

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

FSIS DIRECTIVE

5000.5
Rev. 1

09/28/11

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

Verification of Less Than Daily (Ltd) Sanitation Procedures in Processing Operations

I. PURPOSE

This directive provides instructions to FSIS inspection program personnel (IPP) on how to verify compliance with the sanitation regulations in establishments that conduct a complete cleaning less frequently than every day in processing operations. This directive provides new instructions for IPP to stop allowing less than daily (LTD) sanitation procedures in slaughter operations because FSIS has found that LTD sanitation, in most circumstances, cannot ensure that slaughter operations maintain sanitary conditions (See Chapter I, VI, A in FSIS Directive 5000.4). This directive provides instructions to IPP for verifying the adequacy of documentation associated with these cleaning procedures. It also instructs IPP on when and how to conduct inspection verification Performance Based Inspection System (PBIS) 01B02 and 01C02 procedures; and Public Health Information System (PHIS) task Pre-Op SSOP Sanitation Review and Observation and Operational SSOP Review and Observation) at these establishments.

NOTE: In this directive, 'pre-op verification' will refer to the performance of either PBIS procedure 01B02 or PHIS task Pre-Op SSOP Sanitation Review and Observation. In addition, 'operational sanitation' verification will refer to the performance of PBIS procedure 01C02 or PHIS task Operational SSOP Sanitation Review and Observation.

KEY POINTS:

- *FSIS recognizes that LTD sanitation procedures are prerequisite programs as described in Federal Register (see 68 Fed. Reg. 34224; June 6, 2003)*
- *IPP are to evaluate LTD sanitation procedures using 9 CFR 416 and 417 because sanitation procedures of this type are the foundation of food safety systems*

- *Establishments are not required to submit their procedures to FSIS for prior review or approval to implement a less than daily cleaning program*
- *Establishments may conduct a complete cleaning at frequencies other than daily in processing operations*
- *LTD sanitation procedures are to be incorporated into the establishment's food safety system (e.g., HACCP system or Sanitation SOP or other prerequisite program)*
- *An establishment conducting LTD sanitation procedures is responsible for meeting all of the regulatory requirements regarding sanitation, specifically 9 CFR 416.1 through 416.16, including maintaining records that demonstrate the effectiveness of its LTD program*
- *The directive explains when to perform 01B02 versus 01C02 under PBIS or Pre-Op SSOP Review and Observation versus Operational SSOP Review and Observation under PHIS in establishments that conduct sanitation on a less than daily basis*
- *Attachment 1 provides IPP with a visual decision tree*

NOTE: The information presented in this directive does not eliminate the need to perform Lock Out and Tag Out in accordance with [FSIS Directive 4791.11, Lock Out and Tag Out Safety Procedures](#).

II. CANCELLATION

FSIS Directive 5000.5, Verification of Less than Daily (LTD) Sanitation Procedures (Oct 20, 2009)

III. REASON FOR REISSUANCE

This directive is being revised to specify that it applies to processing operations rather than slaughter operations. LTD sanitation procedures are typically limited to processing operations, except for certain slaughter operations described in FSIS Directive 5000.4, Section VI, A. The directive is also being revised to reflect PBIS and PHIS information and to update Attachment 1. Beginning no less than 45 days from the issuance of this directive, IPP in slaughter establishments that utilize LTD sanitation procedures are to begin traditional preoperational sanitation inspection verification in all slaughter operations. See FSIS Directive 5000.4, Rev.1.

IV. REFERENCES

[9 CFR Part 416](#)

[9 CFR Part 417](#)

[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](#)

[FSIS Directive 5000.4, Performing the Review Component of PBIS 01B02 Procedure and PHIS Pre-Op SSOP Review and Observation Task in Federally Inspected Processing, Slaughter and Import Establishments](#)

V. BACKGROUND

A. The production of safe meat and poultry products requires HACCP systems that are built upon a solid foundation, including certain prerequisite programs. A sanitation standard operating procedure (Sanitation SOP) is a fundamental prerequisite program to any HACCP plan. The requirements of [9 CFR 416.12 \(a\)](#) are that an establishment's Sanitation SOP describes all procedures that the establishment will conduct daily, before and during operations, to prevent direct contamination or adulteration of product. Because sanitation is an essential component of food safety, complete cleaning of the facilities and equipment is to be conducted at a frequency that ensures that the establishment maintains sanitary conditions. Insanitary facilities or equipment create an environment that could result in product contamination or adulteration.

B. FSIS regulations for meat and poultry establishments do not require that establishments perform cleaning or sanitation procedures at any specified frequency (e.g., every twenty-four hours); however, the regulations do require that establishments clean as often as necessary to maintain sanitary conditions and to prevent direct contamination or adulteration of product. When an establishment performs cleaning or sanitation procedures in processing operations at a frequency that is less than daily, the establishment is to consider the effect of this frequency on its food safety system.

