

*Insert Facility/Institute Logo Here*

**STANDARD OPERATING PROCEDURE (SOP) *TEMPLATE***

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| Facility: |
| SOP Title: *Autoclave Operation and Maintenance SOP* |
| Document Number: *3-02-006* | Version Number: *00* |
| Process Leader: | Effective Date: *MM-DD-YYYY* |
| Other documents cross-referenced in this SOP (i.e., manuals, SOPs, forms, records):* Biorisk Management Manual Chapter V, Biorisk Assessment; Chapter XII, Equipment (*4-00-001*)
* *Attachment B, Protocol Risk Assessment Form*
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| Revision Number | Sections Changed | Description of Change | Date | Approved By |
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INSTRUCTIONS: The Biorisk Management Manual and supporting Standard Operating Procedure (SOP) templates provide a general overview of common considerations and information that should be addressed within a biorisk management system and program. These templates are not exhaustive and facilities must customize each document to ensure it is locally applicable and relevant.

* **Black text** can be considered generic text which may be appropriate for inclusion in a facility’s biorisk management manual and SOPs.
* ***Red text*** should be considered guidance or examples and must be reviewed and replaced with facility-specific information.
1. Purpose

The purpose of this document is to establish procedures for proper use and maintenance of autoclaves used by *Insert Institute/Facility Name.* Adherence to this procedure allows the autoclave to function as designed in order to provide the appropriate level of sterilization and/or decontamination of biological work supplies and waste.

1. Scope

This document applies to all facility personnel and visitors who use autoclaves within *Insert Institute/Facility Name* and is used when determined necessary by risk assessment to provide the appropriate level of sterilization and/or decontamination of biological work supplies and waste.

1. Responsibilities
* **Process Leader** ensures autoclaves are properly selected, located, operated and maintained and that users are trained on this procedure.
* **Facility personnel** who use autoclaves follow the procedures outlined in this SOP and report any problems to the Process Leader.
* ***Facilities Management Office*** ensures that all autoclaves are installed, serviced, calibrated and validated properly.
1. Preparation
	1. Materials
* Biohazard waste bags and containers
* Temperature indicator strips
* Steam sterilization indicator tape
* Biological indicator for steam sterilization
* Appropriate growth media or self-contained biological indicator and media ampule
* Heat-resistant Gloves
* *PPE as determined by risk assessment*
* Mild detergent/cleaning agent
* “Out of Service” sign
	1. Equipment
* Autoclave, *size, type and model*
	1. Records and Forms
* Autoclave Calibration Test Report
* Autoclave Validation Test Report
* Equipment Use Log
1. Procedure *(refer to Attachment A, Autoclave: Operation and Maintenance SOP Template Flow Chart)*
	1. Autoclave Selection, Procurement, Installation
		1. Selection
			1. *Describe steps to be taken based on questions from flow chart steps 1-3*
		2. Procurement
			1. *Describe steps to be taken based on questions from flow chart step 4*
		3. Installation
			1. *Describe steps to be taken based on questions from flow chart step 4*
	2. Routine Operations
		1. Set-up procedures and cycle selection
			1. *Describe steps to be taken based on questions from flow chart step 6A*
		2. Safety considerations and work practices
			1. *Describe steps to be taken based on questions from flow chart step 7A*
		3. Removal of materials and performance verification
			1. *Describe steps to be taken based on questions from flow chart step 8A*
	3. Scheduled Maintenance
		1. *Describe steps to be taken based on questions from flow chart step 6B*
	4. Unscheduled Maintenance
		1. *Describe steps to be taken based on questions from flow chart step 7B*
2. References
	1. *Manufacturer’s Instructions*
3. Attachments
	1. Autoclave: Operation and Maintenance SOP Template Flow Chart
	2. *Attachment B, Protocol Risk Assessment Form*



* *Who authorizes purchase (Scientific Manager/Director)?*
* *Who coordinates delivery and installation (Facilities Management)?*
* *How are users trained prior to use?*