LESS THAN DAILY SANITATION PROCEDURES
COMPLIANCE GUIDELINE
10-19-09

I. PURPOSE

This guidance document was developed to help establishments that are considering or planning to implement less than daily (LTD) sanitation procedures. These guidelines provide an overview of the planning, development, implementation and maintenance of LTD sanitation procedures. These guidelines address FSIS' expectations with respect to regulatory requirements, especially those relative to Sanitation SOPs in 9 CFR 416.11-416.16 and for prerequisite programs under 9 CFR 417.2 and 417.5.

II. BACKGROUND

As a common practice, establishments have conducted complete cleaning and sanitizing of their operations on a daily basis. However, there have never been FSIS regulations that required an establishment to conduct cleanup every twenty-four hours or within any other specified period.

For the purposes of this document, "traditional" cleaning addresses the complete cleaning that is typically performed every twenty-four hours and includes procedures such as:

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

Establishments can choose to extend their production operations without conducting "traditional" cleaning every twenty-four hours. They can select an alternative cleaning frequency provided they ensure that, as a result of the methods utilized, insanitary conditions are not being created that may result in adulteration or contamination of product.

Establishments utilizing an alternative sanitation frequency would still conduct "traditional" cleaning except it would be less frequent, for example one time per week. In addition, they typically will conduct more frequent operational sanitation procedures that may include:

- Removing the gross contamination from equipment and production areas either by hand or with water of a suitable temperature;

- Applying chemicals (detergent, acid or alkali soap) to emulsify or dissolve the food (protein) materials and fats adhering to the equipment;

An establishment using LTD sanitation procedures must meet all of the sanitation regulatory requirements . 9 CFR 416.1 through 416.5, Sanitation Performance Standards (SPS), and 9 CFR 416.11 through 416.16, Sanitation SOP, set out those requirements. In addition, establishments that implement these procedures as part of a prerequisite program will need to ensure that they address the 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 hazard analysis (9 CFR 417.1(a)).

NOTE: Establishments that develop a LTD sanitation program but continues to conduct their complete pre-op sanitation procedures daily would not be considered to have a LTD sanitation program. These establishments would still be subject to FSIS pre-op sanitation procedures (01B01 and 01B02) as they are scheduled in PBIS

III. IMPLEMENTING LESS THAN DAILY SANITATION PROCEDURES

When developing an LTD sanitation program, an establishment should consider all factors that may impact its program. In most cases, FSIS expects that microbial factors affecting sanitary conditions will be the primary focus of LTD sanitation programs. It is well known that bacterial growth is a function of time, temperature, and environmental factors (available nutrients and moisture). In addition, bacteria found on food contact surfaces will affect the condition of the product. Microbes cannot be directly observed by organoleptic methods; therefore, it is likely that most LTD sanitation programs will need to include sampling methods to measure levels of bacterial contamination on food contact surfaces.

As guidance for the development of procedures of this type, this document will address the following issues:

- Risk considerations
    - Direct food contact surfaces
    - Indirect food contact surfaces
    - Non-food contact surfaces
    - Lot size or recall implications
    - Consistency of operation and potential impact on product
    - Pathogens
    - Chemicals
    - Allergens

- Collection of Meaningful Data
    - Initial (i.e., Baseline)

  - Ongoing

- Analysis of Data
  - Initial (i.e., analysis of baseline data before implementation of LTD sanitation procedures)
  - Ongoing (data collected after implementation of LTD sanitation procedures)

- Maintenance of the Sanitation SOP (9 CFR 416.14)
  - Use of analysis to evaluate the effectiveness of the LTD sanitation procedures

- Documentation Demonstrating Effectiveness of the Sanitation SOP, including LTD sanitation procedures (9 CFR 416.16)
  - Maintenance of Sanitation SOP records that demonstrate that the sanitation procedures, including LTD sanitation procedures, are effective in preventing contamination of product.

- Addressing Noncompliances

A. RISK CONSIDERATIONS

Before implementing LTD sanitation procedures, establishments should consider multiple factors that might have the potential to contaminate product, such as:

- **Direct Food Contact Surfaces:** Surfaces that routinely contact products directly during the course of operations can be the site of growth of bacteria, including spoilage organisms, and these bacteria can contaminate the product when contact occurs. The establishment needs to consider the risk of cross-contamination when designing its LTD sanitation procedures.

EXAMPLES: saws, cutting boards, table tops, inside surfaces of choppers, grinders and other equipment.

- **Indirect Food Contact Surfaces:** These areas have a reasonable likelihood of product contact through the course of normal production. Under proper conditions, bacterial growth and spoilage growth are likely in areas where incidental food contact occurs because these surfaces typically are not thoroughly cleaned as often as direct food contact surfaces. The establishment should consider such areas when designing LTD sanitation procedures.

