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

FSIS DIRECTIVE

5000.5, Revision 3 | 10/14/21

VERIFICATION OF LESS THAN DAILY SANITATION PROCEDURES IN MEAT AND POULTRY PROCESSING OPERATIONS AND EGG PRODUCTS ESTABLISHMENTS

NOTE: DO NOT IMPLEMENT THIS DIRECTIVE IN EGG PRODUCTS ESTABLISHMENTS UNTIL OCTOBER 29, 2021.

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) in meat and poultry processing operations and egg products establishments on how to verify compliance with the sanitation regulations in establishments that conduct a complete cleaning and sanitizing of product contact equipment less frequently than every day. With the issuance of the *Egg Products Inspection Regulations* (85 FR 68649) final rule, FSIS is revising this directive to add instructions for IPP assigned to egg products establishments which explains when to perform a Pre-Operational Sanitation Standard Operating Procedures (Sanitation SOP) Review and Observation task versus an Operational Sanitation SOP Review and Observation task in establishments that conduct a complete cleaning and sanitizing on a less than daily (LTD) basis and how to verify compliance with certain regulations found in 9 CFR 416 and 417.

KEY POINTS:

- *Adds instructions for IPP at egg products establishments for verifying the sanitation requirements in 9 CFR part 416 in establishments conducting LTD sanitation*
- *IPP are to evaluate LTD sanitation procedures using applicable regulations in 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 LTD sanitation program*
- *Meat and poultry processing establishments and egg products establishments may conduct a complete cleaning and sanitizing at frequencies other than daily. FSIS does not allow slaughter establishments to conduct LTD sanitation procedures, with the exception of poultry chillers that have been adjusted to stabilize water pH and temperature and with antimicrobial levels sufficient to inhibit bacterial growth.*

II. CANCELLATION

FSIS Directive 5000.5 Rev. 2, Verification of Less than Daily (LTD) Sanitation Procedures, 3/29/18

III. BACKGROUND

A. 9 CFR 416.12(a) requires that an establishment's Sanitation SOP describes all procedures 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 and sanitizing of the facilities and equipment is to be conducted at a frequency that ensures the establishment maintains sanitary conditions. Insanitary facilities or equipment create an environment that could result in product contamination or adulteration.

B. 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 sanitation program.

C. When an establishment performs cleaning or sanitation procedures in processing operations at a frequency that is LTD, the establishment is to consider the effect of this frequency on its food safety system. LTD sanitation procedures are to be incorporated into the establishment's food safety system (e.g., HACCP system, Sanitation SOP or other prerequisite program). FSIS recognizes that LTD sanitation procedures are prerequisite programs as described in the *Federal Register* (see 68 Fed. Reg. 34224; June 6, 2003).

D. In this directive, "establishment" refers to official establishments and egg products plants.

IV. SCHEDULING TASKS FOR VERIFICATION OF SANITARY CONDITIONS AND SANITATION SOP PROCEDURES IN THE PUBLIC HEALTH INFORMATION SYSTEM

A. The frequency of performing verification may be affected by the sanitation schedule 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.

B. When a Pre-Op SSOP Review and Observation task is scheduled on a day when the establishment has conducted a complete cleaning and sanitizing, IPP are to perform the Pre-Op SSOP Review and Observation task following the instructions in FSIS Directive 5000.4, *Performing Pre-Operational Sanitation Verification.* IPP are to verify that the establishment's procedures related to sanitation and pre-op sanitation monitoring, as outlined in the establishment's Sanitation SOP and LTD sanitation procedures have been performed as written. IPP are to perform pre-op sanitation verification following the same procedures and standards that they would use in an establishment that employs a traditional daily cleaning program and verify that product contact surfaces look, feel, and smell clean before operations begin.

NOTE: FSIS does not consider establishments that have LTD sanitation procedures in place but continue to conduct complete cleaning and sanitizing of their equipment or production areas daily as conducting LTD sanitation procedures. These establishments would still be subject to Pre-Op and Operational SSOP Review and Observation tasks as they are scheduled.

C. When a Pre-Op SSOP Review and Observation task is scheduled on a day when a complete cleaning has been conducted in only some areas of the establishment, IPP are to conduct the Pre-Op SSOP verification in those areas as scheduled, following the instructions in FSIS Directive 5000.4.

