.

D. The directive specifies that the use of LTD sanitation procedures is typically limited to processing operations and certain slaughter operations.

NOTE: In this directive, „pre-op verification' will refer to the performance of either PBIS procedure 01B02 or PHIS task Pre-Op SANITATION SOP Review and Observation. In addition, in this directive „IPP' refers to any FSIS employee who is responsible to conduct pre-op verification, including import inspectors.

KEY POINTS:

- *Reiterates FSIS standards for pre-op sanitation in all federally inspected establishments*
- *Makes clear that a variety of procedures and frequencies for performing those procedures can be used to maintain sanitary conditions in processing and slaughter operations as long as the Agency's standards for cleanliness are met*
- *Combines both processing and slaughter FSIS pre-op sanitation verification instructions into one directive*
- *Provides instructions regarding the selection of the areas and equipment in processing operations and slaughter operations that are to be inspected as part of FSIS' verification of pre-op sanitation*
- *Provides instruction regarding pre-op start times*
- *Clarifies that LTD sanitation procedures are typically limited to use in processing operations and certain slaughter operations described in this directive*
- *Includes Supervisory Responsibility information*

IV. REFERENCES

9 CFR 416.11 through 416.16
9 CFR Part 500

FSIS Directive 5000.1, Verifying an Establishment's Food Safety System
FSIS PHIS Directive 5000.1, Verifying an Establishment's Food Safety System
FSIS Directive 5000.2, Review of Establishment Testing Data by Inspection Personnel

V. BACKGROUND

A. The regulations on Sanitation SOPs require that establishments implement procedures sufficient to prevent direct contamination or adulteration of products while under the control of the establishment. The pre-op procedures in the Sanitation SOPs are to address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

B. FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, and FSIS PHIS Directive 5000.1, Verifying an Establishment's Food Safety System, describe how IPP are to verify an establishment's implementation of its Sanitation SOPs by performing the pre-op verification. Pre-op verification includes both a review and an observation component. As part of the review component, IPP observe the sanitary conditions in the establishment and then compare their observations to the establishment's findings. Also as part of observation, IPP watch establishment employees perform their monitoring procedures as specified in the establishment's Sanitation SOPs.

C. Appendix A of FSIS Directive 5000.1, which has been incorporated into Chapter III of this revised directive, provided a methodology that IPP were to use to verify that slaughter establishments have effectively implemented their Sanitation SOPs, while the previous version of this directive, FSIS Directive 5000.4, provided a methodology for IPP to use in verifying raw and ready-to-eat (RTE) processing operations. Finally, FSIS Directive 5000.5, Verification of Less than Daily (LTD) Sanitation Procedures, provides instructions to IPP on pre-op sanitation verification methodologies in establishments that have LTD sanitation procedures.

D. Some in industry interpreted FSIS Directive 5000.5, as an indication that the Agency would accept a lesser standard of cleanliness if an establishment employed LTD sanitation procedures. This interpretation misreads FSIS' intentions. FSIS expects that surfaces that directly contact product will look clean, feel clean, and smell clean before operations involving their use begin. FSIS is reissuing this directive to clarify its expectations regarding pre-op cleanliness and to provide notification that the use of LTD sanitation procedures should be limited to processing operations only and certain slaughter operations, effective 45 days from the publication of this directive.

VI. STANDARDS OF CLEANLINESS

A. FSIS is aware that there are establishments that effectively use LTD sanitation procedures and other nontraditional cleaning programs, such as a form of continuous cleaning of pieces of their equipment, to maintain sanitary conditions. There is no reason for IPP to interfere with an establishment's use of these programs if they are successful in maintaining sanitary conditions. Examples of the types of operation where LTD sanitation procedures and other nontraditional cleaning programs have been used successfully could include, but are not limited to, the following:

1. Equipment used where dry cleaning (i.e., without water) is appropriate such as a flouring or breading operation;

2. Poultry chillers that have been adjusted to stabilize water pH and temperature, and antimicrobial levels sufficient to inhibit bacterial growth; or,

3. Further processing areas where low room temperatures are maintained during processing.

B. IPP in slaughter establishments that have implemented nontraditional cleaning programs are to perform pre-op sanitation verification following the same procedures and standards that they would use in an establishment that employs a traditional cleaning program and cleans every day. IPP are to apply FSIS' standards of sanitation for pre-op inspection and verify that product contact surfaces look, feel, and smell clean before operations begin.

