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## **1.0 Introduction**

This Standard Operating Procedure outlines measures for the safe operation, maintenance, repair, and service of autoclaves. These procedures will ensure that Queen's autoclaves are in compliance with applicable guidelines and regulations. When autoclaves are used to treat biohazardous waste the Autoclave-Based Treatment of Biohazardous Waste (SOP-Biosafety-09) must also be followed.

## 2.0 Scope

This SOP applies to all autoclaves owned by the University.

Autoclaves having characteristics which place them under the Technical Standards and Safety Authority (TSSA) Regulation on Boilers and Pressure Vessels must comply with all sections which refer to the TSSA. See section 9 for more detail regarding these characteristics.

#### 3.0 Applicable Legislation, Standards and Guidelines

Boilers and Pressure Vessels, Ontario Regulation 220/01, Technical Standards and Safety Authority, 2000

Boilers and Pressure Vessels Code Adoption Document, Technical Standards and Safety Authority

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

Ontario Regulation 558/00, Amending Reg. 347

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 the responsibilities within the university for the implementation of this SOP.

4.1 The Department of Environmental Health and Safety:



• Keep an inventory of all autoclaves owned by the university.

- Ensure that applicable autoclaves (see section 9) are receiving annual inspections by individuals qualified under the Technical Standards and Safety Authority Boilers and Pressure Vessels regulation.
- Maintain documentation of applicable legislation and update as necessary.
- Notify the Director of the Technical Standards and Safety Authority of any autoclave related incidents involving human injury or death, property damage, explosions, or ruptures, as they are reported by responsible Laboratory Supervisors/Principal Investigators.
- Review and amend this Standard Operating Procedure as necessary.

4.2 Department Heads and Safety Officers:

- Ensure that supervisors, employees, and students are notified of their responsibilities for working with autoclaves.
- Notify the Department of Environmental Health and Safety of any new autoclaves purchased by their departments, and of the removal of any autoclaves.
- Ensure that autoclaves undergo regular maintenance.
- Maintain a record of any necessary Autoclave Logs.
- Establish department-specific policies as necessary.
- Post an autoclave operating procedure at the operating station.
- Develop a training program for all autoclaves.

4.3 Laboratory Supervisors/Principal Investigators:

- If the autoclave is associated only with your laboratory, be sure to fulfill any applicable responsibilities listed under Department Heads and Safety Officers.
- Ensure that autoclave users have received the proper training regarding safe operation, and maintain records of operator training.
- Report any incidents involving human injury or death, property damage, explosions, or ruptures to the Department of Environmental Health and Safety immediately.

4.4 Autoclave Users:

- Follow proper autoclave operating procedures and wear all appropriate personal protective equipment.
- Notify the person responsible for the autoclave, as designated by the department, of any malfunctions or other problems.
- Fill in the Autoclave Log with all necessary information each time the autoclave is used.

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#### **5.0 Definitions**

Autoclave: a high-pressure vessel used for the steam sterilization of contaminated material.

<u>Biohazardous waste</u> and <u>biohazardous waste treatment</u>: *see Autoclave-Based Biohazardous Waste Treatment (SOP-Biosafety-09)*.

<u>Primary container:</u> the container used to hold materials to be autoclaved—most often an autoclave bag—which is in direct contact with the materials.

<u>Secondary container</u>: the container used to hold the primary container, which will prevent any spills from occurring.

<u>Qualified inspector:</u> an inspector from either the Technical Standards and Safety Authority or the Boiler and Machinery Insurance provider for the autoclave.

#### 6.0 Training

- It is the supervisor's responsibility to ensure that all autoclave users are properly trained.
- Operators must undergo a training session which covers autoclave hazards, function, safety precautions, and operating procedure. Training should be specific to the autoclave(s) which will be used.
- A quiz must be taken by those trained to ensure that they understand how to safely use an autoclave. Appendix A is a sample quiz which should be modified as appropriate.
- Documentation of training, which includes the signature of both the supervisor and the person trained, must be kept by the supervisor.

## 7.0 Record Keeping

Records must be kept in order to track autoclave processes and ensure that autoclaves are meeting regulatory requirements. The following information must be recorded:

1. Autoclave Log: for all autoclaves which are used by multiple labs a log of autoclave use, with each entry containing the date, user, items autoclaved, and time of removal, must be maintained. These records must be kept for a minimum of two years. A template for this log may be found in Appendix B.



2. Problem/Incident

Log: a record of any problems encountered. This information can be recorded as part of the Autoclave Log or it can be kept separate.

