MSA DIRECTIVE	5000.4 Rev. 2	3/27/18

PERFORMING THE PRE-OPERATIONAL SANITATION STANDARD OPERATING PROCEDURES VERIFICATION TASK

CHAPTER I – GENERAL

I. PURPOSE

A. This directive provides instructions to inspection program personnel (IPP) regarding how to perform the Public Health Information System (PHIS) Pre-Operational (Pre-Op) Sanitation Standard Operating Procedures (Sanitation SOP) verification task in meat and poultry slaughter and processing operations. MSA has revised this directive to remove references to Performance Based Inspection System (PBIS) procedure 01B02, to remove the prescriptive instructions to develop inspection units and areas specific to slaughter, to provide clarification based on data obtained through trend analysis of questions submitted through askFSIS, and data obtained through reviewing Noncompliance Records (NRs) issued during the performance of this task.

B. IPP assigned to meat and poultry establishments that maintain less than daily (LTD) sanitation procedures are also to follow the instructions in MSA Directive 5000.5, *Verification of Less Than Daily (LTD) Sanitation Procedures in Processing Operations*, when performing the Pre-Op Sanitation SOP verification task.

KEY POINTS:

- *Provides instructions regarding the development of a risk-based approach for selecting equipment to examine in meat and poultry processing and slaughter operations (Chapter II)*

- *Clarifies how non-food contact surfaces and non-production areas are to be addressed during the performance of the Pre-Op Sanitation SOP verification task*

- *Clarifies the appropriate regulations to cite when documenting noncompliance with the regulatory requirements in 9 CFR 416*

II. CANCELLATION

MSA Directive 5000.4, Revision 1, *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*, 9/28/11

III. BACKGROUND

A. 9 CFR 416, sections 416.11 through 416.17, Sanitation SOPs, requires establishments to implement procedures sufficient to prevent direct contamination or adulteration of products while under the control of the establishment. The pre-op sanitation procedures in the Sanitation SOPs are to address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils prior to use.

B. MSA Directive 5000.1, *Verifying an Establishment's Food Safety System*, provides the instructions IPP are to follow when performing the Pre-Op Sanitation SOP verification task. The Pre-Op Sanitation SOP verification task includes both a review and observation component and a recordkeeping component. IPP observe the sanitary conditions in the establishment and compare their inspection findings to what the establishment has documented. Also as part of observation, IPP watch establishment employees perform their monitoring procedures as specified in the establishment's Sanitation SOPs.

C. In this directive, "IPP" refers to any MSA employee responsible for conducting the Pre-Op Sanitation SOP Review and Observation verification task.

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

A. IPP, through discussion with their immediate supervisor, need to consider two issues before performing the Pre-Op Sanitation SOP verification task:

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

2. The amount of time needed for MSA to conduct this verification task.

B. It is possible that IPP will be performing the Pre-Op Sanitation SOP verification task, including conducting records review, at the same time the establishment is conducting their Sanitation SOP pre-op monitoring procedures. This provides an excellent opportunity for IPP to perform the observation part of the Pre-Op Sanitation SOP verification task.

C. In some cases, the establishment might conduct its monitoring of the implementation of the pre-op Sanitation SOP's before IPP arrive at the establishment. In these situations, IPP are to seek direction from supervisory personnel regarding how frequently they are to directly observe the establishment conduct its monitoring procedures. Supervisory personnel are to consider several factors when making this decision:

1. Establishment compliance history;

2. Documentation in the MSA file; and

3. Information from Sanitation SOP records.

D. The time necessary for performance of the Pre-Op Sanitation SOP verification task does not include the time necessary to verify that equipment is locked out and tagged out. The information presented in this directive does not eliminate the need for IPP to:

1. Perform Lock Out and Tag Out;

2. Have the establishment disassemble equipment for thorough inspection, if feasible and if necessary; or

3. Initiate regulatory control actions

NOTE: The establishment can elect to reassemble equipment once they have performed their monitoring of the implementation of the pre-op Sanitation SOP procedures. However, IPP can request that it be disassembled in order to perform their pre-op sanitation verification.