C. If, after the instructions in this directive are implemented, IPP find an establishment using LTD sanitation procedures in slaughter operations other than those listed in Section VI. A above, IPP are to evaluate whether insanitary conditions are being created as a result. If insanitary conditions are being created, IPP are to issue a non-compliance record (NR) using either PBIS procedure 01B02 or PHIS task Pre-Op Sanitation SOP Review and Observation. If indicated, IPP are to effect a regulatory control action in accordance with 9 CFR 500.2 and are also to contact the District Office (DO). The DO will determine whether to send an Enforcement, Investigations, and Analysis Officer (EIAO) to determine whether other enforcement action is warranted.

VII. PRE-OP START TIME AND TIME NEEDED FOR INSPECTION

A. The inspector's tour of duty is not to be confused with the pre-op start time. The start time of the inspector's tour of duty may be different from the pre-op start time. If the pre-op start time is before the inspector's tour of duty begins, the establishment is to discuss approval of overtime with the Inspector in Charge (IIC) and Front Line Supervisor (FLS). IPP need to consider two issues before initiating pre-op sanitation verification:

1. The time of day when the production areas will be made available for FSIS to conduct pre-op sanitation verification; and

2. The amount of time needed for FSIS to conduct this inspection.

B. It is possible that IPP might be performing their review and observation procedure, including conducting records review, at the same time the establishment is monitoring its pre-op procedures. This provides an excellent opportunity for IPP to perform the observation part of the pre-op procedure. In some cases, the establishment might conduct its monitoring of the implementation of the Sanitation SOP procedures before IPP arrive at the establishment. In these situations, IPP are to seek direction from supervisory personnel as to how frequently they are to directly observe the establishment conduct monitoring. The supervisor is to consider several factors when making this decision, including the following:

1. establishment compliance history;

2. documentation in the FSIS file; and

3. information from Sanitation SOP records.

C. The time necessary for performance of the verification procedures does not include the time necessary to verify that equipment is Locked Out and Tagged Out. The instructions in this directive do not eliminate the need to (1) conduct Lock Out/Tag Out, (2) have equipment disassembled, if feasible and if necessary, for thorough inspection; or (3) initiate regulatory control actions as defined in the Rules of Practice (9 CFR 500.2).

D. FSIS personnel are to discuss with establishment management, and mutually agree on, when (i.e., the time of day) production areas will be made available for FSIS inspection. This information is to be documented in accordance with the Agency's instructions regarding the documentation of a Memorandum of Interview (MOI) in FSIS Directive 5000.1, Part V.C or FSIS PHIS Directive 5000.1, Chapter V. If the time of day when production areas will be made available for FSIS inspection has previously been discussed with establishment management, mutually agreed to, and documented in an MOI, IPP do not have to repeat the discussion and documentation, unless there have been changes to the information.

NOTE: The "time of day" refers to the point in time, prior to the initiation of operations during each production day, that the production areas will typically be available for FSIS inspection. It does not mean that there will be mutual agreement as to the actual days when pre-op verification will be performed by FSIS. That verification will continue to be determined and performed at the frequency, and on the days, scheduled by PBIS and in PHIS.

E. IPP are to determine the amount of time needed to conduct pre-op sanitation verification based on the areas and equipment selected.

VIII. PLANNING PRE-OP VERIFICATION IN RAW AND RTE PROCESSING AREAS AND SLAUGHTER OPERATIONS

A. The differences in the planning for pre-op inspection in processing and in slaughter operations are briefly covered in sub-sections 1 and 2 below. Each is covered in greater detail in Chapters II and III, respectively.

1. For raw or RTE processing operations, IPP are to use a risk-based approach, as described in Chapter II of this directive. The questions in Chapter II, Section II, Gathering Information, provide a thought process that IPP are to use in order to choose the equipment and areas that they will include in their pre-op inspection. IPP are then to follow the pre-op verification instructions in FSIS Directive 5000.1, Chapter I, XV.D or FSIS PHIS Directive 5000.1, Chapter II, Part III

2. For slaughter operations, IPP are to develop and to use a Pre-op Sanitation Inspection Plan to choose the areas and units of the facility that they will inspect. The instructions in Chapter III explain how to develop this type of plan. IPP are

then to follow the pre-op verification instructions in FSIS Directive 5000.1, Chapter I, XV.D or FSIS PHIS Directive 5000.1, Chapter II, Part III

B. For both raw and RTE processing, and for slaughter operations as well, IPP are to perform the pre-op procedure at the frequency scheduled by PBIS and in PHIS or at an adjusted frequency based on any relevant information that they have gathered (e.g., that there is a developing trend of noncompliance).

