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Revision: 1.0	Subject: Autoclaves – Biohazardous Waste Treatment	

1.0 Introduction

This Standard Operating Procedure outlines necessary procedures regarding the autoclave-based disinfection of biohazardous waste. These procedures will ensure that Queen's autoclaves are in compliance with applicable guidelines and regulations. All autoclaves and autoclave users must also be in compliance with the general Autoclave Standard Operating procedure (SOP-LAB-02).

2.0 Scope

This SOP applies to all autoclaves owned by the University which are used to treat biohazardous waste.

3.0 Applicable Legislation and Guidelines

Environmental Protection Act –R.R.O. Regulation 347, 1990

Ontario Regulation 558/00, Amending Reg. 347

Guideline C-4, The Management of Biomedical Waste

Guideline C-17, Non-Incineration Technologies for Treatment of Biomedical Waste

Laboratory Biosafety Guidelines 3rd Edition, 2004, Public Health Agency of Canada

Containment Standards for Veterinary Facilities, Canadian Food Inspection Agency

4.0 Responsibilities

This section outlines responsibilities within the university for the implementation of this SOP.

4.1 Department of Environmental Health and Safety

- Provide any necessary Biohazardous Material labels.
- Review and amend this Standard Operating Procedure as necessary.
- Confirm that proper sterilization verification testing is being done and records are being maintained.

4.2 Department Heads and Safety Officers

- Ensure that waste-treating autoclaves receive the proper sterilization verification testing, and maintain records of this testing.
- Ensure that the autoclave settings required for proper waste sterilization are determined.



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4.3 Laboratory Supervisors/Principal Investigators

- Ensure that the proper packaging and labeling for waste awaiting autoclave treatment is available.
- Ensure that waste-treating autoclaves receive the proper sterilization verification testing, and maintain records of this testing.
- Ensure that the autoclave settings required for proper waste sterilization are determined.

4.5 Autoclave Users

- Package biohazardous waste appropriately, taking care not to compact the waste in the bag and not to overload the bag.
- Use the correct autoclave settings, as determined by the department, when treating biohazardous waste.

5.0 Definitions

Biohazardous waste: waste that includes human anatomical waste (not including teeth, hair and nails), animal waste, human and animal cultures, stocks or specimens, live or attenuated vaccines, cell lines, and material that has come into contact with any of these items, human liquid blood or semi-liquid blood and blood products, items contaminated with blood or blood products that would release liquid or semi-liquid blood if compressed, body fluids visibly contaminated with blood, and body fluids removed in the course of surgery, treatment, autopsy, or for diagnosis, sharps including needles, needles attached to syringes, and blades, or is cytotoxic waste.

Biohazardous waste treatment: the processing of biohazardous waste which results in waste that is no longer considered hazardous and may be disposed of as municipal garbage.

Pathological waste: the following materials are considered pathological waste:

- Any part of the human body, including tissues and bodily fluids but excluding non-infectious fluids, extracted teeth, hair, nail clippings and the like.
- Any part of the carcass of an animal infected with a communicable disease or suspected by a licensed veterinary practitioner to be infected with a communicable disease.
- Non-anatomical waste infected with a communicable disease.
- Waste derived from any of the wastes listed above, including autoclaved pathological waste.



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6.0 Operation

Autoclaves must be operated in compliance with the Autoclave Standard Operating Procedure (SOP-LAB-02).

7.0 Record Keeping

7.1 Biological Indicators

In addition to the required records mentioned in the SOP-LAB-02, a log of all verification testing, including Biological Indicator testing, must be kept. The Biological Indicator test log must include the date, the cycle time and settings, the indicator information (brand, expiry date, and lot #) and the test results. Validation records must be kept for a minimum of two years. Appendix A is a sample Biological Indicator Testing Log.

7.2 Cycle Logs

A record of the cycle logs produced by the autoclave must be maintained. These records must be kept for a minimum of two years.

