

SOP Template: Corrective Actions for Inadequate Cleaning or Contamination

This SOP details the **corrective actions for inadequate cleaning or contamination**, outlining steps to identify contamination sources, implement proper cleaning protocols, verify cleaning effectiveness, and prevent recurrence. It emphasizes timely response, documentation, staff training, and continuous monitoring to maintain hygiene standards and ensure product safety.

1. Purpose

To outline the procedure for responding to inadequate cleaning or contamination in order to maintain hygiene standards and ensure product safety.

2. Scope

This SOP applies to all personnel responsible for cleaning, sanitation, and quality assurance.

3. Responsibilities

- **Cleaning Staff:** Execute cleaning procedures and report inadequacies or contamination.
- **Supervisors:** Oversee corrective actions, verification, and staff retraining.
- **Quality Assurance:** Approve corrective actions and monitor effectiveness.

4. Procedure

1. **Immediate Response**
 - Cease operations in affected area to prevent further contamination.
 - Isolate or quarantine contaminated products/equipment as necessary.
 - Notify supervisor and relevant personnel immediately.
2. **Identify Source(s) of Contamination**
 - Conduct inspection to determine the cause (e.g., equipment failure, human error, ineffective cleaning agents).
 - Collect samples for microbiological or chemical analysis if required.
3. **Implement Corrective Cleaning Protocols**
 - Repeat or intensify cleaning of affected areas with approved agents and methods.
 - Disassemble equipment if necessary for thorough cleaning.
4. **Verification of Cleaning Effectiveness**
 - Perform visual inspection and/or sampling to confirm cleanliness.
 - Document results in cleaning records.
5. **Prevent Recurrence**
 - Review and update cleaning SOPs as needed.
 - Retrain staff on proper cleaning procedures.
 - Enhance monitoring and frequency of inspections.
6. **Documentation**
 - Record all corrective actions taken, verification results, and involved personnel.
 - Submit incident and corrective action reports to management and QA.

5. Record Keeping

- Maintain logs of cleaning procedures, incidents, and corrective actions.
- Ensure records are readily accessible for audits and reviews.

6. Training

- All cleaning staff must undergo initial and periodic retraining.
- Training should include recognition of contamination, effective cleaning methods, and documentation practices.

7. References

- Internal Cleaning and Sanitation Procedures

- Regulatory Guidelines (e.g., FDA, GMP, ISO standards)

8. Revision History

| Revision # | Date | Description of Change | Approved By |
|------------|------------|------------------------------|-----------------|
| 01 | 2024-06-27 | Initial SOP template issued. | Quality Manager |