D. When a Pre-Op SSOP Review and Observation task is scheduled in a processing

operation on a day when a complete cleaning and sanitizing has not been conducted by the establishment, IPP are to:

1. Reschedule the Pre-Op SSOP Review and Observation task to another day (e.g., click and drag the task to another day); and

2. Conduct a Pre-Op SSOP Sanitation Record Review task focusing on establishment records that document the implementation and effectiveness of the LTD sanitation procedures.

NOTE: When conducting verification of the LTD sanitation procedures, if these procedures have been addressed in the establishment's HACCP plan and a Pre-Op SSOP Review and Observation task is scheduled to be performed, IPP are to reschedule the procedure to another day and conduct the appropriate HACCP verification task for that HACCP plan as instructed in Section V. D.

E. IPP are to periodically conduct an Operational SSOP Review and Observation verification task before the start of the production shift (e.g., pre-shift) to verify the establishment is implementing the LTD sanitation procedures as written. IPP are to seek direction from supervisory personnel as to how frequently they are to observe implementation of establishment LTD sanitation procedures occurring prior to the start of the approved hours of operation.

V. PERFORMING FSIS VERIFICATION OF LTD SANITATION PROCEDURES

A. 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 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.

NOTE: 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.

B. IPP are to verify establishments have included their LTD sanitation procedures for processing operations in their food safety system (e.g., Sanitation SOP, other prerequisite program, or HACCP). IPP may need to review more records than just pre-op records in an establishment that has LTD sanitation procedures. The LTD sanitation programs may include, but are 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 a complete daily cleaning and sanitizing;

3. Increased operational cleaning 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

NOTE: For the purposes of this directive, gross contamination is the accumulation of product residue on direct food contact surfaces during operations. With the implementation of LTD

sanitation procedures, the presence of product residue does not automatically represent noncompliance. As stated in FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System* the IPP's primary role is not to identify areas that are clean and areas that are unclean for the establishment. The IPP's primary role is to use their findings to determine whether or not the establishment is implementing Sanitation SOPs effectively to prevent contamination or adulteration of products. IPP are to consider the information they have gathered related to the LTD sanitation procedures and the food safety system as a whole along with the guidance in Section V. C. and Section VI when making compliance determinations.

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. IPP are to follow the instructions in this directive, in addition to FSIS 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. IPP are to verify the establishment is meeting all of the sanitation regulatory requirements in 9 CFR 416.1 through 416.5 and 9 CFR 416.11 through 416.16, the establishment is implementing its sanitation procedures as written, and that the establishment's sanitation procedures are effective in preventing direct contamination or adulteration of product.

1. When verifying the implementation of the procedures in the Sanitation SOP, IPP are to consider all available information to decide whether noncompliance exists, or whether a trend of noncompliance is developing. IPP are to verify and consider the following:

    a. Verify if the establishment is implementing the Sanitation SOP, including any LTD sanitation procedures, as written;

    b. Verify the establishment maintains Sanitation SOP records in accordance with 9 CFR 416.16, including the implementation of the LTD sanitation procedures;

    c. Verify the establishment responds to observed conditions, such as the identification of insanitary conditions or product adulteration in those areas where the establishment is implementing LTD sanitation procedures, and restores sanitary conditions; and

    d. If the establishment elects to use sampling as a means to demonstrate the effectiveness of the Sanitation SOP, verify the establishment uses those findings as a means to assess the effectiveness of the LTD sanitation procedures and the effectiveness of the Sanitation SOP as required by 9 CFR 416.14. See Attachment 2 for more information about microbial sampling.

2. 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, *Review of Establishment Testing Data by Inspection Program Personnel.*

3. IPP are to inspect one or more areas of the establishment to ensure that the establishment's sanitation procedures are effective in preventing direct contamination and adulteration of product.

4. IPP are to observe the establishment performing monitoring procedures.

5. 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:

    a. Observe the location at which establishment personnel collect samples;

    b. Observe the frequency at which samples are collected;

    c. Determine whether samples are being collected as per the LTD sanitation procedures;

    d. Determine whether the establishment routinely reviews the sample results;

    e. Determine whether the establishment responds to any results that indicate it has exceeded its established control limits; and

    f. Verify that measures to restore sanitary conditions are taken when necessary.

