

## **01B01 Procedure**

The 01B01 SSOP procedure is the pre-operational recordkeeping procedure. This recordkeeping procedure instructs you to review the daily documentation of the establishment's implementation and monitoring of the SSOP pre-operational procedures and any required corrective actions.

You should review the SSOP to become familiar with the pre-operational sanitation procedures. When you perform the 01B01 procedure, you are reviewing the daily pre-operational sanitation records. This procedure should be performed to verify that the establishment has daily records that demonstrate the establishment has implemented the pre-operational procedures, monitored those procedures, and taken corrective actions when necessary. You should also verify that the establishment employee responsible for the implementation and monitoring has authenticated the daily records with his or her initials and the date.

You should review the SSOP prior to beginning the review of the records to ensure that it has not been modified since you last reviewed it and that you are familiar with the pre-operational sanitation procedures. When performing the recordkeeping procedure for pre-operational sanitation, you should be reviewing the records to determine if the establishment is complying with the regulatory requirements.

You should be looking at the records to verify that the monitoring is conducted daily prior to the start of operations. You should review the records to verify that each time the establishment documents that direct contact surfaces are found to be unclean or contaminated product is observed, there are corrective actions documented that meet the requirements of §416.15. You should ensure that the corrective actions implemented and documented are adequate to: 1) ensure appropriate disposition of product, if necessary; 2) restore sanitary conditions; and 3) prevent recurrence. While reviewing the pre-operational sanitation records, you should also verify that the establishment employee responsible for the implementation or monitoring has authenticated the records with initials and date.

If the establishment has not recorded its monitoring activities, has not recorded corrective actions, or when product or direct contact surfaces contamination is observed, or has not initialed and dated the daily record for authentication, there is noncompliance.