C. IPP are to verify that establishments that choose to use a LTD sanitation frequency are satisfying all of the regulatory requirements regarding sanitation. IPP are to verify that the establishment maintains compliance with [9 CFR 416.1 through 416.5](#) for sanitation performance standards (SPS) and is meeting the regulatory requirements set out in [9 CFR 416.11 through 416.16](#) for Sanitation SOPs. IPP are also to verify that establishments have included their LTD sanitation procedure for processing operations in their food safety system (e.g., a prerequisite program, Sanitation SOP, or HACCP).

D. Under the HACCP regulations, establishments must perform ongoing activities to verify that their HACCP plans are being effectively implemented per [9 CFR 417.4\(a\)](#). In addition, establishments are required to maintain documents supporting that those activities, and the frequency at which those procedures are performed, are appropriate to accomplish their intended purpose. Therefore, IPP are to verify that the establishments have addressed their prerequisite programs in their ongoing verification activities as a means to ensure that the prerequisite programs are being implemented such that they continue to support the decisions made in the establishment's hazard analysis ([9 CFR 417.1\(a\)](#))

E. Establishments are not required to submit their LTD sanitation procedures to FSIS for review or approval prior to implementation. If IPP have specific questions regarding verification after review of the establishment's LTD sanitation procedures, they are to

raise their questions first through their supervisory chain or through [askFSIS](#).

VI. DEFINITIONS

A. Pre-Operational Sanitation (pre-op): The complete cleaning typically performed prior to the start of operations, which includes procedures such as:

1. Removing the gross contamination from equipment and production areas either by hand or with potable water of a suitable temperature;
2. Applying chemicals (detergent, acid or alkali soap) to emulsify or dissolve the food (protein) materials and fats adhering to the equipment;
3. Scrubbing the soiled surfaces, if necessary;
4. Rinsing to remove the dissolved food and fat materials with potable water of a suitable temperature; and
5. Applying a sanitizer (e.g., chemical disinfectant, hot water) to the cleaned food contact surfaces, in accordance with the label instructions, to address any remaining microorganisms.

NOTE: Establishments that conduct their complete pre-op sanitation procedures daily would not be considered to have LTD sanitation procedures. These establishments would still be subject to FSIS pre-op sanitation verification (PBIS procedure 01B02 and 01C02 or PHIS tasks Pre-Op and Operational Sanitation Review and Observation) as they are scheduled.

B. Less Than Daily (LTD) Sanitation: The complete cleaning of equipment and production areas at a frequency of less than daily (i.e., less frequently than every 24 hours of operation). This cleaning and sanitation program may include, but is not limited to, such components as:

1. Documentation demonstrating that the Sanitation SOP is effective;
2. Documentation demonstrating that the LTD sanitation procedures maintain the equivalent level of sanitation as achieved through daily cleanings;
3. Increased operational sanitation procedures to remove gross contamination from equipment and production areas throughout the processing day either by hand or with water of a suitable temperature; or
4. Applying a sanitizer (e.g., a chemical disinfectant) to the cleaned food contact surfaces, in accordance with the label instructions, to address any remaining microorganisms.

C. Aerobic Plate Count (APC): The APC microbial test method is an indicator of the level of bacteria in a food product, or the method can be used to evaluate the sanitary conditions of food contact surfaces on equipment. APC does not measure the entire bacterial population, but rather the number of bacteria that grow in the presence of

oxygen (aerobically) and in the medium temperature range (70-110° F). If performed during processing, APC can be used to evaluate the significance of residue buildup on food contact surfaces. If performed after sanitation, it can be used to gauge the effectiveness of the cleanup process.

D. Statistical Process Control (SPC): Statistical process control involves using statistical techniques to measure and analyze the variation in processes. Most often used for manufacturing processes, the intent of SPC is to monitor processes in an operation and maintain the processes based on fixed targets. A system of this type would identify upper and lower limits or control points for a given process. To monitor the process in question, the establishment collects data about the process and then uses the data gathered to make adjustments to the process.

VII. FSIS VERIFICATION OF SANITARY CONDITIONS AND SANITATION SOP PROCEDURES UNDER PBIS OR PHIS

A. IPP are to follow the methodology set out in [FSIS Directive 5000.1](#), [FSIS PHIS Directive 5000.1](#), and FSIS Directive 5000.4 when performing sanitation verification. When performing hands-on procedures in the establishment, IPP are to perform an overall assessment of the sanitary conditions in the establishment, including determining whether there is direct product contamination or any insanitary conditions in and around the establishment. As a result of the hands-on procedure in the establishment, IPP may make observations that are representative of pre-operational and operational sanitation and SPS. The frequency of performing these verifications may be affected by the sanitation schedule that the establishment implements in its LTD sanitation procedures. Before performing any verification activities in establishments that implement LTD sanitation procedures, IPP need to be aware of, and understand, the establishment's LTD sanitation procedures and its Sanitation SOP.

