

VERIFICATION OF LESS THAN DAILY (LTD) SANITATION PROCEDURES

FSIS Directive 5000.5

**Policy Development Division
Office of Policy and Program Development
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PURPOSE

**To provide instruction to FSIS personnel
on how to verify compliance with the
sanitation regulations in establishments
that conduct complete cleaning
less frequently than every day**

KEY POINTS

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

KEY POINTS (CONTINUED)

- Establishments **are not** required to submit their procedures to FSIS for prior review or approval to implement a less than daily cleaning program in their facility
- Establishments may conduct a complete cleaning at ***frequencies other than daily***
- Sanitation procedures are ***to be incorporated into the establishment's food safety system*** (e.g., HACCP system or Sanitation SOP or other prerequisite program) when performed other than daily

KEY POINTS (CONTINUED)

- An establishment conducting sanitation at a less than daily frequency is responsible for meeting **all** of the regulatory requirements regarding sanitation, specifically **9 CFR 416.1 through 416.16**, including having records that demonstrate the effectiveness of its program
- When to perform **01B02 vs. 01C02** in establishments that conduct sanitation on a less than daily basis

BACKGROUND

- Sanitation is essential to food safety
- An effective sanitation program is a fundamental prerequisite program
- FSIS regulations do not require that complete cleaning be done at a specific frequency
 - Cleaning must be done as often as necessary to:
 - maintain sanitary conditions
 - prevent the contamination or adulteration of product

BACKGROUND

- Establishments can:
 - implement LTD sanitation procedures in all or only some of their production areas.
 - Include the procedures (in total or in part) in either:
 - The Sanitation SOP
 - The HACCP plan
 - A prerequisite program
- When utilizing LTD sanitation procedures, the establishment will need to consider how the LTD procedures affect their food safety system

NOTE

***Establishments that develop LTD procedures
yet continue to conduct
complete cleaning procedures
on a daily basis would not be considered to have a
less than daily sanitation program.***

***These establishments would still be subject to FSIS
pre-op sanitation procedures (01B01 and 01B02)
as they are scheduled in PBIS.***

DEFINITIONS

- Pre-operational Sanitation
- Less Than Daily (LTD) Sanitation
- Aerobic Plate Count (APC)
- Statistical Process Control (SPC)
 - Attachment 2

DESCRIPTION

- Prerequisite Programs
 - Directive does not “define” these programs but does address them
 - Are a foundation for the development and implementation of a food safety system
 - Essentially any program, by any title, that is used to support food safety decisions



FSIS VERIFICATION: OVERVIEW

- When performing any verification procedures, IPP are to:
 - Be aware of and understand, the establishment's:
 - LTD program
 - Sanitation SOP
 - Prerequisite program
 - HACCP plan
 - Verify that establishment's LTD procedures meet all the sanitation regulatory requirements
 - 9 CFR 416.1 through 416.5
 - 9 CFR 416.11 through 416.16

FSIS VERIFICATION: 01B01

- When performing the 01B01 procedure, IPP are to:
 - Conduct the 01B01 procedure on days that it is scheduled by PBIS, or as warranted based on the professional judgment of the IIC
 - review all available establishment records associated with the implementation of the LTD procedure
 - This could include records from the :
 - Sanitation SOP
 - Prerequisite program
 - HACCP plan



FSIS VERIFICATION: 01B01

(CONTINUED)

- Verify that the pre-operation sanitation inspection procedures were implemented as written
- Document regulatory noncompliance

FSIS VERIFICATION: 01B02 PRE-OP

- IPP are to verify pre-operational sanitary conditions in accordance with:
 - FSIS Directive 5000.5, Section VII
 - FSIS Directive 5000.1, Appendix A, in slaughter operations
 - FSIS Directive 5000.4 in processing operations
- When performing 01B02, IPP are to make an overall assessment of the sanitary conditions in the plant

FSIS VERIFICATION: 01B02

- Directive provides instruction to IPP regarding how to perform the 01B02 procedure:
 - On the days that the establishment has conducted a complete cleaning
 - When it is scheduled on a day when a complete cleaning **has not** been conducted in any part of the establishment
 - When it is scheduled on a day when a complete cleaning **has been conducted only in some areas** of the establishment



NOTE

Even though the procedure may appear on the PBIS schedule, IPP are not to conduct the 01B02 procedure on days when it is scheduled unless complete cleaning has been conducted in all, or part, of the facility in accordance with the establishment's LTD program.

All sanitation verification performed by FSIS between complete cleanings will be performed as 01C tasks.

