

Cleaning Frequency Questions and Answers

1. May establishments operate without daily clean-up?

Yes, there is no specific requirement in 9 CFR Part 416 that an establishment must conduct a clean-up at least daily. To decrease downtime, increase production efficiency, and minimize expense, establishments can extend the period between clean-ups. However, establishments must comply with 9 CFR 416.11, which requires that plants develop, implement, and maintain written standard operating procedures for sanitation, and with 9 CFR 416.14, which requires that those Sanitation SOPs be effective in preventing direct contamination or adulteration of product. Establishments, particularly those that are operating with extended periods between clean-ups, must ensure that their Sanitation SOPs are effective in meeting these requirements of the regulations, and FSIS will verify that the establishments are doing so.

2. What factors should an establishment consider in deciding whether less than daily clean-ups can be employed in its operation?

When developing a sanitation program, an establishment should consider operational characteristics that may have an impact on sanitary conditions. These characteristics should be considered in developing a Sanitation SOP that supports alternative clean-up procedures and frequencies. For example, an establishment may be able to reuse cooking trees more than once without cleaning them between uses. The operational characteristics that would support that cleaning between uses is unnecessary are the facts that the product is in casings, that there is no accumulation of product on the trees that transfers to product, and that microbial data have been collected on the condition of the trees between uses to establish a baseline. The establishment collects microbial data on the trees that do not receive sanitation between uses, and these data show that the condition of the trees is comparable to the baseline.

The operational characteristics, along with associated operational sanitation procedures, will affect microbial growth in certain areas on equipment and this will affect how much flexibility an establishment has to employ for alternative cleaning procedures and frequencies. The establishment should always carefully consider the potential for product contamination or adulteration before implementing alternative procedures.

Most importantly, attention to these characteristics does not relieve the establishment from its paramount responsibility of developing procedures that will prevent conditions from developing in the establishment that will cause contamination or otherwise create the possibility of product adulteration. Establishments must maintain sanitary conditions throughout their operation. Without a sanitary environment, product contamination becomes likely.

For example, Agency inspectors must be able to find that product is not adulterated to provide the mark of inspection. If they are unable to do so because they have questions as to whether the processing environment is sanitary, they may find it appropriate to withhold the mark of inspection under 9 CFR 500.4 (Rules of Practice).

3. How should an establishment go about deciding whether less than daily clean-ups are appropriate for its operation?

Because of the variety of parameters involved in a typical operation, the establishment should consider the conditions, particularly microbial conditions, of its entire operation. A microbiological baseline study may provide a starting point for such consideration.

There are no regulations requiring a baseline study, nor are there any requirements for levels of testing in a baseline study. However, a baseline study can serve as a starting point to provide the establishment with a basis on which to determine the microbiological operating levels/limits for its facility under normal operating conditions, including the establishment's preoperational and operational sanitation conditions before implementation of any changes in procedures or frequency. The generation of baseline microbial data provides a mechanism that enables the establishment to determine where it started from under normal operating conditions. That data then forms the basis for comparison of alternative clean-up procedures and frequencies to that of traditional procedures and frequencies, that is, at least daily. If the establishment is planning on implementing less than daily clean-up, baseline studies can provide information for the establishment to use to compare the efficacy of alternative sanitation procedures and frequencies in controlling microbial levels to those of their traditional sanitation procedures and frequencies. The data obtained for the establishment's traditional operations might, for example, be used to develop acceptable tolerance levels that would be a component of a statistical process control monitoring program.

If the data show that the microbial levels associated with the alternative sanitation program are higher than those of the normal/traditional program, the efficacy of the alternative program in preventing product contamination or adulteration would be in question. Consequently, a comprehensive baseline study may be the best means an establishment can use as a starting point to demonstrate the Sanitation SOPs' effectiveness for less than daily cleanup.

If the establishment chooses not to conduct a baseline study, it may have difficulty demonstrating that it is maintaining sanitary conditions. Although a baseline study is the method of choice, it is not required. Establishments that do not perform a baseline study will need to demonstrate that their alternative cleaning procedures and frequencies meet Sanitation SOP regulatory requirements.

Once the establishment determines its microbial conditions under traditional operating conditions, it may decide to conduct on-going microbial testing (verification testing) under their alternative cleaning procedures and frequencies in order to ensure that its alternative procedures are effective over time.

4. If an establishment decides to conduct a baseline study, how would it develop

one?