NOTE: In import establishments where product is exposed to the environment, hands-on verification of the pre-op procedures is to take place daily.

C. For both raw or RTE processing and for slaughter operations during the performance of the review component of the pre-op procedure, IPP are to:

1. Look at selected pieces of equipment rather than all pieces of equipment. The equipment selection process for RTE or raw processing operations is described in Chapter II, of this directive.

2. In very small facilities that have a limited amount of equipment, follow the same thought process addressed in this directive when determining what equipment to look at during the performance of the pre-op verification.

3. Select a representative sample (e.g., one or two of each) when there are large numbers of simple equipment such as pans, buckets, trays, or hand tools, rather than looking at all of the equipment.

4. Avoid repetitive review of equipment following incidental findings, such as one small piece of fat or particulate matter on that equipment.

CHAPTER II - RAW AND RTE PROCESSING OPERATIONS: DEVELOPING A RISK-BASED APPROACH TO SELECTING EQUIPMENT AND AREAS TO EXAMINE IN RAW AND RTE PRODUCTION AREAS

I. GENERAL

A. Using the information gathered by following this chapter of this directive, IPP responsible for performing pre-op sanitation verification in raw and RTE processing operations are to select the areas and equipment that they will inspect. IPP are encouraged to discuss their thought process for making these selections on an on-going basis with their IIC or FLS. IPP are not expected to put this thought process in writing, nor are they required to share it with plant management. IPP may need to adjust their thought process periodically based on their verification findings or those documented by the establishment.

B. Each time IPP perform the review component of the pre-op procedure in ***raw or RTE processing operations***, they are to use the thought process that they have developed to choose the equipment and areas that they will include in their pre-op inspection. They are then to follow the pre-op verification instructions in either FSIS Directive 5000.1, Chapter I, XV.D or FSIS PHIS Directive 5000.1, Chapter II, Part III .

II. GATHERING INFORMATION

A.. Using sound professional judgment, IPP are to gather information to assist them in selecting equipment or areas of the plant for pre-op sanitation verification and for deciding the extent of their pre-op inspection (i.e., how many pieces of equipment, or how many production areas, they will inspect on a particular day). IPP can use, but are not limited to, the following questions as a mechanism to decide what they will inspect:

1. Which pieces of equipment will directly contact exposed product?

2. Which pieces will contact RTE product post lethality?

3. Which pieces of equipment are the hardest to clean?

4. Which pieces of equipment are easiest to clean?

5. How recently has the sanitary condition of equipment in the processing areas been verified by FSIS?

6. Is there a history of pre-op noncompliance documented by FSIS?

7. Does the establishment have a history of finding and correcting insanitary conditions in processing areas and on equipment?

8. How many pieces of equipment or areas of the plant do IPP need to observe to have confidence that the establishment begins operations under sanitary conditions?

9. Has an EIAO conducted any verification testing at the establishment, and if so, what were the results?

B. While performing the weekly review of establishment testing records as described in FSIS Directive 5000.2, Review of Establishment Data by Inspection Personnel, IPP are to gather any information that is indicative of the sanitary conditions in the establishment and factor it into their determination as to whether there are sanitary conditions at the start of operations. Questions that the IPP are to consider in reviewing establishment records include, but are not limited to, the following:

1. Does the establishment conduct any type of swabbing of food contact surfaces, and if so, what have the results been?

2. Does the establishment have other testing results that reflect increase or fluctuation in the presence of pathogens in-plant or on product?

3. Does the establishment have records that document the cleaning that it does between shifts? For example, an establishment may have a first, second, and third shift and would perform a full clean-up after the last shift. Does its program include any clean-up procedures between first and second shifts? Do these records show that the establishment verifies the effectiveness of this cleaning?

