

SOP Template: Record-keeping and Traceability of Sterilized Equipment

This SOP defines the **record-keeping and traceability of sterilized equipment**, detailing procedures for documenting sterilization processes, maintaining accurate logs of equipment used, tracking sterilization dates and methods, ensuring equipment traceability from sterilization to usage, and implementing audit trails for quality control. The goal is to maintain high standards of hygiene, ensure compliance with regulatory requirements, and enable timely identification and correction of any sterilization failures.

1. Purpose

To establish standardized procedures for maintaining accurate and complete records, ensuring traceability of all sterilized equipment, and supporting quality control and regulatory compliance.

2. Scope

This SOP applies to all staff involved in the cleaning, sterilization, storage, distribution, and use of equipment requiring sterilization in the facility.

3. Responsibilities

- **Sterilization Technician:** Perform sterilization, complete records, and affix traceability labels.
- **Supervisors/Managers:** Verify completeness and accuracy of records and conduct periodic audits.
- **Users:** Confirm and record equipment use, report anomalies and document traceability numbers.
- **Quality Assurance:** Audit traceability and record-keeping procedures, initiate corrective actions if deficiencies are identified.

4. Procedures

4.1 Documentation of Sterilization

- Document sterilization cycle parameters for each batch (date, time, operator, equipment ID, load contents, cycle number, method, lot number).
- Record physical and chemical indicator results.
- Affix a unique traceability label or barcode to each sterilized item or tray.

4.2 Equipment Log Maintenance

- Maintain electronic and/or paper logs for each piece of sterilized equipment.
- Include the following details:
 - Equipment identification number/item code
 - Sterilization date and time
 - Sterilization method and parameters
 - Operator's initials/signature
 - Traceability number or lot/batch code
 - Expiration/re-sterilization due date

4.3 Traceability from Sterilization to Usage

- Ensure equipment is distributed with intact traceability label.
- At point of use, record the traceability number, user/department, and date/time of usage in the equipment usage log.
- Log any adverse events, malfunctions, or sterilization failures associated with traced equipment.

4.4 Audit Trail Implementation

- Periodic review of equipment sterilization and usage records by Quality Assurance personnel.
- Maintain an archive of records for the retention period specified by regulatory guidelines (e.g., 3-7 years).
- Document and investigate any record discrepancies or reported failures. Initiate corrective actions as required.

5. Record-Keeping Template (Sample Log Table)

Date	Equipment ID	Sterilization Method	Cycle/Lot No.	Operator	Traceability/Label No.	Expiry/Re-sterilization Date	Distributed To	Usage Date & User	Comments
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2024-06-20	EQ-1234	Autoclave	AC-3321	J. Smith	TRC-20240620-01	2024-07-20	OR1	2024-06-25 / Dr. Lee	-
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6. References

- Regulatory Guidelines (local/ISO/CDC/WHO)
- Facility Infection Control Policy

7. Revision History

Date	Version	Summary of Changes	Approved By
2024-06-20	1.0	Initial SOP issuance	QA Manager