Autoclave Installation and Operation Guidelines

Part 70 of Title 10 (Health) of the official Compilation of Codes, Rules and Regulations of the State of New York (10 NYCRR Part 70) states that a facility seeking to operate an autoclave shall develop an operation plan that is submitted to the Department of Health for review and approval prior to using the autoclave to treat regulated medical waste (RMW). An operation plan are the policies and procedures that are used for a facility's operation of an on-site autoclave. Any modification of an approved operation plan will need to be submitted to the Department for approval and may require revalidation of your autoclave. In addition to the operation plan facilities must submit a standard operating procedure that include validation testing, operational requirements and record keeping. Please use the information below to prepare the required documentation and submit the information for review to:

US Postal Service:

Biggs Laboratory
Wadsworth Center
NYS Department of Health
Empire State Plaza
Albany, NY 12237

UPS, FedEx, Courier:

Biggs Laboratory
Wadsworth Center
NYS Department of Health
Dock J - P1 Level
Empire State Plaza
Albany, NY 12237

Phone: (518) 485-5357
Email: rmwp@health.ny.gov

Section 1: General Information

Facility Name_____

Facility Address_____

Contact Person_____

Phone_____

Fax_____

Email_____

Section 2: Operation Plan

The goal of an operation plan is to promote safe and effective operation of an autoclave. The operation plan shall include the following information:

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	Procedures that were used to validate the autoclave and prove the autoclave effectively treats the types of regulated medical waste that will be autoclaved. This would include a description of the protocols used for validation testing and any supporting data obtained from the validation studies. *See section 3 below for additional information.
	Policies that have been established to ensure that the regulated medical waste being treated are limited to the types of waste that have been shown to be effectively treated through validation testing.
	Procedures describing how the residence time, temperature and pressure will be monitored and documented to ensure that each load is run under conditions for which the system was validated.
	Preventative maintenance procedures used to monitor autoclave operation. A description of the steps that will be taken and the frequency to monitor autoclave operations. Autoclave operations include: • Calibration verification and recalibration of parametric controls. • Monitoring by challenge testing or other demonstration that treatment has been attained. • Preventative maintenance of engineering controls and diagnostic procedure for electronic controls.
	Policies describing how occupational exposures are minimized and physical injury to operators is prevented during loading the cycle and unloading the autoclave.
	Information on how staff will be trained on the operation of the autoclave and use of emergency procedures for handling malfunctioning systems and untreated waste. Initial training an annual retraining need to be described.

Section 3: Validation Testing

Prior to using an autoclave to treat regulated medical waste, a facility shall conduct validation testing under conditions, including, but not limited to load configuration, composition and volume, that simulate conditions anticipated during actual waste treatment. Validation testing must be performed and approved upon installation of a new autoclave, if there is no record initial validation approval, or when there is a change in the operational parameters.

Validation testing needs to be performed using *Geobacillus stearothermophilus* spores at a minimum concentration of 6 log 10 spores per indicator unit that are placed in the center of the load or otherwise coldest point in the autoclave chamber as identified by the manufacturer.

Effective treatment of regulated medical waste shall be demonstrated by a 4 log 10 reduction in viable *Geobacillus stearothermophilus* spore concentration.

The following information needs to be submitted as part of the validation studies:

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	A description of the simulated load of waste that will be used. Include a description of the load configuration, composition and volume of waste to be treated per load.
	The approximate percentage of inorganic and organic components of the waste composition.
	Verification that loads are equal to the autoclave's treatment capacity.
	A description of the quantity and placement of the biological indicators and thermal indicator devices. Please refer to Table 1 for the number of indicators and controls that should be used based on waste load in pounds.
	Information pertaining to the supplier, lot number and the starting concentration of the biological indicators (which may be in the form of a package insert).
	The protocol used for the validation studies, a summary of the results obtained and any original data that demonstrates that the simulated waste load was effectively treated as evident by a 4 log 10 reduction in viable *Geobacillus stearothermophilus* spore concentration. A minimum of three (3) separate runs, using distinct loads (preferably on separate days) is required.
	A dated print out verifying that the operating parameters of time, temperature and pressure were attained during each of the three validation runs.

Table1: **Quantity of Biological Indicators and Thermal Indicator Devices for Validation Studies**

Waste Load in Pounds	**# of Indicators in each**		**# of Control Indicators**
	Thermal	**<u>Biological</u>** ***Spore Strip* or *Self Contained***	**<u>Biological</u>** ***Spore Strip or Self Contained***
0-110	4	4	2
111-550	6	6	2
551-1100	8	8	4
1101-1650	10	10	6
>1650	12+	12+	6

***Guidance**: The quality control indicators remain outside the autoclave and are not treated.

Section 4: Operational requirements

In addition to the policies and procedures included in the operation plan and the validation testing, there are additional procedures that need to be included in your autoclave standard operating procedure (SOP).

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	A procedure for handling failure of a system during operation, including appropriate documentation and notifications. This procedure shall include steps that will be taken to: • discontinue use of the autoclave, using emergency shutdown procedure if appropriate, until corrective action has been taken and validation testing has verified that effective treatment can resume; • handle all RMW processed since the last documented compliant run as untreated RMW • document the failure, including date and autoclave identifier; • document the facility response, including corrective action; • in addition to known untreated RMW, any RMW that is believed to be untreated but was sent out as treated shall be notified to the waste transporter as soon as practicable and notify the Department within seventy-two (72) hours of the waste's leaving the facility.
	Procedure on how monitoring of autoclave operations will be documented and conducted by one of two methods: • by parametric controls, employed to monitor operating parameters automatically and continuously throughout the entire cycle and to generate a record of operating parameters for each cycle • in the absence of parametric controls, routine operational performance of an autoclave shall be monitored by challenge testing, conducted every forty (40) hours of autoclave operation or once a week, whichever occurs first, using the same protocol as was approved by the Department of validation testing and time/temperature-sensitive materials used in each load.
	A description of the container or containment system designed to withstand the temperature and pressure of autoclaving.
	A description of the procedure used to insure steam will come into direct contact with waste materials and proper treatment is achieved.
	A description of how treated sharps will be destroyed prior to disposal.

Section 5: Record Keeping

A variety of records must be maintained by the facility and such records should be retained for 3 years and be available for inspection by this Program. Records to be maintained include:

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	Validation testing and challenge testing, including protocols and test results.
	Documents demonstrating routine system monitoring.
	Evidence of employee training and/or retraining.
	Documentation of corrective action.
	Documentation of any modification to an approved operation plan, regardless of whether the modification is subject to Department approval.
	Documentation of residence time, pressure and temperature of each load treated (parametric controls).

***Note**: Any facility that seeks to operate an autoclave in any way other than the generally accepted operating parameters (see section 70-3.3 (a) and (b)) or to treat human tissue, animal parts and carcasses, must apply for approval as an alternative treatment system (see section subpart 70-5).