C. IPP are to consider whether, based on the information that they gather and the results of their verification activities, they need to increase the extent (i.e., how much equipment or how many areas) of their pre-op sanitation verification activities. Information that the IPP are to consider includes the following:

1. The establishment's testing results,

2. The establishment's historical sanitation records and other records reviewed under FSIS Directive 5000.2, Review of Establishment Data by Inspection Personnel,

3. The establishment's findings during their own pre-op inspection, or

4. Repetitive noncompliances found by FSIS during previous pre-operational sanitation inspections.

CHAPTER III - SLAUGHTER OPERATIONS: DEVELOPING PRE-OP SANITATION INSPECTION PLANS AND SELECTION OF AREAS AND UNITS TO EXAMINE

I. GENERAL

A. A Pre-op Sanitation Plan is necessary to provide the basis for consistency in how IPP conduct pre-op sanitation inspection by identifying areas and units for random sampling. IPP only need to develop a Pre-op Sanitation Inspection Plan for slaughter operations. IPP do not need to develop a new plan if IPP in the establishment to which they are assigned have put a plan in place. IPP do need to develop a plan or to update the plan for a new establishment or for an establishment that has been remodeled or expanded.

B. Each time IPP perform the review component of the pre-op procedure in slaughter operations, they are to use the Pre-op Sanitation Inspection Plans that they have developed to choose the equipment and areas for their pre-op inspection. They are then to follow the pre-op verification instructions in FSIS Directive 5000.1, Chapter I, XV.D or FSIS PHIS Directive 5000.1, Chapter II, Part III

C. Developing the Pre-op Sanitation Inspection Plan:

1. In the first part of the plan, IPP are to determine the amount of time needed for pre-op inspection, including Lock Out and Tag Out procedures and establish the pre-op start time for each assignment based on their knowledge of the operation. Plans will differ with the size of the establishment. Establishments that have 15 or more inspection units (IUs) will be subdivided into areas and have a certain time allotment as compared to establishments that have 14 or less units, which do not need to be divided into areas and thus will have a shorter time allotment.

2. In the second part of the plan, IPP are to include a schematic drawing of the slaughter area that IPP are to request from establishment management. The schematic needs to include major landmarks in the area such as walls, doors, and posts, and an outline of the principal equipment. The IIC is to identify and designate areas and units on the schematics.

a. An “area” is a major portion of an establishment designated in the Pre-op Sanitation Inspection Plan for pre-op sanitation inspection. Examples of an area include the picking area, the eviscerating area, or major equipment groupings or systems. IPP are to define the boundaries of each area. IPP are to inspect one to five areas during a pre-op inspection assignment.

b. Each area is subdivided into IUs. An area may be composed of from 15 to 50 units. An IU is a numbered three-dimensional section within an area that can be inspected in approximately one minute. Each IU needs to be easily identifiable on the schematic drawing by IPP who rotate into a pre-op sanitation inspection assignment. An IU may have irregular boundaries that are usually drawn based on landmarks such as an individual piece of equipment, utensils, associated floors, walls, drains, or other vertical structures and overhead structures. To the extent practical, units are to be numbered to reflect product flow for each area.

c. Large, complex equipment may be divided into smaller IUs. 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 IU.

d. Portable equipment or other equipment that is displaced during cleaning may not always be located entirely within a unit at the time of inspection. IPP are to inspect such equipment that would be included within the boundaries of a unit.

3. Slaughter establishments with 15 or more units are to be subdivided into areas as described above. Slaughter establishments with fewer than 15 IUs are small slaughter establishments and are not be subdivided into areas.

II. SELECTING AREAS AND INSPECTION UNITS TO EXAMINE

A. One to five days before the pre-op procedure is to be performed, IPP are to randomly select the IUs for each of the days pre-op will be performed the next week. An example of selection method is described in section C. below. IPP are not to share the selected IUs with the establishment, and the information is to be kept in the USDA files.

