Autoclave Program

1. PURPOSE: This autoclave program has been designed by the Office of Safety and Risk Management (SRM) to assist researchers in the safe operation of autoclaves during the sterilization of regulated medical waste (RMW), and to ensure compliance with Virginia Waste Management Board: Chapter 120, Regulated Medical Waste Management Regulations (VA RMW Regulations) throughout the process. The VA RMW Regulations define regulated medical waste (RMW) as:

- Cultures and stock of microorganisms and biologicals
- Human blood and body fluids, and items contaminated with human blood or body fluids
- Tissues and other anatomical wastes
- Sharps (such as needles, syringes with attached needles, suture needles, and scalpels), including sharps generated through veterinary practice
- Animal carcasses and related wastes when animals are intentionally infected
- Mixtures and residues of regulated medical waste (such as from cleanups of RMW spills)
- Solid waste suspected by the health care professional in charge of being capable of producing infectious disease in humans

Per VDEQ*: "Prior to disposal, all regulated medical waste must be properly treated at a permitted RMW Treatment Facility using steam sterilization (autoclaving), incineration, or an approved alternative treatment method. RMW Treatment Facilities are required to obtain a permit from DEQ and are subject to additional operational and recordkeeping requirements in accordance with the VA RMW Management Regulations Waste that has been properly treated at a permitted RMW Treatment Facility in accordance with the requirements of the VA RMW Management Regulations is considered a solid waste that can then be disposed of at a permitted*

solid waste management facility (e.g. sanitary landfill), provided the facility's permit allows acceptance of the material". VCU is permitted to treat regulated medical waste on site through steam sterilization (autoclaving) this process is referred to as "Orange-bagging" or "Orange Bag Disposal" and requires strict adherence to the VA RMW Regulations. The purpose of this document is to provide VCU researchers with the information needed for safe and compliant autoclave operations.

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3. RESPONSIBILITIES: Principal Investigators (PIs) shall ensure that all laboratory staff have completed applicable BioRAFT-based safety training and laboratory-specific training prior to utilizing autoclaves for the sterilization of regulated medical as defined under the RMW regulations. In addition, each user shall read and understand the operator's manual for the specific model of the autoclave that he/she will be using. Following these initial steps, a lab staff member with suitable experience and training in regard to the orange bag disposal will provide guidance for a new user until they are competent in the process. For access to laboratory safety training modules go to vcu.bioraft.com.

PIs are also required to register all research involving biological materials via submission of a BioRAFT Biological Registration (vcu.bioraft.com). The BioRAFT registration will verify how the laboratory will manage all RMW which will be generated under the protocol. VCU permits RMW to be managed by three potential routes:

- "Orange-bagging" (autoclaving as detailed under this guidance document). PI will be responsible for identifying autoclave spaces/equipment to be utilized and for confirming that instruments will be operated subjected to monthly QC as required VA RMA Regulations.

- "Red-bagging" (incineration offsite as detailed under SRM: Bloodborne Pathogens - Infectious Waste Management Operating Procedure webpage)

- Bleaching/disposal of liquid waste down sanitary sewer (again detailed under SRM: Bloodborne Pathogens - Infectious Waste Management Operating Procedure webpage).

4. GUIDELINES / INSTRUCTIONS: AUTOCLAVE OPERATION AND SAFETY

4a. Autoclave Operation:

Autoclaves use high pressure and high temperature steam to kill microorganisms and to ensure that biohazardous material is rendered inactive. For effective sterilization, the materials/load must be saturated with steam under pressure. Air pockets or insufficient steam supply will prevent effective sterilization. Ensuring effective decontamination of infectious waste is achieved using autoclave biological test indicators. This process is detailed on pages five and six of this program.

Using an autoclave has risks. Heat and steam burns, hot fluid scalds, injuries to hands and arms from the door, and bodily injury in the event of an explosion cause the most injuries. Exposure to biohazardous material may also occur if biohazardous waste is improperly packaged or manipulated, or the temperature and duration of the cycle has not properly sterilized the load. (See page five, section 6a).

For questions regarding the autoclaves in your department, contact the building manager or SRM.

4b. Autoclave Safety

Following these guidelines will prevent injuries:

Never autoclave the following:

- Sharps: including used/unused needles and syringes, contaminated broken glass, microscope slides and coverslips, Pasteur pipettes, scalpel or razor blades, and other potentially contaminated items posing laceration hazard must be placed in a sharps disposal container. Full sharps containers must be placed in a red bagged lined incineration box to be picked up and transported off site for disposal by the university's regulated medical waste disposal contractor. Additional information regarding sharps/red bag disposal protocol can be accessed at the SRM: Bloodborne Pathogens - Infectious Waste Management Operating Procedure (SRM BBP Management) webpage.
- Hazardous chemicals (including items that have been contaminated by hazardous chemicals). Do not autoclave flammable, reactive, corrosive, or toxic chemicals (e.g., alcohols, chloroform, acetic acid, formalin, or fixed tissues). Lab coats that have been contaminated with chemicals should not be autoclaved. They should be cleaned by an approved laundry service or disposed of as chemical waste.

