Annual Autoclave Validation and Verification

1. SCOPE

Note: This document replaces LAB-SOP-001 Autoclave Validation Protocol.

The following information provides guidance to develop your own annual autoclave validation protocol in compliance with the Canadian Biosafety Standards, 3rd edition Matrix 3.6.5, 3.6.7, 4.1.10, 4.7.7, 4.7.10, 4.9.12, 5.1.1, and 5.1.4. It is not intended to be specific to a particular autoclave model. It is merely a guide to what should be considered when creating a protocol for your facility. Standard Operating Procedures must be followed when using autoclaves to ensure that all autoclaves in UBC facilities are used and maintained in a safe manner.

2. RESPONSIBILITY

It is the responsibility of the supervisor or person assigned responsibility for the autoclave room to:

- Annually validate all cycle programs used to sterilize materials prior to reuse, removal from the containment zone, or disposal
- train new users in safe use and maintenance of the autoclave, and supervise autoclave use where necessary
- ensure that the safety procedures and autoclave use log are kept close to the instrument
- ensure all users fill out the autoclave use log
- ensure that all the regular and periodic maintenance required is carried out and recorded in the maintenance log
- contact a service representative when repair is necessary and record repair details in autoclave maintenance log

It is the responsibility of the user to:

- Attend a mandatory training session on autoclave lab safety, use, care and maintenance before being allowed to operate an autoclave
- operate autoclaves in accordance with good laboratory procedures and safety procedures as required,
- read and follow all instructions for safe use and maintenance of the autoclave.
- refer to the instruction manual for details and/or ask the employee responsible for the autoclave, or the laboratory supervisor, for assistance if unsure of the safe operation of the instrument
- fill out the log each time the instrument is used,
- report damage to autoclave to the laboratory supervisor so repair can be performed.

After the training takes place, the training must be documented in accordance to WorkSafeBC, CFIA and PHAC regulations.

3. OVERVIEW

Decontamination technologies are in place to inactivate hazardous biological materials prior to reuse of items like glassware, removal of materials from the containment zone, or final disposal of materials contaminated with biohazardous substances. Equipment like autoclaves used for these purposes require regular validation and verification to test the efficacy of the parameters used.

Autoclave validation is more stringent than verification and is a requirement under regulations enforced by the CFIA and PHAC. It tests that cycle parameters are effective at inactivating materials under the most challenging load conditions for a particular cycle used. It is to be conducted annually, after repairs or modifications to the equipment, and/or introduction of new regulated materials or processes. Validation is required for each load type, e.g. solid waste, liquid waste, glassware, using representative loads. The representative load would be the maximum quantity of material for that load type that could possibly be decontaminated per cycle. If a particular cycle is used for multiple load types, the type of material that would be most challenging to decontaminate could be used as the representative load. 'Mock' loads are used to allow placement of efficacy monitors within the load without potential exposure to infectious materials. Efficacy monitors would be placed within the load as centrally as possible. The CFIA has indicated a preference for monitors placed in the top, middle and bottom of a load to show sterilization is achieved throughout the autoclave. It is not necessary to use the same efficacy monitor for validation and verification. There may be cost savings in using a chemical integrator or a calibrated, independent temperature sensor for validation where more expensive biological indicators are used for verification.

Verification of autoclaves is intended to test processes between annual validations to detect process or equipment failures. The frequency of verification should be determined by a Local Risk Assessment (LRA). The degree to which the autoclave is used largely determines the verification needs. Units used daily may consider weekly or bi-weekly verification runs. For less frequently used autoclaves, monthly verification may be sufficient. The different types of load and inherent risks of materials to be sterilized should also be considered. Third party preventive maintenance schedules could also influence verification frequency. Where monitors for validation are placed inside a load, monitors would be placed outside the load for verification to avoid potential worker exposure to infectious materials.

4. MATERIALS

Appropriate laboratory PPE
Autoclave bags
Autoclave buckets

Heat resistant gloves
Biological indicators, chemical integrators or independent temperature sensors suitable for load
Tape or string to secure indicators/integrators
Log sheet or book
Printer paper or chart paper for autoclave

5. REFERENCES AND DEFINITIONS

Decontamination: The process by which materials and surfaces are rendered safe to handle and reasonably free of microorganisms, toxins, or prions; this may be accomplished through disinfection, inactivation, or sterilization.

Decontamination Technology: Equipment proven by validation to render materials safe to handle and reasonably free of microorganisms, toxins, or prions. Examples include autoclaves, incinerators, tissue digesters, and effluent decontamination systems.

