

FACULTY OF MEDICINE
INTERIM AUTOCLAVE PROCEDURES

(Autoclave consolidation Project)

February 10, 2003-May 2003

(EFFECTIVE FEBRUARY 17, 2003)

The autoclave consolidation project was conceived to replace aging autoclave equipment, to consolidate services to minimize duplication of resources, both financial and technical, and to ensure that all autoclaves in use at the Faculty of Medicine adopt strict safety guidelines and comply with regulatory requirements governing the biomedical waste.

While the various phases of the project are ongoing, it is necessary to ensure that sterilization, decontamination and other associated services continue to serve the research community.

For this reason, the various departmental autoclaves (CMM: rooms 3203 and 2225 and NRI: room 2483) will no longer be available for general use during work hours (8:00 am to 4:30 pm).

Rather, the experienced technical staff of the BMI central preparation services will be operating these autoclaves to process all faculty materials requiring autoclaving. This service will ensure that safety, quality control and regulatory compliance elements will enhance the current autoclave facilities.

- **Room 3203 will be for materials requiring decontamination**
- **Room 2483 will be for materials to be sterilized**

1. **DEFINITIONS**

Sterilization: a preventative treatment, such that any viable microorganisms are destroyed prior to being used in experimental procedures.

Decontamination: reduction of biological contamination to a level which no longer poses a risk to persons or the environment.

2. **SERVICE HOURS**

Autoclave facilities will be operated by the BMI technical staff during regular work hours, Monday to Friday, 8:00 to 4:30.

- Materials requiring sterilization during regular hours may be left in room **2483**, in the designated area, at any time. The time of the last autoclaving load for the day will be posted.

- Materials requiring sterilization outside of regular hours (evenings and weekends) may be sterilized by individuals using the autoclave in room 2225 (all users) or 2483 (for NRI staff only). The autoclave located in room 3203 will not be made available. Prior to using any of these autoclaves, staff must have received training on their safe operation.
- Materials to be decontaminated are to be transported to room **3203** using appropriate measures (see below) **during regular working hours only**, Monday to Friday. After hours, all materials are to be maintained in the individual laboratories.

3. **TRANSPORTING MATERIALS** (sterilization or decontamination)

The requirement for all autoclave users to transport their materials to the 3rd or 2nd floor autoclaves will result in increased movement of materials throughout the building, and combined with the ongoing construction project, with a greater potential for accidents.

Additionally, provincial biomedical waste regulations and Health Canada laboratory biosafety guidelines require that measures be in place to avoid spills of potentially infectious biological materials. For this reason, it is necessary to establish guidelines to transport materials to and from these facilities.

- All materials being transported both to and from autoclaves are to be transported on suitable carts. (These include Faculty purchased heavy duty Rubbermaid carts with 3" elevated sides).
- All soiled material being transported for decontamination should also be held within secondary containers (such as rubbermaid or other tubs) on the carts, such that potential spills are minimized. Ideally, these secondary containers should be sealed. (Examples of these sealed containers are currently being evaluated for full implementation with the new facility operating procedures).
- All flasks containing biological/biohazardous material (liquid or solid) must be capped at least with aluminum foil.
- Any materials originating from the containment facility and requiring decontamination must adhere to additional, more stringent criteria. All autoclave bags must be surface decontaminated with a disinfectant appropriate for the material. The secondary container used to transport the materials on the lab cart must be a sealed container. In addition, prior arrangements must be made with the BMI staff (ext 8166) prior to removing the material from the facility. This ensures that materials are decontaminated immediately.
- Carts are to carry spill containment materials (absorbent pads, gloves and Virox 5 or other disinfectant, appropriate for the materials being transported).

4. **STERILIZATION (Room 2483, pick up Room 3203)**

A dedicated autoclave is being used to sterilize (no decontamination) all materials. These will include items such as glassware, plastic-ware, culture media (both solid and liquid), wrapped materials, and any other materials requiring sterility prior to use.

- All items must be **CAPABLE** of being autoclaved, without deleteriously affecting the staff operating the autoclaves, or the autoclaves themselves. If unsure, consult the technical staff for advice.
 - Due to the large assortment of materials to be sterilized, it is essential that items be clearly identified, to permit staff to maximize use of the autoclaves by combining loads. Stickers and markers will be provided.
 - Identification **MUST** include:
 - Principal investigator's name
 - Name of person bringing materials
 - Contents (for all liquids)
 - Room #
 - Tel #
- Unidentified or incompletely identified items will not be autoclaved, and the user will be notified by the technician in charge.

Once the materials have been sterilized, they will be removed from room 2483, and transferred to room 3203 to a pick up area within the room, and identified by supervisor. Be advised that all items will carry heat sensitive tape, so ensure that **ONLY** items which have the color-changed heat sensitive tape are picked up!

As the facility will serve the needs of the entire faculty, staff are reminded to promptly remove all items.

Note: All sterilization will be performed according to standard protocols, and validated through biological indicator testing, chemical indicators and temperature charts.

5. **DECONTAMINATION (Room 3203)**

Packaging

- Use only approved autoclave bags. (Note: certain Biohazard bags are designed for incineration, and are not suitable for autoclave use.
- If outside of biohazard bags are contaminated, apply a second autoclave bag.
- Do not overfill autoclave waste bags. This will ensure that all materials are effectively decontaminated, but more importantly, will ensure that staff are not

exposed to potential injury from overfilled containers.