FSIS VERIFICATION: 01C02

- The 01C02 procedure is to be conducted in accordance with the following instructions:
 - When an 01C02 procedure 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



FSIS VERIFICATION: 01C02

(CONTINUED)

- When an 01C02 procedure 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 procedure unscheduled as performed in PBIS
- Periodically conduct the 01C02 procedure before the start of the production shift (e.g., pre-shift).
 - The 01C02 procedure is to be conducted 1-2 times per month prior to the start of the approved hours of operation for the establishment



FSIS VERIFICATION: MICROBIAL SAMPLING

- If microbial sampling is included in the LTD sanitation procedures, IPP are to verify that the establishment is following its procedures
- Verification is to be done by performing all of the following:
 - Observe the location at which establishment personnel collect samples
 - Observe the frequency at which samples are collected
 - Determine whether samples are being collected as per the LTD sanitation procedures



FSIS VERIFICATION: MICROBIAL SAMPLING

(CONTINUED)

- Determine whether the establishment responds to any results that indicate it has exceeded its established control limits
- Determine whether the establishment routinely reviews the sample results
- Verify that measures to restore sanitary conditions are taken when necessary
- Compare the above observations to what the establishment has documented in its record

ISSUES TO CONSIDER

- Questions asked in the directive related to the HACCP plan are:
 - Intended to be thought provoking
 - Not intended to be prescriptive
 - Not all inclusive

NOTE

A negative response to any of the questions in sections VIII. C through F of the directive does not automatically result in noncompliance.

IPP are to consider all available information in order to decide whether noncompliance exists, or whether a trend of noncompliance is developing.

ISSUES TO CONSIDER

- Sanitation SOP
- Prerequisite Programs
- HACCP
- Microbial Sampling
- Baseline Testing

NOTE

When conducting FSIS verification of the LTD procedures, if the LTD procedures have been addressed in the HACCP plan and PBIS procedure 01B02 is scheduled to be performed, IPP are to replace the procedure with the appropriate 03 HACCP procedure

DETERMINING NONCOMPLIANCE

- When making compliance determinations as to whether sanitary conditions have been maintained, IPP are to take into consideration the observed sanitary conditions and then evaluate the risks to product
- IPP will need to:
 - gather information
 - Assess that information
 - Determine compliance

NOTE:

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



DOCUMENTING NONCOMPLIANCE

SSOP

- When the records associated with the implementation of the LTD sanitation procedures are not being maintained, IPP are to document noncompliance:
 - 01B01 or 01C01 procedure codes
 - cite 9 CFR 416.14 or 416.16
- When the implementation of the LTD sanitation procedures may have failed to prevent direct contamination or adulteration of product, IPP are to document noncompliance:
 - 01B02 or 01C02 procedure codes
 - cite 9 CFR 416.13



DOCUMENTING NONCOMPLIANCE HACCP

- If IPP determine a prerequisite program has not been implemented or results documented as specified in the hazard analysis, HACCP plan, or Sanitation SOP, IPP are to document noncompliance
 - using the appropriate HACCP procedure code
 - cite 9 CFR 417.5 (a)(1) and 417.2

ENFORCEMENT

- If IPP determine there are repeated 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 EIAO, through supervisory channels, to determine what actions to take, if any



SUPERVISORY RESPONSIBILITIES

- The supervisor plays a key role in assuring decisions made by IPP are consistent with FSIS statutory authority, Agency policy, and duties are performed in accordance with prescribed inspection methods and procedures

SUPERVISORY RESPONSIBILITIES

(CONTINUED)

- Supervisory personnel are to ensure that IPP are:
 - Applying the correct inspection methodology
 - Gathering information before making regulatory decisions,
 - Documenting noncompliance accurately, and
 - Taking the appropriate enforcement action
- Supervisory personnel should refer to the current version of the *FSIS Guide for Conducting In-Plant Performance System (IPPS) Assessments*, for additional guidance and instructions

SUMMARY

- The LTD procedures are viewed by FSIS as prerequisite programs
- LTD procedures do not require FSIS review or approval prior to being implemented
- In establishments that implement LTD procedures, PBIS procedures 01B02 and 01C02 are to be performed in accordance with the instructions in this directive



SUMMARY

(CONTINUED)

- Verification of operations that implement LTD programs requires:
 - Looking at the food safety system, not just one aspect of the operation
 - Gathering information before making compliance determinations
 - Being familiar with all aspects of the establishment food safety system and sanitation procedures