POLICY ON REGULAR VALIDATION TESTS FOR STERILIZATION ARE CARRIEDOUT AND DOCUMENTED

1.0 Purpose

The purpose of this policy is to ensure that all sterilization processes conducted within the facility are consistently effective, reliable, and compliant with national and international standards. This policy establishes the requirements for performing **regular validation tests**, monitoring sterilizer performance, and ensuring complete documentation.

2.0 Scope

This policy applies to:

- All sterilization equipment (e.g., steam sterilizers/autoclaves, dry heat sterilizers, low-temperature sterilizers).
- All staff involved in sterilization processes, including Central Sterile Services Department (CSSD), operating theatre staff, and Infection Prevention and Control Team (IPCT).

3.0 Policy Statement

The facility is committed to ensuring that sterilization processes are validated, monitored, and documented through routine biological, chemical, and mechanical testing.

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Infection Control Officer	Medical Director	Chief executive Officer

No sterilizer shall be used for patient care unless it has passed required validation tests. All test results must be recorded, reviewed, and retained.

4.0 Definitions

- **Validation Testing**: Procedures to ensure that a sterilizer is functioning correctly and effectively.
- **Biological Indicator (BI)**: A test containing highly resistant microorganisms (e.g., *Geobacillus stearothermophilus*) to verify sterilization efficacy.
- **Chemical Indicator (CI)**: A device that changes color when exposed to sterilization parameters.
- **Mechanical Monitoring**: Verification of sterilizer cycle parameters (time, temperature, pressure).

5.0 Responsibilities

5.1 CSSD/Assigned Sterilization Staff

- Conduct validation tests for each sterilizer as required.
- Ensure proper loading, packaging, and placement of test packs.
- Record and report all test results immediately.
- Remove sterilizers from service if validation tests fail.

5.2 Infection Prevention and Control Team (IPCT)

- Oversee compliance with validation testing procedures.
- Audit sterilization records and investigate failures.
- Provide training and updates to staff.

5.3 Facility Management

- Ensure availability of testing materials (BIs, CIs, logs, equipment).
- Support equipment servicing, calibration, and repairs.

6.0 Required Validation Tests

6.1 Daily Tests

- **Mechanical Monitoring**: Verify and record cycle parameters for each sterilization load.
- **Chemical Indicators**:
  - Internal and external CIs must be used for every pack.
  - Bowie-Dick test for steam sterilizers (pre-vacuum type), performed **daily before first load**.

6.2 Weekly Tests

- **Biological Indicator (BI)** test for each steam sterilizer at least once per week, or more frequently depending on risk level or manufacturer guidelines.
- BI test shall include a control indicator.

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6.3 Monthly and Periodic Validation

- Full sterilizer validation by qualified personnel (engineers or certified technicians), including:
  - Temperature uniformity testing
  - Penetration tests
  - Calibration of gauges
  - Performance qualification checks

6.4 After Repairs or Relocation

- Complete revalidation must be performed after:
  - Major repairs
  - Replacement of critical components
  - Sterilizer relocation
  - Failure of any BI, CI, or mechanical parameter

Sterilizers must not return to service until they pass validation.

7.0 Non-Compliance and Corrective Actions

- If any validation test fails, the sterilizer must be **immediately removed from service**.
- All loads processed since the last passed test must be **quarantined** and reprocessed after repairs.

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- Investigation must be conducted by CSSD and IPCT, and findings documented.
- Revalidation is mandatory before returning sterilizer to service.