NOTE: As FSIS recognizes that an establishment's LTD sanitation procedures are prerequisite programs, if the establishment elects to use microbial sampling as a means to support the LTD sanitation procedures, the sampling data would be considered supporting documentation. IPP will verify testing records are being maintained in accordance with 9 CFR 417.5(a)(1) and are made available to FSIS personnel upon request per 9 CFR 417.5(f).

D. If an establishment elects to include its LTD sanitation procedures in its HACCP plan, IPP are to follow instructions in FSIS Directive 5000.1 Chapter III to verify that the establishment is implementing the HACCP plan in accordance with the regulations in 9 CFR Part 417.

VI. DOCUMENTING NONCOMPLIANCE

A. IPP are to follow the methodology for documenting noncompliance described FSIS Directive 5000.1, Part V and are to initiate regulatory control 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 describe the observed conditions in clear and concise terms. IPP are to describe the size, shape, consistency, or odor of the insanitary condition as necessary to convey fully the finding they are documenting. IPP also need to describe how the conditions observed could result in product contamination or adulteration.

C. Product food contact surfaces must be maintained in a condition that will not lead to the contamination or adulteration of product. 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 the applicable Pre-Op or Operational SSOP Review and Observation task, citing 9 CFR 416.13. If the establishment has included the LTD sanitation procedure in the HACCP plan, IPP are to follow the instructions in FSIS Directive 5000.1, Chapter V, Section V for documenting noncompliance.

1. If IPP determine that product contamination or adulteration has occurred, they are to take the appropriate regulatory control action per FSIS Directive 5000.1, Chapter V.

2. Establishments are required to initiate corrective actions in accordance with 9 CFR 416.15.

3. 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).

4. If IPP determine over time that the establishment has multiple documented instances of insanitary conditions because the establishment has failed to implement its LTD sanitation procedures as written or if IPP have documented in multiple associated noncompliance records (NRs) that the implementation of the LTD sanitation procedures may have failed to prevent direct contamination or adulteration of product, enforcement action may be necessary. IPP are to take appropriate regulatory action and discuss with their supervisor if further enforcement action may be needed.

5. If IPP have questions about the scientific design or supportability of the LTD sanitation procedures, IPP are to request the assistance of an Enforcement, Investigations, and Analysis Officer (EIAO), through supervisory channels.

D. When the records associated with the implementation of the LTD sanitation procedures are not being maintained, IPP are to document noncompliance using the applicable Pre-Op or Operational SSOP Review and Observation task, citing 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 or HACCP plan, IPP are to consider whether the decisions made in the hazard analysis and HACCP plan related to implementation of the LTD sanitation procedures continue to support the decisions made. If not, noncompliance may need to be documented using the appropriate HACCP procedure code, citing 9 CFR 417.5(a)(1) and 9 CFR 417.2.

VII. 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 regulatory control actions.

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

VIII. QUESTIONS

Refer questions regarding this directive to your immediate supervisor or to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select General Inspection Policy for the inquiry type.

NOTE: Refer to FSIS Directive 5620.1, Using askFSIS, for additional information on submitting questions.

Assistant Administrator
Office of Policy and Program Development

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.

Evaluation of Establishment Sampling Procedures

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 contamination or adulteration of product has not occurred.

The establishment's sampling program may include, but is not limited to the following:

1. Size of area or amount of product to be sampled;

2. Frequency at which samples will be collected;

3. Testing methodology that will be used;

4. Description of how the collected data will be evaluated. For example, the establishment uses Statistical Process Control (SPC) to evaluate its data collection, sampling results and its overall sanitation procedures. Please refer to Attachment 1: Statistical Process Control – An Overview, for information about SPC.

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

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 sanitation procedure is implemented that exceed the establishment's baseline testing results may be an indication that the overall sanitation program requires corrective measures.

Aerobic Plate Count (APC): The APC microbial test method can be used to evaluate the sanitary conditions of food contact surfaces or 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 (70-110º 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.

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 effects that change can have on its sample results and LTD sanitation procedures?