NOTE: As addressed in FSIS Directive 5000.4, IPP in establishments that implement LTD 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

B. When performing pre-op verification in an establishment that employs LTD sanitation procedures, IPP are to review available establishment records associated with the implementation of the procedures. However, IPP may need to review more records than just pre-op records in an establishment that has LTD sanitation procedures. Specifically, IPP are to:

1. Conduct the pre-op verification procedure on the days it is scheduled or as warranted based on the professional judgment of the Inspector in Charge.
2. Verify that the pre-operation sanitation monitoring procedures included in the Sanitation SOP, and any additional procedures associated with the establishment's LTD sanitation procedures, are implemented as written.
3. Document any regulatory noncompliance in accordance with this directive and

[FSIS Directive 5000.1, Chapter IV, Enforcement](#) or [FSIS PHIS Directive 5000.1, Chapter V](#).

C. When pre-op verification is scheduled on a day when the establishment has conducted a complete cleaning, IPP are to perform the pre-op sanitation verification following the instructions in FSIS Directive 5000.4. Specifically, IPP are to:

1. Conduct the pre-op verification on the days that the establishment performs its pre-op monitoring procedures in accordance with [9 CFR 416.13](#) as well as in accordance with the LTD sanitation procedures.
2. Verify that the establishment's procedures related to sanitation and pre-op sanitation monitoring procedures, as outlined in the establishment's Sanitation SOP and LTD sanitation procedures, have been performed as written.
3. Document regulatory noncompliance in accordance with the instructions in [Section X](#) of this directive and in [FSIS Directive 5000.1](#), [FSIS PHIS Directive 5000.1](#), and FSIS Directive 5000.4.

D. When pre-op verification is scheduled in a processing operation on a day when a complete cleaning has not been conducted by the establishment, IPP are to follow the instructions in either paragraph 1 or 2 below.

1. In establishments under PBIS, IPP are to:

- a. Mark the procedure as "not performed – Other" using code 3 and conduct an 01C02 procedure as unscheduled (unless the procedure is already on the schedule), or
- b. Mark it as "not performed" and conduct an 01B01 as an unscheduled procedure (unless the procedure is already on the schedule). IPP are to focus on establishment records that document the implementation and effectiveness of the LTD sanitation procedures.

2. In establishments under PHIS, IPP are to;

- a. Reschedule the Pre-Op SSOP Sanitation Review and Observation Task to another day (e.g., click and drag the task to another day).
- b. Conduct Pre-Op SSOP Sanitation Record Review and Observation Task using one of the following methods:
 - i. Select a previously scheduled Operational SSOP Review and Observation task on the task calendar and click/drag it to the current day, or
 - ii. If there are routine Operational SSOP Review and Observation tasks available on the task list, IPP can schedule the Operational SSOP Review and Observation on the task calendar, claim it and perform the task.

iii. If there are no routine Operational SSOP Review and Observation tasks available on the task list, IPP can schedule the Operational SSOP Review and Observation task as a directed task.

iv. When IPP have an Operational SSOP Review and Observation task scheduled for that day on their task calendar, IPP would claim the task and perform the task.

NOTE: When pre-op verification is scheduled in a processing operation on a day when a complete cleaning has not been conducted by the establishment, IPP are to focus on establishment records that document the implementation and effectiveness of the LTD sanitation procedures.

E. When pre-op verification is scheduled on a day when a complete cleaning has been conducted in only some areas of the establishment, IPP are to conduct pre-op verification in those areas as scheduled, following the instructions in FSIS Directive 5000.4, Performing the Review Component of PBIS 01B02 Procedure and PHIS Pre-Op SSOP Review And Observation Task In Federally Inspected Processing, Slaughter and Import Establishments.

F. When pre-op verification is scheduled on a day when a complete cleaning has not been conducted by the establishment, IPP are to perform operational sanitation verification (i.e., PBIS procedure 01C02 or PHIS task Operational Sanitation Review and Observation) in accordance with the following instructions:

NOTE: PBIS procedure 01C02 and PHIS task Operational SSOP Review and Observation are the verification activities that IPP conduct to verify sanitation during establishment operations. All sanitation verification performed by FSIS between complete cleanings will be performed as operational sanitation verification (i.e., PBIS procedure 01C02 or PHIS task Operational SSOP Review and Observation). IPP are not to conduct the Pre-Op SSOP Record Review task or the PBIS 01B02 procedure on days when complete cleaning has not been conducted by the establishment, even though the procedure or task may appear on the schedule.

1. Periodically conduct the operational sanitation verification procedure before the start of the production shift (e.g., pre-shift). The procedure is to be conducted 1-2 times per month prior to the start of the approved hours of operation for the establishment.
2. When the operational sanitation verification is performed prior to the beginning of operations, it is to be recorded as follows:
 - a. In PBIS:
 1. When operational sanitation verification is scheduled per the PBIS generated shift schedule, and IPP are able to perform the procedure either before the start of the approved hours of

operation or during the production shift, mark the procedure as “Performed” in PBIS.

