



John R. Kasich, Governor  
Mary Taylor, Lt. Governor  
Craig W. Butler, Director

**MAY 29, 2014**

Mr. Jon Bricken  
Bluestone Medical, Inc.  
47 Old South Salem Road  
Ridgefield, CT 06877

Thermal Eliminator  
TE-5000  
Notification  
IW  
IWT020357

**Subject: Approval of the Thermal Eliminator, model TE-5000,  
Alternative Infectious Waste Treatment Technology**

Dear Mr. Bricken:

In accordance with Ohio Administrative Code (OAC) Rule 3745-27-38, Bluestone Medical, Inc., submitted an Evaluation of Infectious Waste Treatment Technology Information Request Form. Bluestone Medical, Inc. is requesting statewide approval of the Thermal Eliminator, model TE-5000 as an alternative method for treatment of infectious waste. According to the information received by the Ohio Environmental Protection Agency (Ohio EPA) on November 27, 2006, the Thermal Eliminator, model TE-5000 is designed to treat infectious waste generated in medical offices.

The Thermal Eliminator, model TE-5000 is a dry-heat treatment system with continuous parametric monitoring that treats infectious waste. The infectious waste is collected in specially designed one-gallon containers that are constructed of tin with a high temperature plastic lid system. Once sealed, the container is tamper resistant preventing access to the infectious waste throughout the treatment and the disposal process. During treatment, the system heats the container to a minimum temperature of 350°F and holds at or above this temperature for a minimum of 90 minutes. The treated infectious waste is encapsulated in a block of plastic at the bottom of the container.

Pursuant to OAC Rule 3745-27-38, the Thermal Eliminator, model TE-5000 is granted statewide approval if Bluestone Medical, Inc., and the owner or operator of each installed unit conforms to the following conditions:

- A. Bluestone Medical, Inc. shall provide the following to each operator of the Thermal Eliminator, model TE-5000 unit:
  1. A copy of the Director's approval letter (this letter) is in the front of each operating manual of the Thermal Eliminator, model TE-5000 unit.

2. A daily operating log form permanently maintains a record of the date and time of each treatment cycle, and name of the person operating the treatment unit for each treatment cycle.
- B. The owner or operator of a Thermal Eliminator, model TE-5000 unit shall comply with the following operational requirements and conditions:
  1. The Thermal Eliminator, model TE-5000 unit must be operated at a minimum temperature of 350°F and hold at or above this temperature for a minimum of 90 minutes for each treatment cycle.
  2. Perform on-site validation testing of the Thermal Eliminator, model TE-5000 unit after installation prior to use.
  3. Perform quality assurance testing semi-annually to ensure that the dry-heat encapsulation system is capable of achieving the performance standard of a minimum four  $\log_{10}$  reduction of bacterial spores.
  4. Keep quality assurance records and the daily log of operations on site for a minimum of three years.
  5. Develop and maintain in one area on the premises of the infectious waste treatment unit, a Facility Management Plan (FMP) that includes the following information and documentation:
    - a. A statement signed by each treatment unit operator certifying that training has been provided to them regarding the operation and maintenance of the Thermal Eliminator, model TE-5000 unit.
    - b. A statement signed by each person filling the one gallon container with infectious waste certifying that the operator of the treatment unit has provided instruction on the use of the canister and the types of infectious waste the unit is approved to treat.
    - c. A daily operating log form for each unit for each day that infectious waste is treated in the unit.
    - d. A list of preventative maintenance checks and services as stated in the operating manual.
  6. Perform the quality assurance testing upon request by, and in the presence of, the Ohio EPA or approved health department to verify that the written operating procedures located in the facility management plan are sufficient to meet the performance standard of a four  $\log_{10}$  reduction in bacterial spores.

7. Comply with all applicable infectious waste treatment rules in OAC 3745-27-32.
8. Each operator shall utilize a daily operating log form for each unit for each day that infectious waste is treated in the unit. All daily operating logs for a treatment unit shall be grouped together and arranged by date within the grouping.
9. Conduct preventative maintenance checks and services as stated in the operating manual (include dates and name of person completing the checks and services).
10. Manage as infectious waste all wastes contained inside the unit, if the Thermal Eliminator, model TE-5000 unit fails any parametric monitoring for any reason. The operator shall cease to use the treatment unit until such time that the treatment unit is repaired or calibrated and passes a quality assurance test. Infectious waste may be temporarily maintained within the treatment unit unless the waste becomes putrescent or becomes a food source or breeding ground for insects or rodents.
11. Operate the treatment unit using only the specially designed one-gallon containers (constructed of tin with a high temperature plastic lid system) containing infectious waste from medical offices similar to that which the treatment technology has been tested against.
12. Wastes containing chemotherapeutic wastes, pathological wastes, and hazardous waste as defined in 40 CFR Part 261 and OAC Chapter 3745-51 or radioactive material as defined in Chapter 3748 of the Ohio Revised Code (ORC) shall not be introduced into the Thermal Eliminator, model TE-5000 unit.

Upon compliance with the conditions stated herein, infectious waste treated by this unit is to be handled in the same manner as solid waste and must be disposed in a licensed solid waste facility. Additionally, this approval does not release the owner or operator from compliance with all other federal or local laws or regulations. This approval is not a substitute for a Permit-to-Install and license as cited in ORC Chapter 3734.

You are hereby notified that this action of the Director is final and may be appealed to the Environmental Review Appeals Commission pursuant to ORC Section 3745.04. The appeal must be in writing and set forth the action complained of and the grounds upon which the appeal is based. The appeal must be filed with the Commission within thirty (30) days after notice of the Director's action. The appeal must be accompanied by a filing fee of \$70.00 which the Commission, in its discretion, may reduce if by affidavit it is demonstrated that payment of the full amount of the fee would cause extreme hardship. Notice of the filing of the appeal shall be filed with the Director within three (3)

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days of filing with the Commission. Ohio EPA requests that a copy of the appeal be served upon the Ohio Attorney General's Office, Environmental Enforcement Section.

An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission  
77 South High Street, 17<sup>th</sup> Floor  
Columbus, Ohio 43215

If you have any questions concerning this authorization, please contact Ohio EPA, Division of Materials and Waste Management, Solid Waste Compliance and Inspection Support Unit at (614) 644-2621.

Sincerely,



Craig W. Butler  
Director

CWB/hh/jb