EXAMPLES: doorways and posts, employee clothing, outside surfaces of equipment, and rail pull switches.

- **Non-Food Contact Surfaces**: Growth of pathogens and spoilage organisms may be present in areas where incidental food contact accidentally occurs. These

surfaces may become a source of direct product contamination or create insanitary conditions that ultimately may affect sanitary conditions in the rest of the establishment. The establishment should consider such areas when designing LTD sanitation procedures.

EXAMPLES: floors, walls, and undersides of tables and work platforms.

- **Lot Size or Recall Implications:** The establishment should consider how its sanitation procedures and frequencies affect the determinations of lot size and amount of product represented by any FSIS or company sample. The effectiveness of sanitation may greatly affect the amount of product involved if a recall of product became necessary.

- **Consistency of Operations and Potential Impact on Product:** The establishment should consider whether changes to operational sanitation procedures for extended periods between complete operational sanitation procedures would affect its ability to maintain sanitary conditions, thereby preventing the contamination or adulteration of product

- **Pathogens:** In addition to the general microbial growth, the establishment should consider pathogen growth on surfaces that might ultimately contaminate the final product. For example, *Listeria monocytogenes* can form microscopic biofilms on equipment surfaces that the establishment may find difficult to remove during LTD sanitation procedures and that may later affect product through direct contact.

- **Chemicals:** Detergents and sanitizers (chemicals) can be toxic at certain levels. The establishment should consider accumulation of residual chemicals on surfaces.

- **Allergens:** the establishment may wish to consider other information such as the effects allergens might have on all products produced between complete sanitation cleaning procedures. The allergenic proteins can become fixed to food contact surfaces during on-going operations (i.e., between complete sanitation procedures) and potentially become a labeling issue in other foods being processed that would not otherwise contain the ingredient.

B. COLLECT MEANINGFUL DATA

After an establishment has considered the risks associated with its operation, the establishment will need to consider what information it should collect. The initial data collected likely will be related to microbiological conditions of the equipment. However , many factors (e.g. ph, water activity, product characteristics) could affect the product and therefore affect the type, and amount , of data that the establishment ultimately decides is needed to ensure that the alternative cleaning procedures are effective and that sanitary conditions are maintained.

1. Initial Testing (i.e. baseline data collection)

When developing a sanitation program, the establishment should consider all factors that may have an impact on the program and address them when developing a Sanitation SOP. A microbiological baseline study may provide a starting point for such consideration. Baseline testing, while not required, is highly recommended as a means to develop criteria that can be used to evaluate the ongoing effectiveness of a LTD sanitation program. Using the criteria developed from the baseline study, ongoing microbial testing may be an effective means to demonstrate that all food contact surfaces are cleaned often enough to prevent the creation of insanitary conditions and adulteration of product.

If the establishment chooses not to conduct a baseline study, it may be difficult to demonstrate that the use of a LTD sanitation procedure will meet the sanitation regulatory requirements.

2. Microbiological Baseline Studies:

The regulations do not require baseline studies, nor are there any requirements for levels of testing in a baseline study. However, a baseline study can serve as a basis from which the establishment can determine the microbiological operating levels and limits for its facility under normal operating conditions.

A baseline study would include evaluating the establishment's sanitary conditions following "traditional" pre-operational and operational sanitation procedures before implementation of any changes in sanitation procedures or frequencies. The generation of baseline microbial data provides a mechanism that enables the establishment to determine where it started under normal operating conditions. The data then forms the basis for comparison of the alternative procedures to the "traditional" procedures. In establishments planning on implementing LTD sanitation procedures, baseline studies can provide information for the establishment to use to compare the efficacy of LTD sanitation procedures in controlling microbial levels to those of its traditional sanitation procedures. The establishment can use the data obtained from the traditional operations to develop acceptable tolerance levels that would become part of a statistical process control (SPC) monitoring program.

