Sanitation Standard Operating Procedures

Sanitation Standard Operating Procedures (Sanitation SOPs) are **written** procedures that an establishment develops and implements to **prevent direct contamination or adulteration of product**. The establishment is required to maintain these written procedures on file, and they must be available to FSIS upon request. It is the establishment's responsibility to implement the procedures as they are written in the Sanitation SOPs. The establishment must maintain **daily records** sufficient to **document the implementation and monitoring of the Sanitation SOPs** and any corrective action taken. When the establishment or FSIS determines that the Sanitation SOPs may have failed to prevent direct contamination or adulteration of product, the establishment must implement **corrective actions** that include the appropriate disposition of product, restore sanitary conditions, and develop measures to prevent recurrence.

SSOP plan must:

- contain all the procedures the establishment will conduct daily, before and during operation
- identify the procedures to be conducted prior to operations (pre-op) and address the cleaning of food contact surfaces
- specify the frequency
- identify the establishment employee or position responsible
- be signed and dated by a high-level official of the establishment
- keep daily records of implementation and monitoring SSOP's
- plant management should routinely evaluate the procedures for effectiveness

Ref: 5000.4 Rev. 2 Performing the Pre-Operational Sanitation Standard Operating Procedures Verification Task

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PART 416.11-17 - SANITATION STANDARD OPERATING PROCEDURES – SSOP's

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§ 416.11 General rules

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

§ 416.12 Development of Sanitation SOP's

(**a**) The Sanitation SOP's shall describe all **procedures** an official establishment will conduct daily, **before and during operations**, sufficient to prevent direct contamination or adulteration of product(s).

(**b**) The Sanitation SOP's shall be **signed and dated** by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.

(**c**) Procedures in the Sanitation SOP's that are to be conducted **prior to operations** shall be identified as such, and shall address, at a minimum, the **cleaning of food contact** surfaces of facilities, equipment, and utensils.

(**d**) The Sanitation SOP's shall specify the **frequency** with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

§ 416.13 Implementation of SOP's

(**a**) Each official establishment shall conduct the **pre-operational procedures** in the Sanitation SOP's before the start of operations.

(**b**) Each official establishment shall conduct all **other procedures** in the Sanitation SOP's at the frequencies specified.

(**c**) Each official establishment shall **monitor daily** the implementation of the procedures in the Sanitation SOP's.

§ 416.14 Maintenance of Sanitation SOP's

Each official establishment shall **routinely evaluate** the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

§ 416.15 Corrective Actions

(**a**) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have **failed to prevent direct contamination** or adulteration of product(s).

(**b**) Corrective actions include procedures to ensure appropriate **disposition of product**(s) that may be contaminated, **restore sanitary** conditions, and **prevent the recurrence** of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

§ 416.16 Recordkeeping requirements

(**a**) Each official establishment shall **maintain daily records** sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(**b**) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the **integrity of the electronic data**.

(**c**) Records required by this part shall be maintained for at least **6 months** and made accesable available to FSIS. All such records shall be maintained at the official establishment for **48 hours** following completion, after

which they may be maintained off-site provided such records can be made available to FSIS **within 24 hours of request**.

§ 416.17 Agency verification

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

(**a**) Reviewing the Sanitation SOP's;

(**b**) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(**c**) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(**d**) Direct observation or testing to assess the sanitary conditions in the establishment.

In reference to **custom exempt operations**…

The regulations require that any time custom operations are conducted in an official establishment, all of the provisions of 9 CFR Part 416 (**Sanitation**) must apply to those operations (9 CFR 303.1(a)(2)(i)). Establishments operating under custom exemption also are required to **document the implementation and monitoring** of the Sanitation SOPs and any **corrective actions** required (9 CFR 416.16(a)). These records must be maintained and be available to LDAF (9 CFR 416.16(c)).

FSIS Directive 5930.1 Revision 4 - SSOP **Recordkeeping Requirements in Custom Exempt** Operations states…

When IPP observe a noncompliance with Sanitation SOP recordkeeping requirements in custom exempt operations, they should discuss the issue with plant management during the next weekly meeting and document the discussion on a Memorandum of Interview. Inspection personnel should document that they informed plant management that they must meet Sanitation SOP recordkeeping requirements during custom operations. If the plant continues not to meet Sanitation SOP regulatory requirements, inspection personnel should notify their Supervisor. The Supervisor may elect to schedule a review of the custom exempt operation. Inspection personnel will document Sanitation SOP recordkeeping noncompliance on the Custom Exempt review form when directed to conduct an official custom exempt review.