Monitoring Autoclave Efficiency Guideline

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University of Saskatchewan

Table of Contents

1 Introduction

Biological indicators (BIs) are used to determine how effectively biological material is sterilized in an autoclave and should be used in conjunction with temperature logs to ensure that the autoclave is functioning effectively. The purpose of this guideline is to describe the monitoring of sterilization and efficacy testing and the quality control of an autoclave with the use of BIs.

NOTE: It is mandatory to validate the effectiveness of waste sterilization of every autoclave using biological indicators. This frequency of the use of the BI is dependent on the use of the autoclave.

2 Definitions

Biological Indicator (BI): A biological indicator (BI) is the name given to a process for assessing the sterility of an environment through the use of resistant microorganism strains (e.g. *G. stearothermophilus, B. atrophaeus*). BIs are used to develop the processing times for typical loads and monitor the efficiency of the decontamination processes. They can also be used to confirm thermocouple data when checking heating profiles and validating autoclave efficacy.

Personal Protective Equipment (PPE): Refers to protective clothing designed to protect the wearer's body from injury or infection due to hazards which are physical, electrical, chemical, produce heat, biohazardous, and airborne particulate matter.

Standard Operation Procedure (SOP): A set of step-by-step instructions compiled to help workers carry out complex routine operations. SOP's aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations.

3 Safety

1. Manuals for the autoclave and biological indicators should be readily available in close proximity to the autoclave.

2. Autoclave User Log should be filled out after each use (refer to Appendix).

3. If a glass BI ampule is used, ensure the following safety procedures are followed:
    - Handle hot BIs with care as crushing or excessive handling before cooling may cause the glass ampule to burst;
    - Wear safety glasses and disposable gloves when removing the BI from the sterilizer;
    - Handle the BI by the cap only;
    - Do not use your fingers to crush glass ampule. Use the incubator to break the ampule or an edge;
    - Wear safety glasses and disposable gloves when crushing the BI when placing into the BI incubator;
    - Do not roll the BI between fingers to wet spore strip.

4 Equipment and materials required

- BIs (e.g. 3M ATTEST, Raven Prospore, Getinge Biosign)
- Incubator
- Autoclave User Log
- Autoclave tape
- Autoclave Biohazard bags
- SHARPs Container

5 Procedure

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1. Monitoring of autoclaves with BIs should be done monthly, or as determined by the frequency of use of the autoclave.

2. Write the date and the load number on the BI.

3. Place the BI in the center of the load. (*Note:* Each type of load must be tested individually when developing processing times and temperatures)

   Liquid Loads: Attached the BI to a wire and place into the bottom of the vessel containing the test liquid (the liquid at the bottom of the vessel takes the longest to reach sterilization temperature).

   Dry or Semi-dry Loads: Attach the BI to a long string or wire and place the BI into the autoclave bag with the string hanging out of the bag; when the cycle is done, retrieve the BI by pulling on the string.

4. Put a piece of autoclave tape on the surface of the autoclave load.

5. Place the temperature probe into the load (if applicable), the BI package, and the load in to the autoclave.

6. Run the cycle to sterilize the load as described in manufacturer's instructions.

7. Prior to opening the autoclave, ensure proper PPE is worn such as lab coat, autoclave gloves, and face protection. When the cycle is complete, open the autoclave, and remove the BI.

8. Allow the BI to cool for a minimum of 10 minutes.

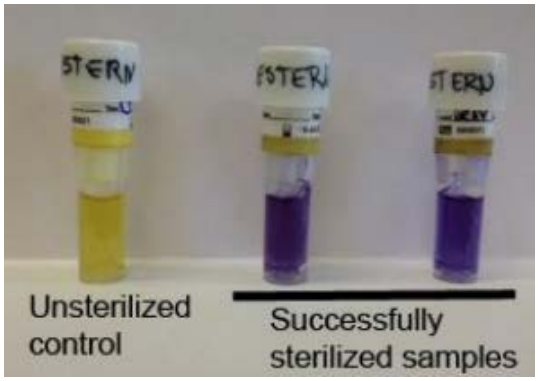
9. Place the autoclaved waste in a holding area for the duration of the incubation time of the BI until the results of the cycle have been determined.