3. Autoclave Training Documents: a record of operator training.

Additional records must be kept if the autoclave is used to treat biohazardous waste. See the Autoclave-based Biohazardous Waste Treatment (SOP-Biosafety-09).

## 8.0 Operation

- Proper personal protective equipment must be worn when operating an autoclave to protect against burns and scalds. Shoes with closed toes and heels must be worn at all times, and it is recommended that a lab coat be worn. Heat-insulating gloves must be worn when loading and unloading. If there is a splash risk, goggles and/or a face shield should be worn as appropriate.
- When preparing materials for sterilization:
  - All material which must be stored outside of the lab in which it is generated while awaiting autoclave treatment must be labeled with the name and contact information of the person responsible for the waste, typically the Principal Investigator.
  - Ensure that any primary containers, which are the containers that are in direct contact with the contaminated material, permit steam penetration.
    - Any caps or lids must be loose or partially open.
    - Plastic bags should be opened slightly.
    - $\circ~$  All containers may be filled to a maximum of 2/3 of their capacity.
  - Ensure that secondary containers are used to contain any spill that may occur. Bags must be autoclaved in a secondary container to avoid contaminating the chamber.
  - **Do not load incompatible materials** (oils, waxes, some plastics, flammable materials, radioactive materials, chlorinated substances, corrosive chemicals, substances which may emit toxic fumes, etc.). Be sure that you know which materials can and cannot be autoclaved.
- If the autoclave has a Boilers and Pressure Vessels Certificate of Inspection, then it may not be operated at a temperature greater than the one listed in the Certificate.
- If a problem is encountered and the load does not undergo the full cycle treatment, then the load must be re-treated with a complete cycle. Record any problems in the Autoclave Log or Problem Log.

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• A full operating

procedure example may be found in Appendix C. Departments must make the appropriate adjustments to this procedure to match the requirements for the safe use of their autoclave models. Full operating procedures must be located at the operating station and must be available to all users.

#### 9.0 Maintenance

Regular Maintenance Check

- It is recommended that a daily or weekly maintenance check be done as appropriate for the frequency of use. Check door gaskets, interior surfaces, screens, containers, exterior surfaces and any other components, if applicable. Clean or disinfect exterior surfaces and clean interior surfaces and screens.
- Check any primary and secondary containers for cracks, stress fractures, chips, and other damage.

Yearly Maintenance and Inspections

- It is recommended that all autoclaves receive more formal maintenance by trained personnel, annually or based on manufacturer's recommendations.
- Autoclave pressure vessels fall under the Technical Standards and Safety Authority (TSSA) Regulation on Boilers and Pressure Vessels if they have a maximum working pressure greater than 15 psi (103kPa), a capacity greater than 1.5 cubic feet (42.4L), an internal diameter greater than 6 inches. Autoclaves which fall under the TSSA Regulation must undergo yearly inspections, described below.
- Autoclaves must be inspected annually by an inspector qualified under the TSSA. At Queen's, this service is provided by Royal & Sun Alliance, our Boiler and Machinery insurance provider.
- A valid certificate of inspection, which must be posted near the autoclave, will be issued after each inspection.
  - All new autoclaves which fall under the above specifications must be inspected by a qualified inspector before they may be operated.
  - If you are responsible for an autoclave which falls under the above specifications and is not receiving annual inspections, please contact the Department of Environmental Health and Safety.

## **10.0** Repairs or Alterations

• No person shall cover or obliterate any of the markings on an autoclave.

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- Autoclave owners and users may not make repairs or alteration to their autoclaves, unless the steps outlined below are followed.
- Repair contractors, manufacturers, owners, or users who wish to make repairs or alterations to autoclaves must have a Certificate of Authorization from the Director of the Technical Standards and Safety Authority (TSSA). In order to obtain this certificate, a Quality Control system outlining the alteration or repair procedure must be produced in accordance with Safety Bulletin SB02-01 Rev. 1, dated April 24 2003, by the TSSA. This bulletin and supporting information may be found here:

https://www.tssa.org/en/boilers-pressure-vessels/boilers-and-pressure-vessels.aspx

#### **11.0 Reporting Incidents**

- When an accident arises out of an autoclave's operation resulting in injury or death to a person, property damage, or when an explosion or rupture occurs, no person shall alter or move any item at the scene of the incident, until they have been given permission to do so in writing from a Technical Standards and Safety Authority qualified inspector, unless for the purpose of saving a life or relieving human suffering.
- Incidents of this type must be reported immediately to the Department of Environmental Health and Safety.
- The Department of Environmental Health and Safety will notify the Technical Standards and Safety Authority of the incident.