2. When operational sanitation verification is not scheduled, but IPP perform the procedure before the start of the approved hours of operation for their shift or during the hours of operation, mark the unscheduled procedure as “Performed” in PBIS.

b. In PHIS:

1. When IPP perform operational SSOP sanitation verification on a day when Operational SSOP Review and Observation is scheduled, IPP are to claim and perform the task.

2. When IPP perform operational SSOP sanitation verification on a day when Operational SSOP Review and Observation is not scheduled, IPP are to:

- i. Select a previously scheduled Operational SSOP Review and Observation task on the task calendar and click/drag it to the current day.

- ii. If there are routine Operational SSOP Review and Observation tasks available on the task list, IPP can schedule the Operational SSOP Review and Observation on the task calendar and claim and perform the task.

- iii. If there are no routine Operational SSOP Review and Observation tasks available on the task list, IPP are to schedule the Operational SSOP Review and Observation task as a directed task.

3. When making compliance determinations as to whether sanitary conditions have been maintained, IPP are to take into consideration the observed sanitary conditions and evaluate the risks to product by considering the following:

- a. The development of insanitary conditions associated with the processing areas within the establishment;

- b. The equipment used;

- c. The effect that any observed conditions can have on product; and

- d. Any available microbial testing data collected by the establishment and reviewed in accordance with FSIS Directive 5000.2.

4. Inspect one or more areas of the establishment to ensure that the establishment’s sanitation procedures are effective in preventing direct contamination and other adulteration of product.

5. Observe the establishment performing monitoring procedures.
 - a. If environmental sampling is included in the LTD sanitation procedures, IPP are to verify that the establishment is following its sample collection procedures. Verification is to be done by performing all of the following:
 - i. Observe the location at which establishment personnel collect samples.
 - ii. Observe the frequency at which samples are collected.
 - iii. Determine whether samples are being collected as per the LTD sanitation procedures.
 - iv. Determine whether the establishment routinely reviews the sample results.
 - v. Determine whether the establishment responds to any results that indicate it has exceeded its established control limits.
 - vi. Verify that measures to restore sanitary conditions are taken when necessary.
 - b. Compare the above observations to what the establishment has documented in its records.

VIII. ISSUES TO CONSIDER WHEN PERFORMING FSIS VERIFICATION OF LTD SANITATION PROCEDURES

A. Official establishments that perform processing operations in have the opportunity to implement LTD sanitation procedures in all or only some of the production areas where they perform processing operations. The LTD sanitation procedures may be included, in total or in part, in the establishment's Sanitation SOP, HACCP plan, or a prerequisite program. IPP are to verify the implementation of the LTD sanitation procedures as well as any other sanitary programs.

B. IPP are to follow the instructions in this directive, in addition to [FSIS Directive 5000.1](#), [FSIS PHIS Directive 5000.1](#) and [FSIS Directive 5000.4](#), when verifying sanitary conditions in the areas of the establishment where the establishment is implementing LTD sanitation procedures.

NOTE: A negative response to any of the questions in Sections C through G below does not automatically mean that there is noncompliance. IPP are to consider all available information in order to decide whether noncompliance exists, or whether a trend of noncompliance is developing.

C. Prerequisite programs are conditions and practices that provide the basic environmental and operating conditions that are necessary for the production of safe and wholesome food. The programs provide a foundation for the development and implementation of an effective HACCP system. They frequently function across product

lines and are often managed as facility-wide programs rather than being process or product specific. IPP are to review the establishment's LTD sanitation prerequisite program as instructed in [FSIS Directive 5000.1](#) and [FSIS PHIS Directive 5000.1](#) before conducting any verification procedures. Questions that IPP should consider when verifying the implementation of the LTD sanitation procedures in the prerequisite program, include, but are not limited to:

1. Has the establishment referenced the LTD sanitation procedures as a prerequisite program in its hazard analysis (i.e., as supporting documentation that a food safety hazard is not likely to occur)?
 - a. Does the establishment have written procedures that set out the design of the prerequisite program?
 - b. Is there evidence (e.g., records) that demonstrates that the program is being implemented as written?
2. Does the establishment maintain records including verification records (in accordance with [9 CFR 417.5\(a\)\(1\)](#)) to support the use of the LTD sanitation prerequisite program as part of the food safety system? For example:
 - a. Are there records that demonstrate that the LTD sanitation program is being implemented as written?
 - b. Does the establishment respond to those observed conditions and restore sanitary conditions?
 - c. Does the establishment use the records as a means to identify implementation problems that need to be corrected?
 - d. Does the establishment use those records to assess the effectiveness of the LTD sanitation prerequisite program?
3. Does the establishment elect to use microbial sampling as a means to support the decisions made related to the implementation of the LTD sanitation prerequisite program? If so:
 - a. Are testing records being maintained?
 - b. Does the establishment use those findings as a means to assess the effectiveness of the LTD sanitation program as well as the effectiveness of the Sanitation SOP as required in [9 CFR 416.14](#)?
4. Do records indicate that the use of the prerequisite program may no longer support decisions made in the hazard analysis, done in accordance with [9 CFR 417.2](#), that the food safety hazard is not reasonably likely to occur? For example, do the records show that:
 - a. Parts of the program are not being implemented, or are being implemented ineffectively?