E. The IPP is to discuss with establishment management, and mutually agree on, when (i.e., the time of day) production areas will be made available for MSA inspection. This information is to be documented in accordance with the Agency's instructions regarding the documentation of a Memorandum of Interview (MOI) in MSA Directive 5000.1. If the time of day when production areas will be made available for MSA 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 MSA to perform verification. It does not mean that there will be mutual agreement as to the actual days IPP will perform the Pre-Op Sanitation SOP verification task. The days on which IPP perform pre-op sanitation verification will continue to be determined by IPP at the frequency designated in PHIS.

F. IPP are to determine the amount of time needed to conduct the Pre-Op Sanitation SOP verification task based on the size of the establishment and equipment selected.

V. PLANNING THE PRE-OP SANITATION SOP VERIFICATION TASK IN MEAT AND POULTRY PROCESSING AND SLAUGHTER OPERATIONS

A. IPP are to focus inspection efforts on those production areas and equipment that present the highest risk of becoming insanitary or causing product contamination. IPP need to focus their pre-op verification efforts on food contact surfaces and not on equipment surfaces or facility areas that do not directly contact product.

B. IPP are to follow the same methodology to plan how to perform the Pre-Op Sanitation SOP verification task in processing and in slaughter operations. The process is covered in detail in Chapter II.

1. For slaughter and 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 the thought process that IPP are to use to choose the equipment and areas that they will include in their pre-op inspection. IPP are then to follow the pre-op sanitation verification instructions in MSA Directive 5000.1.

C. In meat and poultry processing and slaughter operations, IPP are to perform the Pre-Op Sanitation SOP verification task at the frequency scheduled by PHIS or at an adjusted frequency based on relevant information (e.g., a developing trend of noncompliance).

D. When performing the Pre-Op Sanitation SOP verification task, IPP are to use both the Review and Observation verification activity and the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products prior to operations. IPP are to select the "Both" option on the Activity tab in PHIS.

E. In establishments that include both slaughter and processing operations, it will be up to the IPP, based on his/her knowledge of the operation to determine where and when to conduct the Pre-Op Sanitation SOP verification task.

F. If more than one IPP performs the Pre-Op Sanitation SOP task on a given shift, both IPP are to record the task performed and their individual results. In these cases, the first inspector to perform the verification activity is to record performance of the routine task in PHIS and the other inspector is to add a directed instance of the task under their name to record their results.

G. In patrol assignments, there may be times when inspection personnel cannot perform the Pre-Op Sanitation SOP verification task in each establishment once per week. In such cases, IPP are to use good judgment and their knowledge of establishments' compliance histories with sanitation requirements to decide where and when to do Pre-Op Sanitation SOP verification tasks. Likewise, supervisors are to follow good judgment and their knowledge of establishments' operations and histories when reviewing task data to determine if the appropriate mix of verification tasks are being performed.

H. In meat and poultry processing areas and slaughter operations during the performance of the review component of the Pre-Op Sanitation SOP verification task, IPP are to:

1. Look at selected pieces of equipment rather than all pieces of equipment. The equipment selection process for meat and poultry processing and slaughter operations is described in Chapter II of this directive.

NOTE: IPP are to be aware that establishments may determine that equipment or production areas will not be used during production and can elect to remove the equipment from the production area, or consider identifying the equipment, or area, with some type of in-plant control (e.g., a Hold tag). When the equipment or area is returned to production, IPP should be afforded an opportunity, if possible, to conduct pre-op sanitation verification to ensure that sanitary conditions exist.

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 verify during the performance of the Pre-Op Sanitation SOP verification task.

3. Select a representative sample (e.g., one or two 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.

I. When IPP perform the review portion of Pre-Op Sanitation SOP verification task, IPP are to inspect areas in the establishment, equipment and utensils, and places on 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 may serve as microbial harborage sites). IPP are to be aware that direct food contact surfaces must be organoleptically clean. This means that the surfaces look clean, feel clean, and smell clean. IPP are to visually examine the food contact surfaces for product residues that might be left from previous days' operations. IPP are to be aware of any odors in these areas that may indicate insanitary conditions.