#### **Revision History:**

1.0 - August 2009: Initial Release

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#### APPENDIX A

#### **Autoclave Usage Quiz**

- 1- Liquids are always sterilized using a cycle that finishes with:
  - a) A fast exhaust phase.
  - b) A slow exhaust and a drying phase.
  - c) A slow exhaust phase.
  - d) None of the above.
- 2- Example of items that should never be autoclaved are:
  - a) Petri dishes with fungal growth on the media.
  - b) Bleach soaked tissue cultures dishes.
  - c) Cloth or any textile materials.
  - d) Sealed tissue culture flasks.
- 3- Bottles or flasks containing a very dilute amount of phenol can be autoclaved safely: a) True
  - b) False
- 4- Effective dry waste decontamination requires an autoclave cycle that starts with a:
  - a) Pre-vacuum phase that removes most air from the chamber.
  - b) High temperature steam burst to enhance load penetration.
  - c) A dry heat phase to condition the load for the steam phase.
  - d) None of the above.
- 5- Autoclaving tightly sealed containers with liquid in them:
  - a) Prevents scalding hot liquid from escaping.
  - b) Minimizes evaporative losses from the super-heated liquid.
  - c) Creates dangerous pressure inside the containers that can cause explosion. d) a and b
- 6- Keeping a safe distance from the autoclave when opening the door is good practice because:
  - a) Hot steam will escape from the chamber when the door slides open.
  - b) Heat resistant pathogenic organisms can escape as bio-aerosols.
  - c) An alarm will be activated by a proximity sensor if you stand too close. d) All of the above.
  - e) a and b
  - f) a and c
- 7- When removing a load, bubbling or boiling liquid in a container indicates:
  - a) The liquid has been thoroughly sterilized.
  - b) The cap was too loose.

- c) There is a high risk of 'boil over'.
- d) The liquid wasn't heated enough.

- 8- Media bottles filled with liquid should be autoclaved:
  - a) In a secondary container.
  - b) Only on the lower autoclave rack.
  - c) With the caps on loosely.
  - d) a and c
  - e) b and c
- 9- A wrapped cycle is selected when you want to ensure that:
  - a) Steam penetrates the items in the load.
  - b) The items are dry when the cycle is finished
  - c) Fragile items are treated to gentle sterilization.
  - d) Heat sensitive items are sterilized slowly.

#### 10- It is safe to remove material from the autoclave without protective mitts/gloves:

- a) If the cycle has been completed for at least 30 minutes.
- b) At the end of an 'Unwrapped' cycle.
- c) If the material is only made of plastic.
- d) Never. Protective mitts/gloves must always be worn.

#### Trainee

Name:	
Signature:	
Date:	

#### Trainer

Name:	
Signature: _	
Date:	

#### **APPENDIX B**

## **Autoclave Log**

Name	Date	Time In	Principal Investigator	Time Removed	Problems Encountered

## **APPENDIX C**

## **Autoclave Operating Procedure**

### Loading

- Ensure that you are wearing all necessary personal protective equipment (closetoed shoes, insulated gloves, and possibly a lab coat, goggles, and face shield).
- Check that autoclave pressure gauge is at zero and carefully open the autoclave door.

- Place materials inside the autoclave, in a secondary container to protect the autoclave (eg. place flasks with liquid inside a deep tray). Making sure not to overload the sterilizer, thereby allowing for steam circulation.
- Open any garbage bins. Make sure that bags are open to allow for easier steam penetration.
- Close the autoclave door, making sure that it is properly closed
- Fill in the Autoclave Log with all required information.

#### Select the Settings

- From the control panel, choose the appropriate cycle time and type for sterilization.
- Start the autoclave.
- Do not attempt to open the door while the autoclave is running.
- Make sure that the autoclave reaches the desired temperature before leaving it unattended. If the door begins leaking steam, abort the cycle and tighten the door further.
- If you must abort, press the abort button on the control panel. Wait for at least a minute before cautiously cracking open the door to let out steam. Once the steam has been release, reopen the door fully.

## Unloading

- Once again, be sure to wear all protective equipment.
- Check that the pressure gauge is at zero, stand back from the door and crack it open, allowing steam to dissipate before opening it fully.
- Check for any superheated liquids. If liquids are bubbling, leave them to cool further before moving to avoid boil over.
- Remove the items and place them in a safe location.
- Record any problems encountered in the Autoclave/Problem Log.