- Bleach-saturated materials: waste items which have been saturated with bleach are not suitat for autoclaving – dispose of solid waste via red bag protocol and decontaminated liquid wast down sanitary sewer in accordance with SRM BBP Management webpage.
- Radioactive materials: Contact Radiation Safety at 828-9131for guidance regarding the proper disposal of radioactive materials.
- Animal Carcasses. All animal carcasses must be red-bagged and managed as regulated medical waste (RMW), and disposed of through DAR.

4c. Preparing Materials

- To ensure adequate steam penetration, pack solid materials loosely; do not crush waste or overfill autoclave waste bags. **Always** use bags designed for autoclave use which are orange in color.
- The bags/containers should be placed in a leak-proof, non-glass, shallow pan so overflow and any spills are contained. Stainless steel pans or plastics designed for autoclave use (e.g., polypropylene, polypropylene copolymer or fluoropolymers) are recommended.
- Before processing, open the bags/containers so the steam can penetrate and raise the temperature for adequate sterilization. A small quantity of water may be added to ensure heat transfer inside the bag/container.
- If the bag is closed during autoclaving, the temperature of the contents may not be raised sufficiently for decontamination.
- If the cycle is processing more than one tray, ensure the spacing between the trays allows the steam to circulate fully.
- Place containers of liquid (e.g., bottles, beakers, flasks) topped with a cotton plug or steam-penetrable cap in a large, leak-proof, shallow pan. Inspect all glassware to ensure there are no cracks.
- Do not fill containers completely. Bottles with narrow necks may boil over if filled too full.
- Avoid the use of bottles if possible, but if it is necessary, make sure that the screw-cap is nearly unscrewed to allow for pressure changes or the vessel may explode.
- Water should be added to the pan to help prevent heat shock to the containers.

4d. Basic Operating Instructions

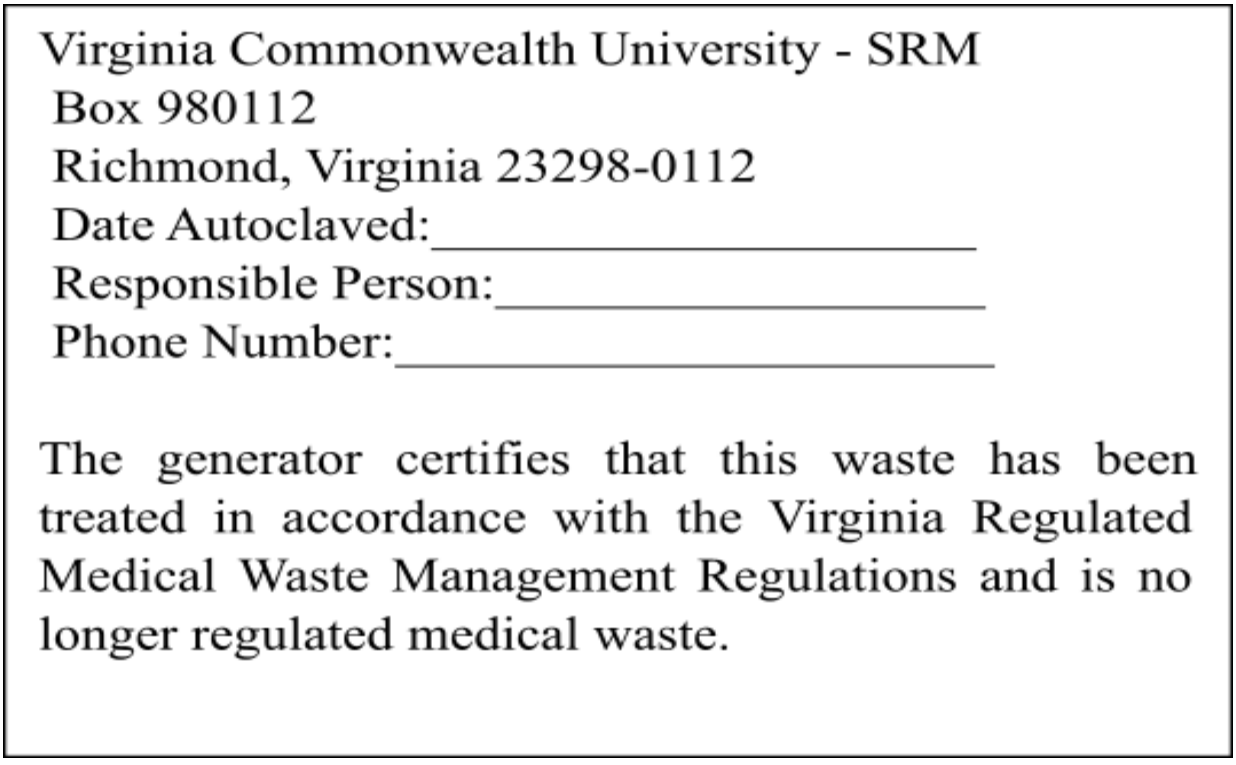
These basic instructions for autoclave use do not replace the manufacturer's operating instructions and hands-on training. Before using any autoclave for the first time, read and understand the owner's manual because different makes and models have unique characteristics.

