SOP: Sterilization Methods and Cycle Parameters

This SOP details the **sterilization methods and cycle parameters** essential for achieving and maintaining aseptic conditions in laboratory and clinical settings. It includes descriptions of various sterilization techniques such as autoclaving, dry heat, chemical sterilization, and gas sterilization, along with the critical parameters like temperature, pressure, exposure time, and humidity. The procedure ensures that all instruments, equipment, and materials are properly sterilized to prevent contamination, ensuring safety, compliance, and reliability in microbiological and medical processes.

1. Purpose

To describe standardized procedures for sterilizing instruments, equipment, and materials using appropriate methods and cycle parameters to maintain aseptic conditions.

2. Scope

This SOP applies to all laboratory and clinical staff performing sterilization of instruments, glassware, media, and other materials within the facility.

3. Responsibilities

- Ensure proper operation and maintenance of sterilization equipment.
- Verify cycle parameters before use.
- Document all sterilization activities.
- Report malfunctions or deviations promptly.

4. Sterilization Methods and Cycle Parameters

Method	Description	Key Parameters	Typical Cycle Parameters	Notes
Autoclaving (Steam)	Uses pressurized steam to achieve sterilization.	Temperature, Pressure, Exposure Time	121Â°C at 15 psi for 15â€“20 min 134Â°C at 30 psi for 3â€–5 min (flash)	Most reliable for heat-stable items.
Dry Heat	Sterilizes by oxidation at high temperatures.	Temperature, Exposure Time	160Â°C for 2 hrs 170Â°C for 1 hr	Suitable for glassware, metal instruments.
Chemical Sterilization	Uses chemical agents (e.g., ethylene oxide, hydrogen peroxide vapor).	Chemical Concentration, Temperature, Humidity, Exposure Time	Ethylene oxide: 450â€“1200 mg/L at 37â€–63Â°C for 2â€–5 hrs, humidity 40-80% H_2O_2 vapor: as per manufacturer	Good for heat/moisture-sensitive items.
Gas Plasma	Uses low-temperature hydrogen peroxide plasma.	Plasma Concentration, Temperature, Exposure Time	45â€–50Â°C for 45â€–75 minutes	Non-toxic residues; not for cellulose items.
Radiation	Uses gamma rays or electron beams.	Radiation Dose, Exposure Time	Typically 25 kGy	Industrial applications only.

5. Procedure

1. Select appropriate sterilization method based on material compatibility and intended use.
2. Set cycle parameters according to the table above or manufacturer's recommendations.
3. Load instruments/materials appropriately to allow steam/agent circulation.
4. Start the cycle, monitor parameters throughout the process.
5. Upon completion, verify cycle completion and sterility indicators (chemical/biological).
6. Document cycle parameters and outcomes.

6. Documentation

- Record:
  - Date and time
  - Equipment used
  - Cycle parameters
  - Operator name
  - Verification results

7. References

- WHO Laboratory Biosafety Manual
- Manufacturer's Equipment Manuals
- CDC Guidelines for Disinfection and Sterilization

8. Revision History

Version	Date	Description	Author
1.0	2024-06-26	Initial release	ChatGPT