# SOP: Sterilization Cycle Monitoring and Documentation

This SOP details the procedures for **sterilization cycle monitoring and documentation**, ensuring all sterilization processes are accurately tracked and verified for effectiveness. It includes guidelines for routine monitoring of sterilization equipment parameters, recording cycle data, identifying deviations or failures, corrective actions, and maintaining comprehensive records for compliance and quality assurance. The goal is to guarantee the sterility of instruments and materials used in clinical and laboratory settings, thereby ensuring patient safety and regulatory adherence.

## 1. Purpose

To outline the standardized procedures for monitoring, documenting, and reviewing sterilization cycles in order to ensure the sterility of equipment and materials.

## 2. Scope

Applicable to all personnel involved in the operation, monitoring, and documentation of sterilization processes in clinical and laboratory environments.

## 3. Responsibilities

- **Operators:** Perform and document sterilization cycles. Monitor parameters and record deviations.
- **Supervisors/Managers:** Review records, investigate deviations, implement corrective actions, and ensure compliance.
- **Quality Assurance:** Audit records and verify ongoing effectiveness of sterilization procedures.

## 4. Procedure

1. **Before Cycle:**
    - Verify that the sterilizer is clean, loaded correctly, and that biological/chemical indicators are included as required.
    - Record initial information in the Sterilization Log (see Section 6).
2. **During Cycle Monitoring:**
    - Continuously monitor and document key parameters (e.g., temperature, pressure, time).
    - Check for alarm signals or indicator color changes.
3. **After Cycle Completion:**
    - Document final cycle parameters (time completed, cycle type, operator initials).
    - Remove, check, and record results from biological and chemical indicators.
    - Visually inspect load for any signs of process failure (e.g., wet packs, torn wrappers).
4. **Deviations/Violations:**
    - If cycle parameters are out of specification or indicators fail, document the deviation and notify supervisor immediately.
    - Isolate and label affected load â€œDo Not Useâ€ pending review.
5. **Corrective Actions:**
    - Identify root cause and perform corrective actions (e.g., reprocessing, equipment maintenance).
    - Document corrective measures in the record.

## 5. Documentation & Record Keeping

- All sterilization cycles must be documented in a dedicated log (electronic or paper-based).
- Records must be retained for a minimum period as per local policy/regulations (e.g., 3-5 years).
- Include cycles that fail or are aborted, along with corresponding investigations.
- Audit records regularly for completeness and accuracy.

## 6. Sterilization Log Template

| Date | Equipment ID | Cycle Type | Load Contents | Start Time | End Time | Parameters (Temp/Pressure/Time) | Indicator Results | Operator Initials | Deviations | Corrective Actions | Supervisor Review |
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## 7. References

- Manufacturer's instructions for sterilization equipment
- Applicable regulatory and accreditation standards (e.g., CDC, WHO, ISO 17665-1)
- Institutional policies and procedures

## 8. Revision History

| Version | Date | Summary of Changes | Approved By |
|---|---|---|---|
| 1.0 | 2024-06-01 | Initial SOP release | |