- Place the items prepared as above in the autoclave chamber.
- Check the drain screen to make sure that it is not plugged or blocked in any way.
- Close and seal the autoclave door.
- On the keypad, or dials, select:
  a. The type of load: gravity or liquid.
  b. The sterilization time: The minimum sterilization time specified by the Va. RMW regulations for orange bag disposal is 90 minutes/at 121°C and 15 pounds per square inch (PSI). Larger/denser loads may require additional for reaching 121°C for 90 minute duration.
  c. For orange bagging, the chamber temperature is set to 121°C (250°F).

d. If desired, set a dry cycle.
e. A preprogrammed cycle, (i.e,. the "waste" cycle) can be selected if the autoclave has this option. Preprogrammed cycles are either factory set or entered by the technician responsible for running the cycles.

- Run the autoclave cycle. Fill out the **autoclave log book** (note: log book must include user ID, description of load, verification of 90 minute treatment at 120 C, and validation of completion of monthly QD testing). For additional blank log sheets, see the building manager or PI to obtain additional copies.
- At the completion of the cycle, don appropriate Personal Protective Equipment (PPE) before opening the door. Mandatory PPE includes all of the following: safety glasses, a lab coat with long sleeves, closed-toed shoes, and heat-resistant gloves.
- Open the door slowly. First, allow steam to escape slowly.
- Allow the autoclaved items to cool for at least ten minutes before opening the door all the way.
- Check the autoclave tape for a color change. The print-out from the recorder should verify the time and temperature that was attained. If not, the load should be re-autoclaved in another autoclave, and the malfunctioning autoclave shall be taken out of use until repairs can be made. Contact the building manager or Facilities Management: 828-9444.
- Any bag displaying the biohazard symbol must be over-bagged with an opaque trash bag and sealed prior to disposal in the regular waste stream. Bags with the biohazard symbol, regardless of use, must be discarded with the biohazardous waste.

4e. The label shown below must be completed and firmly attached to the outside surface of all orange bags following completion of sterilization cycle and prior to disposal in municipal waste stream.



5. GUIDE TO TEMPERATURES AND TIMES (for items to be disposed of)

Items	Biological Waste, solid	Biological Waste,Liquids	Dry Items	Glassware, sharps materials
Preparation	Open the bag >2", Place in tray, Place indicator if needed	Loosen caps or use a vented closure, Fill containers no more than 75% capacity	**Fabrics** Wrap; **Instruments:** Clean, dry, lay in pan	Not acceptable for orange bag disposal
Placement in Autoclave	In the center	Upright in pan	**Fabrics:** Separated, on edge; **Instruments:** Flat	Not acceptable for orange bag disposal
Temperature	121ºC	121ºC	121ºC	Not acceptable for orange bag disposal
Treatment Time (in minutes).	Minimum 90 minute cycle, depending on load size and packing density	Minimum 90 minutes, volume not to exceed 20 ml	Minimum 90 minute cycle	Not acceptable for orange bag disposal
Exhaust Cycle	Slow exhaust	Slow exhaust	Fast exhaust and dry	Not acceptable for orange bag disposal
Addendum	Avoid puncturing. Double bag and dispose of properly.	Hot bottles may explode. Let cool before moving. Bleach disinfection and sink disposal is recommended when feasible	Check reference for proper packaging methods	Not acceptable for orange bag disposal

6. Testing Autoclaves Effectiveness and Documentation

Autoclaves used for orange bag disposal must be tested monthly quality control (QC) testing to validate killing effectiveness. The most common test method uses commercially available biological indicator kits (most utilize *Bacillus stearothermophilus* for this purpose). For the test, the indicator is placed in the center of a "mock" load that simulates a typical biohazard load. Bury the indicator in the center of the load as waste is placed around it. Run the "mock" load through a sterilization cycle (90 minutes at 120 C). After the cycle is finished, open the bag, remove the indicator, and process the indicator as indicated in manufacturer's instructions (typically this will also involve a control vial and require incubation period which will vary between kits). If the indicator displays no evidence of growth, the autoclave "passes" and is functioning within the required VaA RMW regulations parameters. If growth is observed on indicator the test "fails" and the autoclave unit shall not be utilized for orange bagging until the unit is serviced and follow-up QC testing verifies proper operation. Whenever any QC a test cycle is performed, the technician shall record that specific cycle in the **autoclave log book**, and indicate whether the event was "passed" or "failed". In the event of a failed QC test, alert your building manager and Facilities Management by submitting a work request to Facilities Self Service to initiate repairs. Technicians are responsible for posting an "Out of Order" notice on any autoclave that fails QC testing or is otherwise not suitable for orange bagging. This notice is to remain visible at all times until the autoclave has been re-certified for use.

7. ADDITIONAL RESOURCE:

Autoclave Labels

8. REVISION HISTORY:

Version	*Effective Date*	*Changes Made*
#1	Feb. 8, 2016	New document incorporating VCU Biosafety Manual elements
#2	July 26, 2021	Revised, updated