- b. Similar or same implementation problems continue to reoccur?
 - c. The establishment repeatedly fails to implement the procedures?
5. Has the establishment reassessed its hazard analysis, as required in [9 CFR 417.4\(b\)](#) when it determines that decisions made in the hazard analysis regarding the LTD sanitation procedures may no longer be supported in accordance with [9 CFR 417.5\(a\)\(1\)](#)?

D. Effective establishment sanitation is essential for food safety and is a prerequisite to an establishment's successful implementation of HACCP. The Sanitation SOP is a written procedure, required by [9 CFR 416.11](#), that is designed to clearly define the procedures that each establishment will implement and follow in order to maintain effective sanitation procedures and substantially minimize the risk of direct product contamination and adulteration.

NOTE: IPP are to review the establishment's Sanitation SOP and its LTD sanitation procedures as instructed in [FSIS Directive 5000.1](#), [FSIS PHIS Directive 5000.1](#), and [FSIS Directive 5000.4](#) before conducting PBIS procedure 01C02 or PHIS task Operational Sanitation Review and Observation.

E. Questions that IPP are to consider when verifying the implementation of the in the Sanitation SOP, include, but are not limited to:

- 1. Is the establishment implementing the Sanitation SOP, including any LTD sanitation procedures, as written?
- 2. Does the establishment elect to use microbial sampling as a means to demonstrate the effectiveness of the Sanitation SOP? If so, does the establishment maintain testing records
- 3. Does the establishment use those findings as a means to assess the effectiveness of the LTD sanitation procedures, as well as the effectiveness of the Sanitation SOP, as required in [9 CFR 416.14](#)?
- 4. Does the establishment maintain Sanitation SOP records in accordance with [9 CFR 416.16](#), including the implementation of the LTD sanitation procedures? For example, has the establishment identified insanitary conditions, or product contamination or adulteration in those areas where the establishment is implementing the LTD sanitation procedures?
- 5. Does the establishment respond to those observed conditions and restore sanitary conditions?

F. If an establishment elects to include its LTD sanitation procedures in its HACCP plan, IPP are to verify that the HACCP plan is being implemented as written.

NOTE: When conducting FSIS verification of the LTD procedures, if the LTD sanitation procedures have been addressed in the HACCP plan and PBIS procedure 01B02 or

PHIS task Pre-Op SSOP Review And Observation is scheduled to be performed, IPP are to replace the procedure with the appropriate HACCP procedure, based on the HACCP plan.

G. Questions that IPP are to consider when verifying the implementation of the in the HACCP plan include, but are not limited to:

1. Does the establishment have written procedures that set out the design of the LTD sanitation procedures?
2. Is the establishment implementing the LTD sanitation procedures as designed?
3. Does the establishment evaluate the implementation of the program?
4. Does the establishment maintain records to support the implementation of the program, including verification records (in accordance with [9 CFR 417.5\(a\)\(1\)](#)), that include the implementation of the LTD sanitation procedures?
5. Are there records that demonstrate that the procedures are being implemented as designed?
6. Has the establishment identified insanitary conditions, or product contamination or adulteration in the areas where the establishment is implementing the LTD sanitation procedures?
7. Does the establishment respond to those observed conditions, control any affected product, and restore sanitary conditions?
8. Does the establishment have means to correct implementation problems?
9. Does the establishment use those records to assess the effectiveness of the prerequisite LTD sanitation procedures?
10. Does the establishment elect to use microbial sampling as a means to support the decisions made related to the implementation of its HACCP plan? If so, are testing records being maintained?
11. Does the establishment use those findings as a means to assess the effectiveness of the HACCP plan?
12. Has the establishment reassessed its hazard analysis, as required in [9 CFR 417.4\(b\)](#) when they determine that decisions made in the hazard analysis regarding the LTD sanitation procedures may no longer be supported in accordance with [9 CFR 417.5\(a\)\(1\)](#)?