- Other items to be decontaminated must likewise be in containers capable of resisting the temperatures and pressures they are exposed to during the process.
- All flasks containing biological/biohazardous material (liquid or solid) must be capped at least with aluminum foil

Storing of material

- All items for decontamination are to be deposited in the autoclave basins **on the shelves/counter in room 3203**. If there are no autoclave basins available, items for decontamination are to be returned to the originating laboratory, until a later time, until the next working day if necessary.
- All items are to be clearly identified (see above).
- All autoclave bags will be discarded by BMI staff following decontamination, unless directed otherwise. Tags indicating this need for recovery after decontamination will be available, and are to be applied over the neck of the autoclave bag.
- Other items left for decontamination, and bags designated by tags or sticker as being for reuse will be in a designated area in room 3203 after decontamination, and are to be promptly removed by users. Be advised that all items will carry heat sensitive tape, so ensure that **ONLY** items which have the color-changed heat sensitive tape are picked up!

6. DOCUMENTATION

Under the new provisions of the Environmental Protection Act, documentation of autoclave validation and daily use are particularly stringent. For these reasons, a number of new steps will be introduced for all University, and Faculty autoclave units.

These records will consist of

1. Training records for all users
2. Validation records (includes cycle log recordings and biological monitoring)
3. Autoclave logs
4. Performance records

For the duration of these interim procedures, validation records, autoclave logs and performance records will be maintained by the BMI technical staff who will be operating the autoclaves.

Any persons operating the autoclaves (Room 2483 or 2225) outside of regular hours will be required to complete the autoclave logs, which are posted next to the autoclaves.

Training is an essential component of a successful autoclave program. Not only will this minimize the risk of injury, it will ensure that sterility of materials required for research is achieved, and that decontamination of all biological materials is complete, and in accordance with regulatory requirements.

Documentation of training is required under the new University autoclave guidelines (see appendix). In addition, it is required that all users be trained on the particular autoclave unit they will be using. For the duration of these interim procedures, that will be the small CMM unit room 2225, with the unit in room 2483 for NRI staff. BMI technical staff operating the autoclaves will be pleased to assist with your training.

7. **VALIDATION TESTING** (Performed by BMI staff)

- All autoclaves are to be run with cycle log recorders, which ensure that temperature parameters are achieved. Paper copies of the results are to be maintained for a period of 1 year. Any deviations are to be addressed.
- All loads (sterilization and decontamination) are to include items labeled with temperature sensitive tape. Any load where the tape has not changed color will be re-autoclaved with fresh tape.
- All autoclaves will have biological indicator testing performed to confirm efficacy of decontamination cycles.

Biological Indicator testing

The 3M Attest 1262 Biological Monitoring System will be utilized to validate that autoclave cycles and procedures are consistently decontaminating biological materials to levels in accordance with regulatory controls. Ampules of *Bacillus stearothermophilus* are autoclaved with waste materials, then incubated to confirm that biological materials have effectively been destroyed.

- Read and follow the suppliers instructions.
- Testing will initially be performed daily for all autoclaves, to become weekly once assurances of efficacy are achieved.
- Place *B. stearotheromophilus* in center of representative test load. Run a control sample (do not autoclave).
- Run through normal autoclave cycle. (Autoclave cycles for decontamination will be 50-60 (not finalized yet) minutes in the autoclaves, with all cycles on the liquid settings. Cycles based on biological indicator results).
- Extract and incubate *B.stearothermophilus* sample as instructed by manufacturer.
- Check for color change at regular intervals during the incubation period (8, 12, 24, and 48 hours). If media is yellow and turbid the autoclave process has

FAILED. Any failure is an indication that materials have not been effectively decontaminated, and materials are to be re-processed.

- If failure continues to be noted, either increase time of exposure or initiate repairs to the autoclave. The autoclave will not be used again until validation procedure indicates that autoclave is now adequately sterilizing the material.
- Record all results. (Positive and Negative)

8. **REFERENCES**

- Guideline C-4. Management of Biomedical Waste in Ontario, Environmental Protection Act, SO 1990
- Guideline C. Non-Incineration Technologies for Treatment of Biomedical Waste (Protocols for Microbiological Testing), Environmental Protection Act, SO 1990
- Laboratory Biosafety Guidelines, Draft 3rd Edition, Health Canada, September 2001
- A Guideline for the Safe Use of Autoclaves, Draft, March 2002, University of Ottawa
- Biosafety Manual, Michigan State University, April 1998
- UCSF Autoclave Quality Control Program, University of California, January 1996

Appendix

TRAINING DOCUMENTATION

This document is to attest to the fact I, _____, have read the “Guideline to the Safe Use of Autoclaves” and am aware of the issues that may affect the effectiveness of autoclaving, issues to minimize personal exposure, and the requirements for documentation. In addition I have been trained with regards to the correct use and recommendations associated with the use of the specific autoclave I will be using. I have answered correctly the following questions which confirm my basic knowledge of autoclave safety related issues.

Circle the correct answer.

- | | | | |
|----|---|---|---|
| 1. | The effectiveness of autoclaving is also based a large degree on the appropriate packaging and loading. | T | F |
| 2. | To prevent spillage autoclaving, seal all autoclave bags. | T | F |
| 3. | The technique used to load the autoclave does not greatly influence the success of the cycle. | T | F |
| 4. | All material can be autoclaved. | T | F |
| 5. | A change in colour of temperature sensitive tape does not indicate the material has been successfully autoclaved. | T | F |
| 6. | It is not necessary to use a biological indicator to test (weekly) the efficacy of the autoclave if it consistently achieves the selected temperatures. | T | F |
| 7. | As the material has been autoclaved there is no risk associated with unloading the autoclave upon completion of the cycle. | T | F |
| 8. | The personal protective equipment that must be worn includes glasses (goggles if splash risk), gloves (including heat resistant gloves), lab coat (plus apron if spill risk). | T | F |

Signature of Autoclave User

Date

Signature of Supervisor

Date