



State of Ohio Environmental Protection Agency

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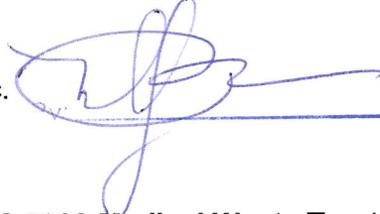
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P.O. Box 1049
Columbus, OH 43216-1049

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.

APR 9 2008

Mr. Joseph Fazio Jr.
Medical Waste Recovery, Inc.
2069 Fletcher Avenue
Fort Lee, NJ 07024

 Date: 4.9.08

APPROVED DIRECTOR'S JOURNAL

APR - 9 2008

OHIO E.P.A.

RE: Approval of the PIWS 3000 Medical Waste Treatment System

Dear Mr. Fazio:

In accordance with Ohio Administrative Code (OAC) Rule 3745-27-38, Medical Waste Recovery, Inc., submitted an Evaluation of Infectious Waste Treatment Technology Information Request Form. Medical Waste Recovery, Inc. is requesting statewide approval of the PIWS 3000 Medical Waste Treatment System as an alternative method for treatment of infectious waste. According to the information received by the Ohio Environmental Protection Agency (Ohio EPA) on August 13, 2007, the PIWS 3000 is designed to treat infectious waste categories routinely generated by hospitals.

The PIWS 3000 system is a continuous feed treatment system that uses a dry chemical, Cold-Ster™, and a grinder to treat infectious waste. The two-stage process cuts the waste while simultaneously mixing it with the dry chemical, Cold-Ster™. The Cold-Ster™ is activated by a water spray, which creates an alkaline environment that renders the waste non-infectious. The volume of waste is reduced by up to 70%. As the treated waste exits the PIWS 3000 unit, a pH probe ensures that proper treatment conditions are maintained. The PIWS 3000 unit's computer control system creates a permanent treatment record by documenting the quantity and pH of the treated waste and the length of time required for treatment.

Ohio EPA has reviewed the microbial testing data submitted by Medical Waste Recovery, Inc. Ohio EPA has determined that the PIWS 3000 system is capable of achieving the performance standard of a minimum four log₁₀ reduction of bacterial spores, which is required for approval of an alternative infectious waste treatment technology.

Pursuant to OAC Rule 3745-27-38, the PIWS 3000 medical waste treatment system is granted statewide approval if Medical Waste Recovery, Inc., and the owner or operator of each installed unit conform to the following conditions:

- A. Medical Waste Recovery, Inc. shall provide the following to each operator of the PIWS 3000 unit:
 1. A copy of the Director's approval letter (this letter) in the front of each operating manual of the PIWS 3000 system.

Ted Strickland, Governor
Lee Fisher, Lieutenant Governor
Chris Korleski, 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 system for each treatment cycle.

B. The owner or operator of a PIWS 3000 system shall comply with the following operational requirements and conditions:

1. Operate the PIWS 3000 system at a pH between 11 and 12.5 for each treatment cycle and ensure the Cold-Ster™ chemical has not expired.
2. Perform on-site validation testing of the PIWS 3000 system after installation, prior to use.
3. Perform quality assurance testing semi-annually to ensure that the PIWS 3000 system is capable of achieving the performance standard of a minimum four log₁₀ 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 PIWS 3000 system.
 - b. A statement signed by each person loading the PIWS 3000 system with infectious waste certifying that the types of infectious waste being loaded into the unit are 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 system.
 - 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 log₁₀ 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 day that infectious waste is treated in the system. All daily operating logs for a treatment system shall be grouped together and arranged by date within the grouping.

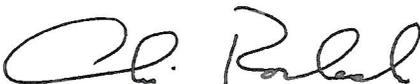
9. Conduct preventative maintenance checks and services as stated in the operating manual (include dates and name of person completing the checks and services).
10. Manage as infectious waste all wastes contained inside the unit, if the PIWS 3000 system fails any parametric monitoring for any reason. The operator shall cease to use the treatment system until such time that the treatment system 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 PIWS 3000 system by treating infectious waste and infectious sharps similar to that which the treatment technology has been tested against.
12. 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 PIWS 3000 unit.

Upon compliance with the conditions stated herein, infectious waste treated by this system 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 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,



Chris Korleski
Director

CK/MF/sw