H. An establishment may elect to use various types of sampling procedures and data collection as a means to demonstrate that its LTD sanitation procedures are effective to prevent direct contamination or adulteration of product, or that a food safety hazard is not reasonably likely to occur. LTD sanitation procedures may include a variety of sampling methodologies, product specifications or characteristics, and environmental

factors that the establishment has determined need to be met to ensure that sanitary conditions are maintained, and that contamination or adulteration of product has not occurred. The establishment's sampling program may include, but is not limited to the following:

1. The size of area or amount of product to be sampled.
2. The frequency at which samples will be collected.
3. Testing methodology that will be used.
4. A description of how the collected data will be evaluated. For example, the establishment uses SPC to evaluate its data collection, sampling results and its overall sanitation procedures. Please refer to Attachment 2: Statistical Process Control – An Overview, for information about SPC.

NOTE: An establishment's sampling or data collection procedures may include, but are not limited to, the following: microbiological, water activity (A_w), product formulation (pH, nitrates), anti-microbial treatments, or other data (e.g.; environmental data such as room temperature or temperature of product contact surfaces).

I. An establishment may also elect to conduct sampling to establish a microbiological base line based on its traditional cleaning program, prior to the implementation of an LTD sanitation procedure. The baseline serves as a starting point from which to evaluate the effectiveness of its LTD sanitation procedures. Baseline testing is a useful tool because microbiological testing results obtained after an LTD procedure is implemented that are not equal to the establishment's baseline testing results may be an indication that the overall sanitation program requires corrective measures.

NOTE: Meaningful data would be information collected by the establishment that provides a basis to assess whether the LTD sanitation procedures and the Sanitation SOP are effective in ensuring food safety, whether product is being contaminated or adulterated, and whether insanitary conditions are being created.

1. Does the establishment consistently gather data related to the selected criteria?
2. Does the establishment use SPC to evaluate its LTD process, and if so, has it identified control limits that it can use to determine process control?
3. Does the establishment analyze the data to determine whether a trend of insanitary conditions may be developing or to address a possible emerging food safety concern?
4. Is the establishment reacting to the control limits it has set when sampling results exceed those limits? For example, does it:
 - a. Initiate actions to restore sanitary conditions?
 - b. Increase sanitation cleaning frequencies?

- c. Re-evaluate its testing program?
 - d. Increase the number of samples it collects?
5. Has the establishment changed cleaning chemicals or sanitizers and addressed the possible affects that change can have on its sample results and LTD sanitation procedures?

IX. DETERMINING NONCOMPLIANCE

A. Using the information gathered during their verification activities (see Sections VII and VIII of this directive), IPP are to determine whether noncompliance exists. IPP are to use their knowledge of the operation and the information gathering skills to evaluate every situation on a case-by-case basis and to make a supportable decision based on the information they have gathered. IPP are to verify that the establishment's Sanitation SOP, pre-op sanitation procedures, and LTD sanitation procedures are in compliance with 9 CFR Part 416.

B. If IPP determine that product contamination or adulteration has occurred, they are to take the appropriate control action per [FSIS Directive 5000.1, Chapter IV](#) and [FSIS PHIS Directive 5000.1, Chapter V](#). Establishments are required to initiate corrective actions in accordance with [9 CFR 416.15](#). In addition, if there is evidence that the implementation of the LTD sanitation procedures no longer supports their hazard analysis decisions, the establishment's corrective actions may include reassessment in accordance with [9 CFR 417.3\(b\)](#). A finding of this type would indicate that the LTD sanitation procedures were not effective in reducing the likely risk in the environment where food is produced.

C. When the implementation of the LTD sanitation procedures may have failed to prevent direct contamination or adulteration of product, IPP are to document noncompliance using PBIS procedures 01B02 and 01C02 or PHIS tasks Pre-Op and Operational Sanitation Review and Observation, citing [9 CFR 416.13](#).

D. When the records associated with the implementation of the LTD sanitation procedures are not being maintained, IPP are to document noncompliance using the PBIS procedure 01B02 and 01C02 or PHIS tasks Pre-Op and Operational Sanitation Review and Observation, citing [9 CFR 416.14](#) or [9 CFR 416.16](#).

E. If IPP observe that a prerequisite program has not been implemented or documented in the manner referenced in the hazard analysis, HACCP plan, or Sanitation SOP, IPP are to document noncompliance using the appropriate HACCP procedure code, citing [9 CFR 417.5\(a\)\(1\)](#) and [9 CFR 417.2](#). Failure to perform the LTD sanitation procedures in the manner set out in the hazard analysis, or if a prerequisite program that is not effective in maintaining sanitary conditions, may mean that there is no longer support for the food safety decisions made in the hazard analysis.

F. IPP may find, when seeking answers to the questions set out in this directive, that a negative response to one question is not an automatic indication of regulatory noncompliance or a system failure. When making determinations of regulatory

compliance and process control, IPP are to consider how all the information they have gathered relates to the food safety system

X. DOCUMENTATION AND ENFORCEMENT

A. IPP are to follow the methodology for documenting noncompliance described in [FSIS Directive 5000.1, Chapter IV](#) or [FSIS PHIS Directive 5000.1, Chapter V.](#), and are to initiate enforcement actions in accordance with [9 CFR 500](#). IPP are to also include in the documentation references to any sections of the establishment's LTD sanitation procedures that are linked to the noncompliance.