Local Risk Assessment (LRA): A site-specific risk assessment used to identify hazards based on the regulated materials in use and the activities being performed. This analysis informs risk mitigation and risk management strategies, which are to be incorporated into the physical containment design and operational practices of the facility.

Representative Load: A simulation batch of materials of a particular load type (e.g., plastics, waste, liquids, carcass), including mixed load types (e.g., containing pipette tips, agar plates and gloves), used to validate a decontamination method for routine loads. The quantity that would be decontaminated in a single load can be a defined amount (e.g., 6 lab coats), size (e.g., an autoclave bag 2/3 full) or weight (e.g., 5 kg).

Secondary Container: A leak-proof container enclosing primary containers (e.g., an autoclave bag within a solid impact-resistant container).

Sterilization: A process that completely eliminates all living microorganisms, including bacterial spores.

Validation: The act of confirming that a method achieves its objective and is suitable for its intended purpose through the provision of objective evidence. This can be achieved by observing that specific conditions have been met (e.g., using biological indicators, chemical integrators, or parametric monitoring devices placed in challenging locations within the load to confirm that a given autoclave cycle can decontaminate a representative load of waste).

Verification: The routine monitoring of equipment and processes to confirm continued efficacy between validations (e.g., testing the performance of an autoclave using biological indicators, viewing airflow gauges to confirm fan function in a BSC).

Verification includes comparing the accuracy of a piece of equipment to an applicable standard or SOP.

6. PROCEDURE

6.1. Validation

Identify the load type for the cycle to be validated, e.g. liquid waste, mixed waste, reusable glassware, contaminated reusable PPE. If a cycle is used for more than one type of load, choose the most challenging load for validation purposes. This may require initially running validation cycles for all load types to determine which is most difficult to pass. This record should be kept for auditing purposes.

Determine the maximum quantity for each load type to be processed in a single run.

Note the cycle parameters in the log book – cycle name, temperature, sterilization time, pressure.

Place the chosen efficacy monitor in the most challenging area of the load to sterilize. For example, if the load consists of two autoclave bags ¾ full of plasticware, the monitor could be placed in the centre of each bag.

Load the autoclave and run the cycle.

Note the cycle parameters captured on the cycle print out or chart paper in the log book. The print out or chart paper should also be stored with the log book.

Retrieve the monitor at the end of the cycle and process as appropriate.

- Read CI
- Download temperature sensor data
- Incubated BI with a positive control from the same lot

Accept the cycle parameters for the load type if the efficacy monitor indicates sterilizing temperature and time were achieved.

Repeat the process with different parameters (e.g. decreased load size, increased sterilization time) if the monitor indicates the cycle failed, until passing parameters are achieved.

6.2. Verification

Standardize the frequency for verification, i.e. weekly, monthly.

The load for verification can be any size that does not exceed the load used for validation.

Place the chosen efficacy monitor outside of the load and in the centre of the autoclave chamber.

Run the cycle with the validated parameters.

Remove the monitor at the end of the cycle and process as appropriate.

Record results in the log book.

6.3. Example Autoclave Validation Log:

Autoclave Make and Model: _____

Load Type: Mixed waste (pipette tips, agar plates, gloves, etc)

Maximum Quantity: 2 bags, ¾ full, loosely closed with tape, placed in autoclave bucket

Biological Indicator: Type/ Model (3M SCBI, Vendor Cat #)

Lot No.:_____

Expiration Date:_____

Placement: One BI in plastic tube with tape tail attached in centre of each bag.

Cycle Program Name: Solid Waste

Cycle Parameters: 121°C, 60 minutes liquid cycle, 15 psi, fast exhaust

Date	Temperature Achieved	Sterilization Time	Pressure	Pass	Fail	Control	Tech Initials

6.4 Example Autoclave Verification Log:

Autoclave Make and Model: _____

Load Type: Mixed waste (pipette tips, agar plates, gloves, etc)

Load size: any amount less than the Maximum Quantity for validation

Biological Indicator: Type/ Model (3M SCBI, Vendor Cat #)

Lot No.:_____

Expiration Date:_____

Placement: One BI taped to middle of bag in middle of autoclave

Cycle Program Name: Solid Waste

Cycle Parameters: 121°C, 60 minutes liquid cycle, 15 psi, fast exhaust

7. REVIEW AND RETENTION

This document is reviewed annually or whenever deemed necessary by the responsible departmental representative.

8. DOCUMENT APPROVAL SIGNATURES

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