



State of Ohio Environmental Protection Agency

STREET ADDRESS:

Lazarus Government Center
50 W. Town St., Suite 700
Columbus, Ohio 43215

TELE: (614) 644-3020 FAX: (614) 644-3184
www.epa.state.oh.us

OHIO E.P.A. MAILING ADDRESS:

NOV 28 2007 P.O. Box 1049
Columbus, OH 43216-1049

NOV 28 2007

Ms. Diane Gorder
Biomedical Technology Solutions, Inc.
9800 Mt. Pyramid Court
Suite 350
Englewood, CO 80112

ENTERED DIRECTOR'S JOURNAL

I certify this to be a true and accurate copy of the
official documents as filed in the records of the Ohio
Environmental Protection Agency.

By: Dmytro Jacke Date: 11-28-07

RE: Approval of the Demolizer™ Infectious Waste Treatment Technology

Dear Ms. Gorder:

In accordance with Ohio Administrative Code (OAC) Rule 3745-27-38, BioMedical Technology Solutions, Inc., submitted an Evaluation of Infectious Waste Treatment Technology Information Request Form. BioMedical Technology Solutions, Inc., is requesting statewide approval of the Demolizer™ Technology 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 Demolizer™ Technology is designed to treat infectious waste and infectious sharps generated in medical offices.

The Demolizer™ Technology is a dry-heat treatment system with continuous parametric monitoring that treats infectious waste and sharp 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 Demolizer™ Technology is granted statewide approval if BioMedical Technology Solutions, Inc., and the owner or operator of each installed unit conforms to the following conditions:

- A. BioMedical Technology Solutions, Inc. shall provide the following to each operator of the Demolizer™ Technology unit:
 1. A copy of the Director's approval letter (this letter) in the front of each operating manual of the Demolizer™ Technology unit.

Ted Strickland, Governor
Les Fisher, Lieutenant Governor
Chris Horne, Director



2. A daily operating log form that 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 Demolizer™ Technology unit shall comply with the following operational requirements and conditions:
1. The Demolizer™ Technology 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 Demolizer™ Technology 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 log₁₀ reduction of *Bacillus subtilis* 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 Demolizer™ Technology 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.

- 6.4. 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 log₁₀ reduction in bacterial spores.
- 7.5. Comply with all applicable infectious waste treatment rules in OAC 3745-27-32.
- 8.6. 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.
- 9.7. Conduct preventative maintenance checks and services as stated in the operating manual (include dates and name of person completing the checks and services).
- 10.8. Manage as infectious waste all wastes contained inside the unit, if the Demolizer™ Technology 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.
- 11.9. 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 and infectious sharps from medical offices similar to that which the treatment technology has been tested against.
- 12.10. Wastes contaminated with chemotherapeutic wastes, pathological wastes, cytotoxic agents, hazardous waste as defined in 40 CFR Part 261 and OAC Chapter 3745-37-51, or radioactive waste shall not be introduced into the Demolizer™ Technology 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.

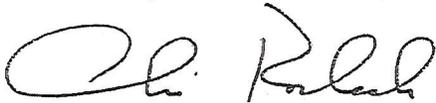
You are hereby notified that this action of the Director is final and may be appealed to the Environmental Review Appeals Commission pursuant to Section 3745.04 of the

Ms. Diane Gorder
Page 4

Ohio Revised Code. 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 you demonstrate that payment of the full amount of the fee would cause extreme hardship. Notice of the filing of the appeal must be filed with the Director within (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 Appeal Commission
309 South Fourth Street, Room 222
Columbus, Ohio 43215.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Korleski". The signature is fluid and cursive, with the first name "Chris" written in a larger, more prominent script than the last name "Korleski".

Chris Korleski
Director

CK/MF/sw