When designing a microbial sampling program, the establishment should survey its operation to determine what measurements of its process can provide an accurate assessment of overall sanitation. Because of the number of variables that could exist, adequate time should be taken to collect enough data to account for all the variables. Some attempt should be made to determine "worst case" scenarios. For example, a "worst case" scenario would consider:

- When to sample (e.g., at the end of the last production shift during the time of day or year when the ambient temperature is the hottest or most humid)

- Where to sample (e.g., areas on the equipment where microbial contamination is most likely to occur; are most likely to affect products; or most likely to harbor bacteria)

3. Baseline Study: Example

There is no required format for baseline studies. Establishments may develop baseline studies following the steps below:

1) Describe testing protocol
   a) Describe the focus of testing (for example)
   b) Aerobic Plate Count (APC)
   c) Total Plate Count (TPC)
2) Identify sample collection methodology
   a) Sponge
   b) Swab
   c) SpongeSicle
   d) Product
      i) Type (pre or post packaged as applicable)
      ii) Amount
3) Identify frequency of testing
   a) How many times per day or week or month
   b) How many pieces of equipment or product per test
4) Identify sample sites
5) Sampling of each identified food contact surface should be conducted using a statistically validated sampling plan so that adequate baseline data are collected for each food contact surface throughout the baseline study.
6) Randomized patterns for sampling each food contact surface are recommended.
7) Define any relevant measurements that are used by the establishment. For example:
   a) CFU/in^2
   b) CFU/cm^2
   c) CFU/g
8) Describe analysis of results
   a) Identify statistical methods
   b) Initial analysis
   c) On-going analysis
9) Describe comparison of microbial results (for example)
   a) Traditional daily sanitation vs. LTD sanitation
   b) Start of operation vs. end of operations
   c) Start of operations vs. during operations
   d) Comparison of results at different sample sites to determine most effective sites for ongoing monitoring
10) Determine operational limits
   a) sanitary vs. insanitary
11) Determine actions to be implemented when limits are exceeded
   a) Initial

b) On-going

4. On-going testing

Once the establishment determines the microbial conditions that exist under traditional operating conditions, it may decide to conduct on-going microbial testing as part of the LTD sanitation procedures. These data will enable the establishment to compare the initial baseline test results to the on-going test results in order to ensure that the procedure is effective over time. The establishment could then demonstrate that the alternative sanitation procedures are effective, and that product is not contaminated.

Ideally, the establishment has collected baseline data so that it knows the sanitation conditions under normal operational conditions. The establishment should conduct on-going testing after it makes the change to LTD sanitation procedures for comparison with the baseline results. This verification testing provides the establishment with an indication of continued success of the LTD sanitation procedures after initial implementation. In order to demonstrate the effectiveness of the sanitation procedures, the ongoing testing program should be designed to make comparisons with the baseline program.

- Ongoing testing should use methods that are the same as those used to collect baseline data

- Ongoing testing should use similar sample sites or a relevant subset, as the baseline sites

- Initially, ongoing testing should be conducted at a high frequency in order to demonstrate that the establishment is consistently maintaining sanitary conditions

Over time, if the data demonstrate that the program is effective, the establishment may be able to support a reduced sampling frequency.

C. ANALYSIS OF DATA

Demonstrating the ongoing effectiveness of alternate frequency sanitation procedures requires more than simply collecting raw data. The data should be meaningful (i.e., it 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). The establishment should consider what the data mean, and how they relate to the ongoing effectiveness of the sanitation procedures. Records should document that the results of the baseline study and ongoing testing (or other information) demonstrate compliance with sanitation requirements. Valid conclusions can only be made if the establishment has adequately developed and implemented the design of their cleanup program.

1. Initial (i.e. baseline or pre-implementation data):

The establishment should analyze its findings in order to establish the effectiveness of its LTD sanitation procedures. Establishments should gather the information and data and put them together in a clear concise format that ties all the information together. Ultimately, the establishment's records should show that it is maintaining sanitary conditions, and that product is not contaminated or adulterated.

2. Ongoing (data collected once procedure implemented):

It is very important that the establishment compare the data collected during ongoing testing to the initial baseline data. The data analysis should demonstrate that, over time, after the procedures have been implemented, microbial levels on equipment are no higher than the baseline levels obtained before the implementation of the new procedures. The comparison of these data should consider general trends over an extended period of time. While small daily variations may be insignificant and are to be expected, the data analysis should demonstrate that over time, microbial levels on equipment have not increased (i.e. are not statistically significant) because of the implementing of the new procedures. The establishment should monitor microbial levels on equipment surfaces as a means of demonstrating that the new procedures are effective. Ultimately, the indicator of success in the use of the procedures of this type is an establishment's ability to demonstrate, by means of data or other documentation, the continual effectiveness of the new procedures and frequencies to maintain sanitary conditions and prevent direct contamination or adulteration of product.

