



Mike DeWine, Governor
Jon Husted, Lt. Governor
Laurie A. Stevenson, Director

APRIL 24, 2019

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

Re: Thermal Eliminator – TE-5000
Non-Permit Related Exemption
Approval
Infectious Waste
IWT020357

**Subject: Thermal Eliminator – TE-5000
Exemption from Condition (B)(3) Director’s Authorization Letter
Small Generators of Infectious Waste**

Ohio EPA APR 24 '19
Entered Directors Journal

Dear Mr. Bricken:

On May 29, 2014, the Director of the Ohio Environmental Protection Agency (Ohio EPA), granted approval to Bluestone Medical, Inc. for the Thermal Eliminator – TE-5000 as an alternative infectious waste treatment technology, pursuant to OAC Rule 3745-27-38, for statewide use as a treatment for infectious waste. As part of the approval, the Thermal Eliminator – TE-5000 is required to perform quality assurance testing to ensure appropriate treatment of the infectious waste. Specifically, Condition (B)(3) of the Director’s approval letter requires the owner or operator of a Thermal Eliminator – TE-5000 to perform semi-annual quality assurance testing to ensure that the unit is achieving the performance standard of a minimum four log₁₀ reduction of bacterial spores.

However, except for specimen cultures and cultures of infectious agents, small generators of infectious waste are not required to treat infectious wastes prior to disposal. Small generators may dispose of infectious waste, except for specimen cultures and cultures of infectious agents, directly into the solid waste stream/trash, provided this method of disposal is in compliance with U.S. Department of Transportation regulations.

Ohio EPA has determined that granting Bluestone Medical, Inc.’s Thermal Eliminator – TE-5000 an exemption from Condition (B)(3) of the Director’s approval letter dated May 29, 2014, for small generators of infectious waste is unlikely to adversely affect public health or safety or the environment. Therefore, pursuant to ORC Section §3734.02(G) and OAC Rule 3745-27-03(B), Bluestone Medical Inc. is hereby granted an exemption from Condition (B)(3) of the Director’s approval letter dated May 29, 2014, for **small generators of infectious waste** only but **does not include** specimen cultures or agar or broth media cultures of infectious agents produced by a small generator. Agar and broth culture media have the potential to significantly contribute to an unquantifiable increased liquid content in the waste material which could

negatively affect the operation and treatment capacity of the unit. Thus, necessitating the use of the semi-annual quality assurance testing requirement in Condition (B)(3) to ensure treatment.

Large generators of infectious waste using the Thermal Eliminator – TE-5000 shall continue performing semi-annual quality assurance testing to ensure the unit is achieving the performance standard of a minimum four log₁₀ reduction of bacterial spores as required by Condition (B)(3) of the Director's approval letter dated May 29, 2014.

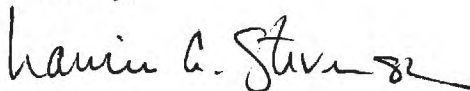
Bluestone Medical, Inc. shall provide a copy of this exemption along with the May 29, 2014 Director's approval letter to each operator of the Thermal Eliminator, model TE-5000, and enclose a copy of these documents in the front of each operating manual distributed to those individuals. This exemption shall remain in effect unless otherwise revoked.

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 made payable to "Treasurer, State of Ohio." The Commission, in its discretion, may reduce the fee 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) 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
30 East Broad Street, 4th Floor
Columbus, Ohio 43215

If you have any questions concerning this letter, please contact Alison Shockley, Ohio EPA, DMWM, at (614) 728-5335.

Sincerely,



Laurie A. Stevenson
Director, Ohio EPA