B. It is essential that IPP accurately describe the noncompliant conditions observed. IPP are to clearly describe the observed conditions in clear and concise terms. It is not enough to document that equipment was "unclean" without including a description of what was "unclean," and why IPP concluded that this description is appropriate. IPP are to describe the size, shape, consistency, or odor of the insanitary condition as necessary to convey fully the finding that they are documenting. IPP also need to describe how the conditions observed could result in product contamination or adulteration.

C. When IPP determine that an insanitary condition exists, or that product contamination has occurred, they are to do the following:

1. Document noncompliance on the PBIS Procedure Schedule under the appropriate PBIS procedure code (i.e., 01B01, 01B02, 01C01, 01C02), or PHIS tasks Pre-Op and Operational Sanitation Review and Observation,
2. Complete a Noncompliance Record (NR) per the instructions in either [FSIS Directive 5000.1, Chapter IV](#) and [FSIS PHIS Directive 5000.1, Chapter V](#); and,
3. Review the NR file in the government office or the NRs in PBIS or PHIS and link any noncompliances (SPS, Sanitation SOP, and HACCP) that are from the same cause in order to document that a history of noncompliance is occurring.

D. If IPP determine, over time, that they have multiple documented instances of insanitary conditions because the establishment has failed to implement its LTD sanitation procedure as written, enforcement action may be necessary. The IPP are to request the assistance of an Enforcement, Investigations, and Analysis Officer (EIAO), through supervisory channels, to determine what actions, if any, to take.

XI. SUPERVISORY RESPONSIBILITIES

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

B. Supervisory personnel are to ensure that IPP are applying the correct inspection methodology, making sound decisions, documenting the basis for their action, and taking the appropriate enforcement actions.

C. Supervisory personnel are to discuss the [key points](#) identified in this directive with inspection personnel and are to clarify any issues of concern.

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.

XII. DATA ANALYSIS

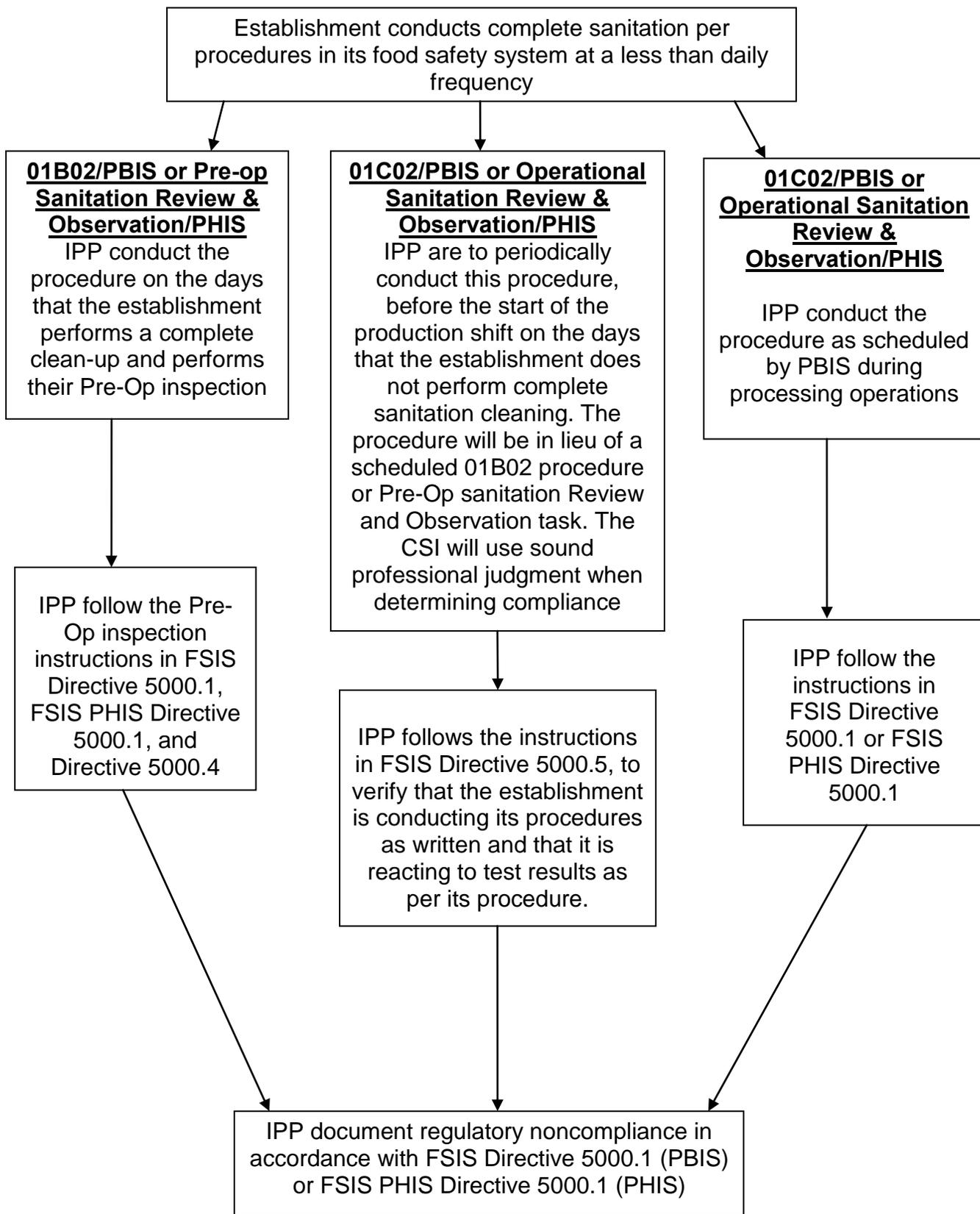
Annually, the Data Analysis and Integration Group within the Office of Data Integration and Food Protection is to review PBIS and PHIS data on verification activities to determine whether trends exist in noncompliances related to less than daily sanitation procedures. The analysis also is to include a review of repetitive noncompliances that are linked by the IPP to determine whether trends exist. Results from these analyses are to be shared with the Office of Field Operations and the Office of Policy and Program Development to determine whether the findings suggest improvements in verification procedures or the need for guidance to IPP.