J. When performing the review (i.e., hands-on) portion of the Pre-Op Sanitation SOP verification task and before verifying the sanitary conditions in slaughter or processing operations, IPP are to have the following:

1. A functional flashlight;

2. A pen or pencil;

3. Texas Rejected/Texas Retained tags and some means (e.g., tape, string, rubber bands) of affixing these tags to equipment, departments, product; and

4. A notepad to record their pre-op findings.

CHAPTER II - MEAT AND POULTRY PROCESSING AND SLAUGHTER OPERATIONS: DEVELOPING A RISK-BASED APPROACH TO SELECTING EQUIPMENT AND AREAS TO EXAMINE IN PRODUCTION AREAS

I. GENERAL

A. IPP are to use the information presented in this chapter to aid in selecting areas and equipment to inspect during pre-op sanitation verification. IPP are encouraged to

discuss their thought process for making these selections on an on-going basis with their IPP or Circuit Manager (CM).

B. 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.

C. This chapter has been revised to include slaughter operations in the risk-based approach to selecting equipment and areas to examine.

II. GATHERING INFORMATION

A. Using sound professional judgment, IPP are to gather information to assist them in selecting equipment or areas for pre-op sanitation verification and deciding the extent of their pre-op sanitation verification. IPP are to focus on those areas and equipment that present the highest risk to public health. The following factors would indicate higher risk to public health:

1. Equipment that will contact exposed product;

2. Equipment that will contact RTE product post-lethality;

3. Equipment that is difficult to clean;

4. Equipment that MSA has not verified recently;

5. Equipment/areas with a history of noncompliance; and

6. Testing results that suggest that specific pieces of equipment may present a risk to public health.

B. While performing the weekly review of establishment testing records as described in MSA 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 regarding how they will conduct their Pre-Op Sanitation SOP verification task (e.g., if any additional equipment should be inspected). Questions that 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 an increase or fluctuation in the presence of pathogens in-plant or on product?

3. Does the establishment have records that document any cleaning that is conducted between 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 IPP are to consider include the following:

1. The establishment's testing results,

2. The establishment's historical sanitation records and other records reviewed under MSA Directive 5000.2;

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

4. Repetitive instances of noncompliance found by MSA during previous Pre-Op Sanitation SOP verification tasks.

CHAPTER III - DETERMINE REGULATORY COMPLIANCE & DOCUMENTATION AND ENFORCEMENT

I. DETERMINING REGULATORY COMPLIANCE

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

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

1. Establishment employees do not implement the pre-op procedures in the Sanitation SOPs prior to operations. (9 CFR 416.13(a)).

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

2. IPP observe unclean food contact surfaces resulting from failure to adequately implement the pre-op Sanitation SOPs or because the pre-op Sanitation SOPs were ineffective. (9 CFR 416.13(a)).

3. IPP observe unclean food contact surfaces resulting from the establishment's failure to restore sanitary conditions after establishment monitoring prior to beginning operations. (9 CFR 416.13(a)).

NOTE: If IPP observe unclean food contact surfaces after completing pre-op sanitation verification but prior to the establishment's beginning operations, IPP are to document the noncompliance under the Pre-Op Sanitation SOP Verification task. If operations have started, IPP are to document the noncompliance under the Operational Sanitation SOP Verification task.

4. Establishment employees do not monitor the implementation of the pre-op Sanitation SOPs at least daily (9 CFR 416.13(c)).

II. DOCUMENTATION AND ENFORCEMENT

A. When IPP determine that there is noncompliance with the pre-op Sanitation SOP regulatory requirements, they are to document the noncompliance on a NR in PHIS in accordance with the instructions in MSA Directive 5000.1. The description of the noncompliance is to clearly explain how the IPP's findings support the determination that the establishment did not meet regulatory requirements and include the problem, time of occurrence, and location. When IPP observe pre-op Sanitation SOP noncompliance that does not result in contamination of food contact surfaces (e.g. failure to initial records), they are not to take a regulatory control action.

NOTE: In establishments that conduct both slaughter and processing operations, when different IPP each perform Pre-Op Sanitation SOP verification tasks in the two operations on the same day, IPP are to document their results on individual tasks, and if each observe a noncompliance, on separate NRs.

B. When IPP observe contamination of direct food contact surfaces during pre-op sanitation verification, they are to reject the affected equipment. Finding contamination during pre-op sanitation will not affect any product. IPP are to remove the Texas reject tag only after the establishment has restored sanitary conditions.

C. When IPP observe contaminated food contact surfaces before operations, the establishment is required to restore sanitary conditions prior to beginning operations as part of implementing the Sanitation SOP procedures in accordance with 9 CFR 416.13, and evaluate the effectiveness of the Sanitation SOPs and revise them when necessary to maintain their effectiveness in accordance with 9 CFR 416.14.