- Describe testing protocol
- Describe the focus of testing (for example)
 - Aerobic Plate Count (APC)
 - Coliforms
- Identify sample collection methodology
 - Equipment
 - Sponge
 - Swab
 - SpongeSicle
 - Product
 - Type (pre or post packaged as applicable)
 - Amount
- Identify frequency of testing
 - How many times per day/week/month
 - How many pieces of equipment/product per test
- Identify sample sites
- Identify site selection method
 - Sampling of each food contact surface should be done using a statistically validated sampling plan so that adequate baseline data is collected for each food contact surface throughout the baseline study. (Randomized patterns for sampling each food contact surface are recommended.)
- Define any relevant measurements
 - CFU/in²
 - CFU/cm²
 - CFU/g
- Describe analysis of results
 - Identify statistical methods
- Describe comparison of microbial results (for example)
 - Alternative cleaning vs. traditional
 - Start of operation vs. end of operations
 - Product vs. food contact surfaces
- Determine operational limits
 - Sanitary vs. insanitary

5. How would an establishment use the results of such a study in establishing that less than daily clean-up is appropriate?

The data from the study would need to demonstrate that microbial levels on equipment when the alternative frequency is employed are no higher than the baseline levels before implementation of the new alternative sanitation procedures and frequencies. The comparison of these data should be on the basis of general trends over extended periods 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 do not increase when the alternative sanitation procedures and frequencies are used. The establishment should monitor microbial levels on equipment surfaces as a means of demonstrating that the alternative sanitation procedures and frequencies are effective. Ultimately, the indicator of success in the use of the alternative sanitation procedures and frequencies is a prudent establishment's ability to demonstrate the continual effectiveness of the alternative sanitation procedures and frequencies.

6. Once an establishment decides that it can perform less than daily clean-up, what are its obligations?

Compliance with Sanitation SOP regulations is necessary if an establishment is to prevent direct contamination or adulteration of product.

In addition to the regulations requiring the establishment to maintain records documenting the implementation and monitoring of the Sanitation SOP and any corrective actions, FSIS would expect an establishment to maintain records and documentation that the Sanitation SOP and the procedures and frequencies specified therein, are and continue to be as effective as traditional cleaning. FSIS also expects that establishments employing alternative clean-up procedures will routinely evaluate the effectiveness of the Sanitation SOP (9 CFR 416.14) at a frequency adequate to prevent direct product contamination or adulteration.

Alternative procedures and frequencies for sanitation do not relieve the establishment of the responsibility to maintain sanitary operations. For example, the establishment should take measures to prevent an accumulation of product residue or fat on the equipment. If substances such as these are permitted to accumulate to the point that insanitary conditions occur (e.g., there is a visible and substantial transfer of the residue or fat onto product), the product can be deemed adulterated with filth under the conditions of the FMIA and the PPIA.

If an establishment's rationale for alternative sanitation procedures and frequencies is that the room is being maintained at a certain temperature, the documentation should be adequate to demonstrate that the room is in fact maintained at that temperature. If no monitoring frequency is specified in the Sanitation SOP, 9 CFR 416.13(c) requires the procedures to be monitored daily. 9 CFR 416.16 requires that the establishment maintain records daily sufficient to document the implementation and monitoring of the Sanitation SOPs. If the monitoring is not conducted at the frequency specified in the Sanitation SOPs, there is noncompliance with 9 CFR 416.13(c).

8. How will FSIS verify that an establishment is meeting its obligation?

Regulatory provisions for Agency verification of SOP adequacy and effectiveness are in 9 CFR Part 416.17. FSIS will verify that each establishment that employs alternative clean-up procedures is evaluating the effectiveness of the Sanitation SOP (9 CFR 416.14) at a frequency adequate to prevent direct product contamination or adulteration. Establishments employing alternative clean-up procedures should make available to FSIS personnel all documents demonstrating the on-going effectiveness of the Sanitation SOP.

Summary

There are no specific regulatory requirements for time intervals between plant clean-up procedures. Establishments may choose to extend clean-up frequencies if they can demonstrate that the alternative sanitary procedures are adequate to prevent the creation of insanitary conditions and the contamination and adulteration of product. The regulatory requirements in 9 CFR part 416 must be met (i.e. development, implementation, maintenance of an Sanitation SOP, corrective actions if necessary, and recordkeeping). FSIS expects prudent establishments to maintain records and documentation supporting the rationale for their Sanitation SOPs and the procedures and frequencies specified therein.