



University of Maryland College Park Animal Care and Use Standard

Confirming Function of Steam Autoclaves and Bulk Sterilizers

[Note: **Units must coordinate with Facilities Management (fmrcr@umd.edu) and the Department of Environmental Safety, Sustainability and Risk (ESSR) Biosafety Office (biosafety@umd.edu) to ensure campus coordination and State of Maryland notification **PRIOR to installing or decommissioning** steam autoclaves and bulk sterilizers.]**

Purpose: This standard describes the minimum requirements for monitoring the performance of steam sterilization equipment in the animal care and use program.

Background: According to the *Guide for the Care and Use of Laboratory Animals*, sterilizers should be regularly evaluated and monitored to ensure their safety and effectiveness. Effective steam sterilization relies on an appropriate combination of steam, temperature, pressure, and time. Additionally, the *Guide* states "...sterilization indicators should be used to validate that materials have been properly sterilized." Most modern steam autoclaves and bulk sterilizers have mechanical devices to monitor and maintain proper internal temperature and pressure during the sterilization process. Even if these devices are present, sterilization effectiveness should be confirmed periodically.

Definitions: *Sterilization*- The process of destroying all forms of microorganisms, microbial life or biological agents present in a specific surface, object or fluid. Sterilization is intended to prevent disease transmission associated with the use of the item and can be achieved through various means, including heat, chemicals, irradiation, high pressure, and filtration.

Standards: Steam autoclaves and bulk sterilizers used in support of animal care and use activities (e.g., for sterilizing caging, equipment, animal feed or bedding, water, surgical instruments or supplies, etc.) will be periodically monitored to ensure sterilization effectiveness. Proper performance and effective sterilization will be documented.

Methodology:

1. **Monitoring.** A combination of mechanical (e.g., monitoring and recording devices in the unit), chemical (e.g., autoclave tape and temperature indicator strips) and biological (e.g., *Geobacillus stearothermophilus*) indicators will be used to monitor the effectiveness of sterilization. Depending on the type of autoclave, appropriate vacuum or air removal in the unit may also be monitored. All indicators will be used in accordance with manufacturer's guidelines.

2. **Recordkeeping.** Results of steam autoclave and bulk sterilizer monitoring will be recorded in an appropriate log. Documentation will be available for review.

3. **Implementation and Oversight.** The Department of Laboratory Animal Resources and ESSR will provide technical guidance and safety oversight for the animal care and use facilities' steam sterilization operations. The University Attending Veterinarian and the Institutional Animal Care and Use Committee will provide oversight for these operations and may review documentation as part of regular facility visits, semiannual facility inspections and program review, or ongoing post-approval monitoring activities.