NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

Installation Approval Guidelines for facilities that use Alternative Regulated Medical Waste Treatment Systems

Facilities that would like to use an approved alternative system to treat regulated medical waste are required to verify, through validation, that the system operates under parameters set by prior efficacy studies performed by the manufacturer of the system. Information that needs to be submitted for review includes the operation parameters and a description of the protocols that will be used to validate operation of the system. Once these documents are approved by the Regulated Medical Waste Program, validation testing can be performed by the facility and data submitted for review by the program. No alternative treatment system should be placed into operation prior to implementation of such operation plan, which should be designed to promote the safe and effective operation of the alternative system. Any future modifications to the plan may require additional efficacy and/or validation testing.

I. Operation Parameters
II. Validation Testing
III. Record keeping

I. Operation Parameters

An operation plan needs to be submitted at least 60 days prior to the start-up of a system. An operation plan needs to include:

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	A description of operating parameters which have been proven to be effective for the treatment of regulated medical waste.
	A description of the waste loads that will be processed. Only those waste loads for which effective treatment has been demonstrated through efficacy studies by the system manufacturer can be processed.
	Indicate the effectiveness of treatment, by including: • procedures for and frequency of calibration verification and recalibration of parametric controls • A description of preventive maintenance procedures (e.g., replacement of HEPA filters and diagnostic procedures for electronic controls).
	Monitoring the operational performance of an alternative regulated medical waste system should be documented and conducted in 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 annual training programs for personnel. This should include guidelines for loading and unloading the system to minimize occupational exposure and physical injury to operators, and emergency procedures for handling malfunctioning systems and untreated medical waste.
	A description of procedures for handling failure of a system during operation, including appropriate documentation and notifications. • discontinue use of the system, using emergency shutdown procedure if appropriate, until corrective action has been take and validation testing has verified that effective treatment can resume; • handle as untreated all RMW processed by the system since the last previous run under documented compliance with such requirements; • document the failure, including date and system identifier; • document the facility response, including corrective action; • whenever the facility has reason to believe untreated waste certified as treated waste has left the facility, notify the waste transporter as soon as practicable ad notify the Department within seventy-two (72) hours of the waste's leaving the facility.

II. Validation Protocols and Testing

Validation testing must be performed before start-up of a newly installed approved alternative regulated medical waste treatment system to demonstrate, under pre-established operating parameters, the effective treatment of regulated medical waste at the installation site. The Program must approve a protocol for such validation testing before testing can begin. Protocol for validation testing should include:

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	A description of the waste treatment process (e.g., chemical, microwave, steam, heat, etc.) that contains an indication of the capacity of the unit, type of shredding device, and, as appropriate, minimum temperatures and adequate residence time for effective treatment.
	A description of the composition and volume of waste to be treated per load that is typically generated by a facility and presents the worst case scenario for treatment.

	A description of how the biological indicator will be used in the validation study. Include information pertaining to the supplier, lot number, and the starting concentration (which should be at a minimum 1.8x106). G*eobacillus stearothermophilus* spores should be used for heat/thermal systems and *Bacillus atrophaeu*s spores should be used for chemical systems. The number of indicators used in the validation study will be determined by the Program on a case by case basis according to the size of the waste load to be treated.
	An indication of the location and time intervals the biological indicator samples will be placed in the load.
	A procedure for testing biological indicator sample to determine final concentrations after treatment.

III. 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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	Documentation of validation testing performed
	Protocol approval and test results
	Documents demonstrating routine system monitoring (including records of annual calibration of parametric controls or monitoring devices)
	Documents describing corrective action for malfunctioning systems and steps to be taken if untreated waste certified as treated waste inadvertently leaves a facility.
	Any modifications to an operations plan that required additional efficacy and/or validation testing.
	Evidence of employee training and/or retraining.
	Evidence that the system to be used has been granted approval to operate in New York State (provided by the system manufacturer).