8.0 Verification Testing

8.1 Chemical Indicators

- Chemical indicators of sterility, such as temperature sensitive tape or strips, must be used on each bag of biohazardous waste that is treated by autoclaving.

8.2 Biological Indicators

- Autoclaves which are used to treat biohazardous waste must be tested with biological indicators once a week, unless the autoclave is not being used to treat waste that week in which case this must be recorded.
- Indicators which are past their expiration dates must not be used.
- Autoclaves which are used to treat biohazardous waste must be capable of causing a $6\log_{10}$ (99.9999%) reduction in spores of *Bacillus stearothermophilus*, and should therefore be tested with an indicator which verifies this level of sterilization (i.e. an indicator with a spore population of 10^6). The indicator must be placed within the waste, in a location which challenges the test (preferably in the center of the load).
- Records of these tests must be kept for a minimum of two years.
- If any test fails, the load and any previous loads which remain on site are considered untreated and must be re-treated only after successful verification takes place.
- Appendix B is a detailed procedure for biological indicator use.



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9.0 Biohazardous Waste Preparation, Treatment and Removal

- Biohazardous waste must be stored in a designated area, in containers bearing an orange biohazard label. These labels can be obtained from the Department of Environmental Health and Safety.
- Waste must be autoclaved using settings that have been proven by biological indicators to be consistently successful for sterilization. If biological indicators frequently show negative results for sterilization more rigorous settings must be used. As an example, at the time of writing this SOP, the Department of Pathology and Molecular Medicine autoclaves waste on a wrapped cycle at 130°C for 45 minutes if it is a medium-sized load or for 60 minutes if it is a large load. In contrast, the Department of Microbiology autoclaves Level 2 waste on a cycle which includes pulses of pre-vacuum and then sterilization for 30 minutes at 121°C, when the waste is being treated in their standard-sized autoclaves.
- Indicator tape or temperature sensitive strips must be used on each load, and the bag must be open to allow steam penetration.
- After successful autoclave treatment, all bags must have any biohazard symbols defaced. These bags must then be placed inside a black domestic garbage bag which is free of any markings or labels, and then tied closed securely. The waste may then be disposed of through the municipal system.

Pathological Waste

- If pathological waste, as defined in the Definitions section above, is produced in any significant amount then it must be treated either by incineration or by an autoclave with the appropriate Certificate of Approval issued by the Ministry of the Environment. The Certificate of Approval states that the waste which is treated by autoclaving no longer has the characteristics similar to the characteristics of the original pathological waste. More information on the Certificates can be found on the Ministry of the Environment website: <http://www.ene.gov.on.ca/en/business/cofa/index.php>.
- In practice, Queen's pathological waste is disposed of by incineration by placing in "burn barrels" obtained through the Department of Environmental Health and Safety, or by removal through Kingston General Hospital waste treatment system.

Revision History:

1.0 - August 2009: Initial Release

APPENDIX B

Biological Indicator Testing Procedure

1. Read and follow the supplier's instructions.
2. Place *B. stearothermophilus* in the centre of the representative test load, attached to a string or any other device for retrieval after autoclaving.
3. Process the load in a normal fashion
4. a) Extract and incubate the *B. stearothermophilus* sample as instructed by the manufacturer.
b) Use another ampoule (same lot #) which is not autoclaved to act as a positive control.
5. Check for a colour change at regular convenient intervals during the incubation period (<18, 24, and 48 hours). If the media is yellow and turbid the autoclave process has FAILED. Re-run all waste bags which remain on site with new biological indicators immediately upon noting yellow colouration.
 - o If failure continues to be noted, either increase the time of exposure or initiate repairs to the autoclave. Note the autoclave cannot be used again for biohazardous waste treatment until a validation procedure indicates that autoclave is now adequately sterilizing the material. Post a sign on or near the autoclave log indicating that it may not be used for waste treatment.
6. Record all results, positive and negative. If the test is positive for growth record all corrective actions taken.