Autoclave Verification Program has been developed by:

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I. Purpose

The purpose of the autoclave verification program is to protect the public health, safety, welfare and the environment for the state of Mississippi by ensuring that all biohazardous waste generated by research departments within Mississippi State University is decontaminated prior to disposal as solid waste in a public landfill.

A. This procedure refers to any steam sterilizer (autoclave) in the Mississippi State University system that is used to sterilize biohazardous waste including recombinant and synthetic nucleic acid molecules.

B. The purpose of this procedure is to provide guidance on how to demonstrate and document that any steam sterilizer used for the decontamination of biohazardous waste is performing as expected.

II. Key Word Definitions

A. Biohazardous waste: Includes infectious medical waste and waste containing recombinant or synthetic nucleic acids.

B. Infectious medical waste: includes solid or liquid wastes which may contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host has been proven to result in an infectious disease. Susceptible hosts include humans, animals and plants.

C. Medical waste: all waste generated in direct patient care or in diagnostic or research areas that is non-infectious but aesthetically repugnant if found in the environment.

D. Biological Indicator (BI): a commercially produced, standardized test system containing viable *Geobacillus stearothermophilus* spores which provides a defined resistance to a specified sterilization process. This is the gold standard for determining adequate steam sterilization conditions.

E. Chemical Indicators (CI): devices used to monitor the attainment of one or more of the parameters required for a satisfactory sterilization process or are used in specific tests of sterilization equipment.

1. External CI: CI intended for use with individual units (e.g. packs, bags, containers) to demonstrate that the unit has been EXPOSED to the sterilization process and to distinguish between processed and unprocessed units. An example is autoclave or sterilizer indicator tape placed on the outside of the load

2. Internal CI: CI intended for use within a load.

a) Class 3 (single parameter): CI designed to react to one of the critical parameters and to indicate exposure during a sterilization cycle at stated values of the chosen parameter.

b) Class 4 (multi-parameter): CI designed to react to two or more of the critical parameters and to indicate exposure during a sterilization cycle at stated values of the chosen parameters.

c) Class 5 (integrating indicator): CI designed to react to all critical parameters over a specified range of sterilization cycles and whose performance is correlated to the performance of a BI under the labeled conditions of use.

F. Sterilization: the use of physical or chemical means to completely kill all microbial organisms on an item or in an area.

G. Decontamination: the broad term used to describe the use of physical or chemical means to render an item, area, device or material safe to handle. The primary objective is to reduce the microbial load so that infection transmission is eliminated.

H. Critical Parameters: The integrity of the steam sterilization process is a function of the four basic parameters; steam, pressure, temperature and time. All four are needed for effective sterilization.

I. BSO: biological safety officer

J. PI: principal investigator

III. Responsibilities and Authorities

A. BSO

1. Monitors the performance of the verification program by the user.

B. User

1. Responsible for performing each verification;

2. Troubleshoots failed results;

3. Arranges for repair of any autoclave that fails the verification procedure.

IV. Items Needed

A. BI for monthly;

B. CI for each load.

C. A means to record results such as a log sheet.

V. Procedure

Even small changes in temperature within the autoclave produce a large effect on the time required to achieve sterilization. Therefore, it is critical to ensure that each autoclave is operating within acceptable limits.

A. Verification with the BI (monthly) and CI (per load)

1. The effectiveness of steam sterilization is monitored with biological and/or chemical indicators;

2. The BI and/or CI will be placed within an actual or mock load as outlined below;

a) Create a recoverable load indicator device

(1) create a 0.25” hole in the center of an Oakridge tube cap or equivalent.

(2) thread a durable autoclave resistant line, such as braided wire, through the cap and secure the line by tying a knot on the underside of the cap.

(3) thread the cap with line onto the tube to ensure it fits securely and that the line through the cap has sufficient gap to breathe during an autoclave cycle.

b) Insert both a Class 5 chemical indicator and biological indicator vial into the tube and secure the cap.

c) For an actual load, the device can be placed on the surface of a bag of waste that is 2/3 full then shaken so as to be mixed in with the waste.

d) For a mock load, a biohazardous waste bag can be filled 2/3 with linen lab coats and the device can be placed in the center of the load.

e) Pour ~250 to 500 ml of water for large loads or ~50 to 100 ml of water for small loads into the bag of waste.

f) Gather the mouth of the bag and wrap autoclave tape around the neck, leaving adequate space for the recovery line and steam venting.

g) Complete processing of biohazardous waste for decontamination by autoclave per local Standard Operating Procedure

3. Record the results in the Test Results Log.

a) **NOTE**: autoclave tape may be used to differentiate between processed and unprocessed loads but **IS Generally NOT** suitable for load verification.

B. Failed indicator (BI or CI)

1. If either type of indicator fails, rerun new BI and CI indicators using a mock load;

2. If the indicator fails again, label the autoclave as “Out of Order” and contact a service representative for repair.

C. Failed automatic reports

1. If the automatic documentation indicates a failure to meet appropriate conditions, label the autoclave as “Out of Order” and consult a service representative and the user’s manual.

D. All records must be maintained for at least one year and will be inspected annually by the BSO.

VI. Associated Forms

A. Test Results Log

VII. Associated SOPs

A. Laboratory specific standard operating procedure for autoclave operation.

B. Autoclave verification program standard operating procedure

VIII. References

A. National Institutes of Health, (2019), Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, Department of Health and Human Services

B. Biosafety in Microbiological and Biomedical Laboratories, 6th Ed. CDC/NIH, February 2020.

C. Mississippi State Department of Health “Adopted Standards for Regulation of Medical Waste”