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Mary Taylor, Lt. Governor
Craig W. Butler, Director

OHIO E.P.A.

JUN 17 2014

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 Donna Cassel Date: 6-17-14

JUN 17 2014

Mr. Steve Pellegrine
Clean Waste Systems, LLC
3535 Plymouth Blvd., Suite 112
Plymouth, MN 55447

Re: Clean Waste Systems, LLC
Director's Authorization
Approval
Infectious Waste
Out of State
IWT020374

**Subject: Alternative Infectious Waste Treatment Technology Approval
OMW-1000**

Dear Mr. Pellegrine:

In accordance with Ohio Administrative Code (OAC) Rule 3745-27-38, Clean Waste Systems, LLC, submitted an Evaluation of Infectious Waste Treatment Technology Information Request Form. Clean Waste Systems, LLC is requesting statewide approval of the OMW-1000 as an alternative method for treatment of infectious waste. According to the information received by the Ohio Environmental Protection Agency (Ohio EPA) on September 23, 2013, the OMW-1000 is designed to mechanically deliver, shred, and treat infectious waste types routinely generated by hospitals, in a contained treatment chamber using high levels of ozone.

The OMW-1000 mechanically disintegrates medical waste through shredding and then exposes the infectious waste to ozone at a minimum of 1500 parts per million for sixty minutes. Medical waste is placed into carts and mechanically lifted and dumped into the shredder through an automatic process. The ozone is bubbled through water and detected by the ozone sensor. The system is designed so that the timer only runs when ozone levels exceed 1500 parts per million.

The microbial testing data submitted by Clean Waste Systems, LLC, demonstrates that the OMW-1000 is capable of achieving a minimum six log₁₀ reduction of bacterial spores in the presence of twenty percent pathological waste. Pathological waste includes human tissues, organs, body parts, and body fluids and excreta that are contaminated with an infectious agent.

Pursuant to OAC Rule 3745-27-38, Clean Waste Systems, LLC is granted statewide approval for the OMW-1000 to treat infectious waste. As part of this authorization,

Clean Waste Systems, LLC and the owner or operator of each installed OMW-1000 unit is subject to the following conditions:

- A. Clean Waste Systems, LLC shall provide the following:
 1. A copy of the Director's approval letter (this letter) shall be included in the front of each operating manual of the OMW-1000 and shall be presented prior to purchase to each prospective purchaser or operator in the State of Ohio.
 2. An updated operating manual that significantly impacts the use or operation of the system shall be provided to Ohio EPA thirty (30) days prior to the operating manual change.
 3. A written notification shall be provided to Ohio EPA a minimum of seven (7) days prior to all new installations of the OMW-1000 in the State of Ohio.
- B. The owner or operator of an OMW-1000 shall comply with the following operational requirements and conditions:
 1. Perform a shift inspection each morning of the OMW-1000 equipment to discover any issues prior to treatment of infectious waste.
 2. Use the *Main Control Monitor* to observe the status of all of the system's components. Since the OMW-1000 is designed to monitor all aspects of the equipment and to turn on, off, or make adjustments automatically, the operator should be aware of this process and be ready to press the emergency stop button in the event that the machine is not processing correctly.
 3. Keep quality assurance records and the daily log of operations on site for a minimum of three years.
 4. 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 OMW-1000.
 - b. A daily operating log form for each unit for each day that infectious waste is treated in the unit.
 - c. 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, Ohio EPA or the approved health department to verify that the written operating procedures located in the facility management plan are sufficient to meet the performance standard.
7. Comply with all applicable infectious waste treatment requirements in OAC Rule 3745-27-32.
8. Utilize a daily operating log form for each operator 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 treatment unit, if the OMW-1000 fails any parametric monitoring for any reason. In the event of such failure, 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 OMW-1000 containing infectious waste, pathological waste, and infectious sharps from medical offices, similar to that for which the treatment technology has been tested. Do not charge more than twenty percent pathological waste during a treatment load.
12. Wastes containing chemotherapeutic wastes, 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 OMW-1000 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

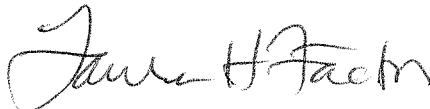
Mr. Steve Pellegrine
OMW-1000 Infectious Waste Treatment Unit
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a filing fee of \$70.00 which the Commission, in its discretion, may reduce if by affidavit it is demonstrated that payment of the full amount of the fee would cause extreme hardship. Notice of the filing of the appeal shall be filed with the Director within three (3) 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, 17th Floor
Columbus, Ohio 43215

If you have any questions concerning this authorization, please contact Maera Flynn of Ohio EPA, Division of Materials and Waste Management at (614) 644-2621.

Sincerely,



Craig W. Butler
Director

CWB/MF