10. Check the chemical indicator strip on the BI for a change in color, if applicable. (Some BI brands include a chemical indicator on the label that will change from one color to another (e.g. Rose to brown) upon exposure to the steam during the sterilization process). If the chemical indicator strip has not changed colour, repeat the sterilization cycle with a new BI.

11. If the indicator strip changes colour, activate (crush) the autoclaved BI by inserting into incubator at 45° angle, as per manufacturer's instructions. Ensure the spore strip is wetted entirely with the growth medium.

12. Incubate autoclaved BI along with a non-autoclaved BI with the same lot number as a positive control at the temperature set forth by the manufacturer. Once incubation is completed, compare the autoclaved BI to the positive control.

    Comparison of Process BI to Positive Control BI:



13. Once the results have been determined and sterilization process was successful, throw the autoclaved waste in regular garbage.

    Note: For janitors to pick up the garbage in an autoclave bag, it must be covered with a regular garbage bags such that the biosafety label cannot be read or have the Biohazard label defaced prior to throwing out in regular garbage).

    If the sterilization process failed (e.g. growth seen in the BI), then the autoclave load needs to be re-autoclaved; repeat the procedure with a new BI.

14. Discard the incubated BIs into SHARPs container.

15. Record the BI results in the Autoclave User Log (see Appendix).

16. Failure to achieve sterilization may be due to:

    - Improper loading or overloading of the autoclave so that the center of the load failed to achieve sterilization temperatures.

    - Insufficient sterilization time to attain 4-6 $\log^{10}$ reduction of the bacterial spores of the BI.

17. In the event of a failed sterilization, repeat the process until necessary loading configuration and sterilization times have been achieved.

18. Effective time and load configuration must be used for all subsequent cycles for that type of load.

19. Monitoring of the autoclave with BIs is dependent on the frequency of use (e.g. If autoclave used twice per month then one should monitor the efficacy of the autoclave each time a load is done).

6 Highlights and Critical Control Points

1. Labels and tape indicators for steam, time, and temperature are useful for day to day monitoring BUT are not indicators for sterilization.

2. Temperature (thermocouple) probes, placed at the center of the load may be used to monitor the internal temperature of that load; these may be used in conjunction with a BI.

7 Reporting

The operator of the autoclave should maintain the Autoclave User Log and keep all records for a minimum of 5 years.

8 Regulatory standards

1. BIs must be included in autoclave load monthly, or more frequently if the autoclave has a high frequency of use (dependent on the frequency of use).

2. A non-autoclaved BI must be incubated as a positive control along with the autoclaved indicator. Ensure same lot number is used for the test and positive control BIs. Record the lot number and results on the Autoclave User Log.

3. Ensure routine monitoring is conducted to confirm proper settings are attained. Any changes in standard loads must be first tested and approved by the autoclave operator. Contact the supervisor if require assistance.

9 Troubleshooting

All users must refer to the manufacturing instructions for the BI for troubleshooting.

If you have questions or concerns about the use of BIs in monitoring autoclave efficiency, please contact Safety Resources at 306-966-4675 or at safetyresources@usask.ca.

10 References

Public Health Agency of Canada. *Canadian Biosafety Handbook*. 2nd Edition, 2016.
Public Health Agency of Canada. *Canadian Biosafety Standard*. 2nd Edition, 2015.

11 Appendix

Autoclave User Log

Manufacturer:_____ Model: _____ Year: _____

Serial No.:_____ Location:_____ Asset No.:_____

Put in service date: _____

Name	Date/ Time	Program Type (gravity or liquid)	Cycle Time (min)	Cycle Temperature (°C)	Type of Load (Dry/Wet)	BI Expiry Date & Lot #	Results (Pass/Fail)