D. If IPP observe both pre-op Sanitation SOP and SPS noncompliance while performing the Pre-Op Sanitation SOP verification task, they are to document both of the instances of noncompliance on a single pre-op Sanitation SOP NR by recording a result of noncompliance for each applicable regulatory citation.

EXAMPLE: *While performing the Pre-Op Sanitation SOP verification task in the fabrication department, IPP observe product residue and grease on several meat hooks, in addition to fat particles and hog hair from the previous days' production on the wall behind the dehairing machine. IPP are to document each noncompliance and cite 9 CFR 416.13 and 9 CFR 416.2(b) under the Pre-Op Sanitation SOP verification task and record the results on a single NR.*

E. When IPP observe that an establishment fails to implement or monitor a pre-op sanitation procedure identified in its Sanitation SOP plan, IPP are to document noncompliance with 9 CFR 416.13. IPP are not to cite noncompliance with 9 CFR 416.4(a) on the NR for the same finding. The primary focus for IPP during pre-op sanitation verification is to verify that the written establishment pre-op Sanitation SOP procedures have been implemented (9 CFR 416.13) and are effective (9 CFR 416.14).

F. If IPP observe only SPS noncompliance while performing a Pre-Op Sanitation SOP verification task, they are to record the noncompliance under the task being performed at the time of the observation. In this example, the noncompliance would be documented under a Pre-Op Sanitation SOP task even though the regulatory citation is 9 CFR 416.1-416.6. IPP are to clearly describe the observations that resulted in the determination of a noncompliance and explain how those observations support the regulatory citation.

G. Many establishments incorporate the cleaning of non-food contact surfaces into the Sanitation SOPs and identify these procedures as pre-op sanitation procedures (e.g., for walls, floors, etc.). In cases like this, if IPP observe an unclean or insanitary non-food contact surface that has been identified by the establishment as an area covered by the pre-op sanitation procedure in its Sanitation SOP plan, IPP are to cite noncompliance with 9 CFR 416.13 because the establishment failed to implement or monitor a pre-op sanitation procedure. Citing multiple regulations on a single noncompliance for the same observation, is not necessary.

EXAMPLE: *While performing the Pre-Op Sanitation SOP verification task, IPP observe product residue from the previous day's production accumulated in a floor drain cover in the picking room after the establishment had performed their pre-op monitoring procedures. After reviewing the establishment's Sanitation SOP plan, IPP are aware that the establishment identifies cleaning and sanitizing the floors and drains as a daily pre-op sanitation procedure. IPP issue a noncompliance citing 9 CFR 416.13(a) because the establishment failed to implement this pre-op procedure, and 9 CFR 416.13(c) because the establishment failed to monitor the implementation of this procedure, but did not also cite 9 CFR 416.2(b)(2).*

CHAPTER IV – ADDITIONAL ISSUES

I. SUPERVISORY PERSONNEL RESPONSIBILITIES

A. Supervisory personnel are to discuss the key points identified in this directive with IPP to ensure that IPP understand their role in verifying whether the establishment is implementing their pre-op Sanitation SOP sufficiently to prevent direct contamination or adulteration of product.

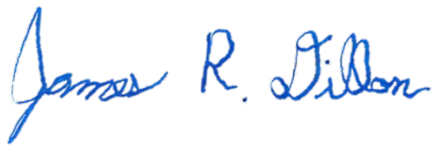
B. Supervisory personnel are to periodically review NRs to ensure that IPP are accurately documenting pre-op sanitation noncompliance. When there is concern that there is an on-going trend of noncompliance, supervisors are to evaluate the NRs to determine if additional regulatory actions are needed.

C. Supervisory personnel are to refer to the current version of the IPPS Assessment Module and MSA Directive 4430.3, *In-Plant Performance System (IPPS)* for additional guidance and instructions.

D. Supervisory personnel are not to grant NR appeals when the entire basis for the appeal is that the noncompliance was documented under a particular task. Task titles are internal MSA classification tools. If a regulation is listed in PHIS as available for verification under a specific task, it may be cited as noncompliant under that same task.

II. QUESTIONS

Refer questions through supervisory channels.



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