SOP: Monitoring and Validation of Sterilization Process (Biological/Chemical Indicators)

Purpose

This SOP defines the procedures for **monitoring and validation of the sterilization process** using biological and chemical indicators to ensure the effectiveness of sterilization cycles. It includes guidelines for the selection, placement, and interpretation of biological indicators to detect viable microorganisms, as well as chemical indicators that signal exposure to sterilizing agents. The purpose is to maintain strict sterilization standards, ensure patient safety, and comply with regulatory requirements by consistently verifying sterilizer performance and validating sterilization efficacy.

Scope

This procedure applies to all personnel responsible for loading, operating, and monitoring sterilization equipment within the facility.

Responsibilities

- Sterile processing staff: Preparation, placement, and documentation of indicators.
- Supervisors: Review of records and validation of process adherence.
- Quality assurance: Investigation and resolution of failed cycles; regulatory compliance.

Definitions

- **Biological Indicator (BI):** A standardized test system containing viable microorganisms to assess sterilization efficacy.
- **Chemical Indicator (CI):** A device that changes color or form when exposed to physical conditions required for sterilization.

Procedure

1. **Selection of Indicators**
    - Choose BIs appropriate for the sterilization method (e.g., steam, ethylene oxide, dry heat).
    - Select external and internal CIs as per sterilization load requirements.
2. **Placement of Indicators**
    - Place BIs in the most challenging location(s) within the load for sterilant penetration (e.g., densest pack, center of load).
    - Include an internal CI in every pack, tray, or peel pouch.
    - Affix an external CI to the outside of each item, where applicable.
3. **Running the Sterilization Cycle**
    - Operate sterilizer according to manufacturer instructions.
    - Document cycle parameters and cycle identification in the sterilization log.
4. **Interpretation of Results**
    - For Chemical Indicators:
      â€¢ External CIs must indicate exposure before items are distributed.
      â€¢ Internal CIs must reflect all critical process variables achieved.
    - For Biological Indicators:
      â€¢ Incubate BIs immediately after the cycle as per manufacturer protocol.
      â€¢ Interpret and record BI results (no growth = pass; growth = fail).
5. **Documentation**
    - Record all CI and BI results, cycle data, and any corrective actions in the sterilization logbook or electronic record.
6. **Response to Failed Indicators**
    - Quarantine all affected items.
    - Notify supervisor/QA.
    - Investigate root cause and repeat sterilization if necessary.

Frequency

- BIs: Use at minimum weekly or per load containing implantable devices.
- CIs: Use with every sterilization pack/load.

Records and Retention

- All records must be retained in compliance with local regulatory and facility guidelines (minimum two years recommended).

References

- Manufacturer's instructions for sterilizer and indicators
- CDC Guidelines for Disinfection and Sterilization
- ISO 11138 (Biological Indicators standards)

Revision History

Date	Version	Change Description	Author/Approver
2024-06-05	1.0	Initial SOP Release	QA Manager