Refer questions regarding this directive to the Policy Development Division through [askFSIS](#) or by telephone at 1-800-233-3935.

A handwritten signature in black ink, appearing to read "David J. Seibert". The signature is fluid and cursive, with a prominent initial "D" and "S".

Assistant Administrator
Office of Policy and Program Development

Attachment 1



The “Statistical Process Control – An Overview” below is taken from the Guidelines for *Escherichia coli* Testing for Process Control Verification in Poultry Slaughter Establishments, published by FSIS. This overview provides inspection personnel with general information on how statistical process control can be used by an establishment for any process or procedures used by an establishment, whether it is for a slaughter operation, the production of a food product or monitoring sanitation procedures.

Statistical Process Control - An Overview

Statistical process control is based on the principle that every product is produced by a process. All processes are subject to variation, which should be understood and controlled by statistical methods. A process that is in control is stable in terms of average level and degree of variation, i.e., it is predictable within limits and is thus "doing its best." Processes that have not been subjected to analysis are not likely to be in control. Control is attained, often by degrees, by detecting and eliminating special causes of variation, those not present all the time or not affecting all product output. This involves initially evaluating data to determine process capability (the typical process performance level), and then checking subsequent data to see if they are consistent with this baseline level, i.e., the process is in control and variations are within normal and acceptable limits. This is accomplished by checking for unreasonably high results, trends, and looking for and correcting problems in the process when these signals occur.

It is important to recognize that an in-control process may not necessarily result in product of the desired quality. Improvements may be needed or the entire process may require reconsideration. Problems in a process may stem from many sources, for example, inadequate knowledge of how a process should work or how a specific process is performing; errors or deficiencies in executing procedures; failure to recognize the need for preventive measures; unnecessary complexity in the process; and uncontrolled variation among inputs.

Specific techniques of statistical process control include the time plot, which charts measurements over time; this is the first technique to use with data collected over time and analyzed for patterns. A further development is the control chart, which plots data over time but also displays an upper control limit for specific measurements, and a centerline, above and below which there is an equal number of sample results (the centerline is in effect a median average). A sample result above the upper control limit would indicate the likely presence of a special cause of variation that should be addressed. Results within control limits indicate simply that the process is in control. Control charts have two essential uses: after-the-fact analysis of process performance and gaining and maintaining control of a process. In most situations more than one type of control chart would be applicable; detailed information can be found in texts on statistical quality control, under the topic "control charts." (Text reference:

Understanding Statistical Process Control, Donald J. Wheeler, David S. Chambers, SPC Press, Inc., Knoxville, TN; 1992.)

In general, statistical process control techniques help to provide experience in "process thinking" (a central tenet of HACCP), develop an historical record of performance, evaluate the long-term stability of a process and determine process capability (i.e., how it is actually working), and judge the effectiveness of process improvement actions.

Microbiological testing, conducted as part of statistical process control will not be directly useful for attaining and maintaining control of a process, as test results will come from the **end** of the process and in any case would not be timely enough; observations made earlier in the process would be more useful for attaining and maintaining control.

Microbiological testing would serve to verify process control. Process control techniques, applied and verified in this manner, would accomplish the essential intent of the Sanitation SOP regulation by integrating process control and microbial testing into slaughter or processing operations.