D. MAINTAINING THE SANITATION SOP (9 CFR 416.14)

Regardless of where establishments choose to incorporate their LTD sanitation procedures (Sanitation SOP, GMP or other prerequisite program), 9 CFR 416.14 requires that establishments maintain their Sanitation SOP and ensure that it continues to be effective. The establishment needs to routinely evaluate the effectiveness of the Sanitation SOP as a means to ensure that the procedures and frequencies continue to prevent the contamination or adulteration of product. There are no regulations that specify how an establishment is to determine whether the Sanitation SOP is effective. Typically, the establishment will periodically review Sanitation SOP records to evaluate the effectiveness of the Sanitation SOP. As previously stated, microbial testing is not a regulatory requirement in Sanitation SOPs; however, it can be one means used by an establishment to demonstrate the effectiveness of its sanitation program. In the absence of microbial data to support the baseline or ongoing testing, the establishment would need to provide other records to document sanitary effectiveness.

Ideally, an establishment's comparison of microbial testing data should indicate that the microbial levels in the facility resulting from the use of the LTD sanitation procedures are the same as, or lower, than those resulting from the use of the establishment's traditional sanitation procedures and frequencies.

If the data show that the microbial levels associated with the LTD sanitation program are significantly higher than those of the traditional program, the efficacy of the program in preventing product contamination or adulteration would be in question.

An establishment would want to review as many available establishment records as possible, including FSIS Noncompliance Records (NR), in order to provide a basis that would assure the establishment that the Sanitation SOP is effective. However, the establishment should not claim that the lack of FSIS NRs demonstrate that the Sanitation SOP is effective. NRs address specific regulatory noncompliances. The absence of NRs provides little assurance of the overall efficacy of the establishment's sanitation procedures and frequencies in preventing product contamination or adulteration.

The most important aspect of the evaluation of the Sanitation SOP is that when the establishment determines that there are issues of concern, it responds to those issues. Operations within an establishment rarely remain unchanged. Without periodic adjustments to the Sanitation SOP, or any sanitation related program, it may be difficult to demonstrate that the procedures in place continue to prevent the contamination or adulteration of product.

The following is a summary of what an establishment may do to ensure that the Sanitation SOP remains effective:

1) Routinely review and evaluate the Sanitation SOP as required in 416.14 (i.e., not simply when FSIS suggests it)
    a) Evaluate Sanitation SOP records and consider what did or did not work
        i) Evaluate monitoring procedures and frequencies and consider if they are working
        ii) Evaluate previous corrective actions
            (1) Consider if they have been fully implemented and effective
            (2) Consider if or how they could be improved
    b) Consider whether the Sanitation SOP procedures have prevented the contamination or adulteration of product (e.g., have there been situations where contamination or adulteration of product, or contamination of food contact surfaces occurred?)
    c) Review the results of any microbiological testing and consider whether those results reflect an environment that will not contaminate or adulterate product
    d) Review any SOP, GMP or prerequisite sanitation related programs that are in use and consider what effect they appear to be having on the Sanitation SOP (e.g., have they been implemented as written? Does their implementation help ensure that product is not contaminated or adulterated?)
        i) Employee Hygiene
        ii) Employee Training
        iii) Product Reconditioning
2) Revise Sanitation SOPs as often as necessary. Sign and date the Sanitation SOP if changes are made (9 CFR 416.12(b))

E. DOCUMENTATION DEMONSTRATING THE EFFECTIVENESS OF THE SANITATION SOP AND LESS THAN DAILY SANITATION PROCEDURES

FSIS believes that sanitation is, as addressed in the Pathogen Reduction/HACCP Final Rule (Federal Register, Thursday July 26, 1996, Page 38805 – 38855), essential for food safety, and that sanitary facilities or equipment create an environment suitable to prevent the contamination or adulteration of products. As a result, establishments are required to develop Sanitation SOPs as a prerequisite to effective operation of their food safety system and as a means to minimize the risk of direct product contamination and adulteration.

Documentation related to the implementation of the Sanitation SOP, as required by 9 CFR 416.16, provides verifiable evidence that the establishment's Sanitation SOP is effective at maintaining sanitary conditions, which prevents the adulteration of product. The establishment is required to maintain records associated with the implementation of the Sanitation SOP. If the LTD sanitation procedures are part of the Sanitation SOP, then the records generated by the implementation of the Sanitation SOP, and all the procedure therein, are subject to FSIS review under 9 CFR 416.17.

Because the Sanitation SOP and any additional sanitation programs are a prerequisite to food safety, it is essential that documentation be available to demonstrate that these programs are achieving their goals, and that establishments are verifying that the implementation of these programs continue to support any decisions related to food safety. FSIS will review those records in order to verify that the establishment is implementing the program as written and that it is effective.

F. ADDRESSING NONCOMPLIANCES

The LTD sanitation procedure should include the means by which the establishment will address noncompliances. If the LTD sanitation procedure is incorporated into the Sanitation SOP, the establishment would be expected to implement corrective actions in accordance with 9 CFR 416.15.