B. The following schedule is to be used by IPP to determine the number of IUs to be selected from each area:

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

C. The IIC is to authorize a method of randomly selecting IUs for inspection, such as the following:

1. Write numbers on pieces of cardboard to correspond with the numbers of the inspection unit in the area to be inspected and place the pieces of cardboard in a container large enough to permit thorough mixing of the cardboard pieces. For example, if selecting IUs from an area containing 15-30 units, 30 numbered pieces would be placed in the container, and 3 would be drawn for inspection;

2. Before each inspection, mix and then select the specified number of pieces of cardboard from the container;

3. Write the IU numbers that have been selected for inspection on a piece of paper; and

4. Return the pieces of cardboard to the containers.

CHAPTER IV - DETERMINE REGULATORY COMPLIANCE & DOCUMENTATION AND ENFORCEMENT

I. DETERMINING REGULATORY COMPLIANCE

A. IPP are to assess the cleanliness of areas or equipment that, if insanitary, would present the greatest risk of transferring pathogens or other contaminants to product (e.g., direct food contact surfaces that are difficult to clean or that may serve as harborage sites). When assessing pre-op sanitation conditions, IPP are to use professional judgment in determining whether the establishment's pre-op measures have resulted in a clean and sanitary environment.

B. IPP are to focus on the following factors in making this determination:

1. The condition of the equipment or surfaces that can have the greatest effect on the safety of the product (e.g., check the cleanliness of slaughter evisceration equipment, RTE food contact surfaces, and difficult to clean food contact surfaces).

2. The condition of surfaces or equipment that may harbor contaminants (e.g., cracked or broken hollow rollers; the underneath of food contact belts; or conveyors that can contain product residues).

3. Conditions that may affect overall sanitation of the equipment and the area. For example, consider whether one small piece of fat or product residue could affect the sanitation of the food contact surface or contaminate or adulterate product.

4. Measures of the establishment's performance over a period of time. Review the establishment's Sanitation SOP records and NRs to assess what the corrective actions implemented by the establishment indicate about the continuing effectiveness of the establishment's Sanitation SOPs.

NOTE: One incident of non-compliance is not an automatic indication that the Sanitation SOPs are no longer effective.

C. Hands-on verification includes a records review component. Before performing the hands-on verification, IPP are to review the establishment's Sanitation SOP records for the previous day's operations or for that day, if available.

II. DOCUMENTATION AND ENFORCEMENT

A. When determining whether noncompliance exists, IPP are only to take into account what they have observed and not engage in speculation. For example, debris build-up on a food contact surface will come in contact with product during operations and thus is to be considered in assessing sanitary conditions. On the other hand, debris build-up on a nearby wall or piece of non-food contact equipment may eventually come in contact with product, but it would be speculative to say that it will. Thus, the latter condition is not to be cited as a noncompliance, although the build-up should be cleaned by the establishment at a frequency that prevents the occurrence of insanitary conditions.

B. IPP are to document noncompliance in accordance with the instructions in FSIS Directive 5000.1, Chapter IV, Enforcement or FSIS PHIS Directive 5000.1, Chapter V, and are to initiate any necessary enforcement actions in accordance with 9 CFR 500.2.

C. When documenting pre-op noncompliance, IPP are to include a detailed description of the observed noncompliance in clear, concise terms and include, at a minimum, the time of occurrence, the location, and any effect on product (i.e., how the conditions observed would result in product contamination or adulteration). The description of the noncompliance is also to include an explanation of why the action violates the regulation cited on the NR.

CHAPTER V- OTHER MATTERS

I. SUPERVISORY PERSONNEL RESPONSIBILITIES

A. Supervisory personnel play a key role in ensuring that decisions made by IPP are consistent with FSIS statutory authority and Agency policy.

B. Supervisory personnel are to discuss the key points identified in this directive with IPP and are to clarify any issues of concern.

C. Supervisory personnel are to ensure that IPP are conducting pre-op verification in accordance with the information in this directive and with procedures addressed in FSIS Directive 5000.1, FSIS PHIS Directive 5000.1, and are properly documenting noncompliance.

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

II. DATA ANALYSIS

Annually, the Data Analysis and Integration Group (DAIG) within the Office of Data Integration and Food Protection (ODIFP) is to review PBIS or Public Health Information System (PHIS) data on verification activities to determine if whether trends exist in noncompliances related to pre-op sanitation. The analysis is also to include a review of repetitive noncompliances that are linked by the IPP to determine if whether a trend exists. Results from these analyses are to be shared with the Office of Field Operations (OFO) and the Office of Policy and Program Development (OPPD) to determine whether the findings suggest potential improvements in verification procedures or instructions to IPP.

Refer questions regarding this directive to the Policy Development Division through askFSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935 or to appropriate Regional Field Import Supervisor.

Assistant Administrator
Office of Policy and Program Development