



State of Ohio Environmental Protection Agency

OHIO E.P.A.

MAILING ADDRESS:

STREET ADDRESS:

Lazarus Government Center
122 S. Front Street
Columbus, Ohio 43215

TELE: (614) 644-3020 FAX: (614) 644-2329

DEC -4 2000 P.O. Box 1049
Columbus, OH 43216-1049

ENTERED DIRECTOR'S JOURNAL

RE: Approval of the WR² Tissue Digester
Infectious Waste Treatment Technology

DEC 4 2000

Mr. Joe Wilson
WR² Waste Reduction by Waste Reduction, Inc.
5711 W. Minnesota Street
Indianapolis, Indiana 46241

Party who is a recipient of a copy of the
official record of the Board of the Ohio
Environmental Protection Agency

Joe Wilson 12-4-00

Dear Mr. Wilson:

Pursuant to Rule 3745-27-38 of the Ohio Administrative Code (OAC), WR² Waste Reduction by Waste Reduction, Inc. submitted a request on November 8, 1999, for statewide approval of the Reductive Cremation by Alkaline Hydrolysis (WR² Tissue Digester) technology as an alternative method of infectious waste treatment. Documentation submitted and reviewed includes:

- the "Evaluation of Infectious Waste Treatment Technology Information Request Form" and request for approval submitted November, 8, 1999;
- microbiological testing submitted by Kaye, Weber et al, on August 24, 1998, Dr. Edward I. Jarroll, Professor of Biology, Cleveland State University, and Dr. Gerald Denys, Clarian Health Methodist Hospital submitted on December 6, 1999;
- comments from Dr. Venezia, Director, Clinical Microbiology, Albany Medical Center, and Dr. Sheila D. Grimes, Ohio Department of Agriculture;
- The Operational Instructions, revised December 1, 1999, and July 2000;
- protocol for spore testing submitted December 27, 1999, with subsequent testing data submitted on July 28, 2000;
- protocol for mycobacterium testing submitted April 7, 2000, with subsequent testing data submitted on July 28, 2000.

The WR² Tissue Digester is designed to treat pathological wastes, human and animal blood specimens and blood products, and contaminated carcasses, body parts, and bedding of animals as these three types of infectious wastes are defined in OAC Rule 3745-27-01 (B)(15).

The WR² Tissue Digester technology operates on the principal^{le} of chemical hydrolysis and heat. Inactivation of the microorganisms is achieved through a two-fold exposure of the waste load to: 1) a measured amount of alkaline chemical solution (sodium, calcium, magnesium, or potassium) and water; and 2) heat. The Tissue Digester system operates with minimum temperature and pressure parameters of 121 degrees Celsius (⁰C) or 250 degrees Fahrenheit (⁰F), 15 pounds per square inch (psi), respectively, for a total treatment time of three (3) hours per treatment cycle.

Bob Taft, Governor
Maureen O'Connor, Lieutenant Governor
Christopher Jones, Director

The WR² Tissue Digester process involves the loading of the infectious wastes into a stainless steel retainer basket in the process tank. The process tank is filled with a measured amount of alkaline chemical solution (concentration is calculated based upon tissue weight) and water. When this is completed, the vessel is closed to create a pressure-tight seal. The waste is submerged in the chemical solution and heated. The alkaline chemical solution is continuously in motion around the waste. The heated waste rapidly dissolves and is hydrolyzed into smaller molecules. Afterwards, a cooling period occurs and the liquid waste exits the treatment unit. The liquid is drained into a sanitary sewer system. Mineral constituents (ash) of bones and teeth of vertebrates remain and are contained in the retainer basket located in the digester, where it is rinsed and can be removed and disposed as solid wastes. The unit is then rinsed with water prior to the next use.

Pursuant to OAC Rule 3745-27-32, the WR² Tissue Digester is granted statewide approval provided that each installation conforms with the following conditions:

1. The WR² Tissue Digester treatment unit shall only be utilized to treat the following types of infectious wastes as defined in OAC Rule 3745-27-01 (B)(15).
 - a. Pathological wastes, including human and animal tissues, organs, and body parts, and body fluids and excreta;
 - b. Human and animal blood specimens and blood products specifically excluding bandages or other fabrics soiled with blood or other body fluids;
 - c. Contaminated carcasses, body parts, and bedding of animals.

In addition, noninfectious wastes such as noninfectious animal carcasses, bedding, feces, and body parts may also be processed in the WR² Tissue Digester unit.

2. Each WR² Tissue Digester treatment unit shall be operated in accordance with OAC Rule 3745-27-32 and utilize the following parameters:
 - a. Charge each treatment load in such a manner that the weight capacity for the model is not exceeded;
 - b. Calculate, measure and add water and sufficient sodium, calcium, magnesium or potassium hydroxide to cover the waste prior to starting the treatment cycle. In the instance of the unit with a maximum capacity of 15 pounds, the operator shall manually add the alkaline chemical solution;
 - c. Monitor and maintain the steam pressure at a minimum of fifteen (15) pounds per square inch (psi) during the treatment cycle;
 - d. Maintain wastes in a stationary manner while the heated alkaline chemical solution is recirculated over the wastes for a minimum time period of three

- (3) hours at minimum operational parameters of 250 °F or 121 °C and 15 psi;
- e. Ensure that the treated waste is cooled to a minimum of 77 °C or 170 °F after completion of the treatment cycle prior to discharge;
 - f. Dilute the liquid effluent with added fresh water then drain (a maximum temperature of 140 °F or in compliance with federal or local laws or ordinances) into a permitted sanitary sewer system;
 - g. Rinse the WR² Tissue Digestor unit with water prior to another treatment cycle;
 - h. Monitor and record the alkaline chemical concentration and exposure time by a permanently connected recording device. In addition, the operator shall verify from the pressure indicator on the unit the minimum pressure in psi, time, and temperature achieved for each treatment cycle and record in the daily log on attachment B;
 - i. Equip the WR² Tissue Digestor unit with a permanently connected recording device. In addition, the permanently connected recording device shall be used during all operations of the treatment unit during infectious waste treatment;
 - j. Record and produce a printout of the permanently connected recording device, and at a minimum, provide the following information for each treatment cycle;
 - date
 - total treatment time
 - amount of alkaline chemical concentration added
 - weight of load
 - amount of water
 - temperature
 - k. Retain a printout of each treatment load with the daily log;
 - l. Perform monthly quality assurance spore testing as prescribed in Attachment A. Testing results from the monthly quality assurance testing shall be maintained for three years;

- m. Cease use if the WR² Tissue Digester unit fails any monthly quality assurance testing. The operator shall cease to use the treatment unit to treat infectious waste until such time that the treatment unit is repaired or calibrated and passes a subsequent quality assurance test.
3. The operator shall develop and maintain in one area on the premises of the infectious waste treatment unit a Facility Management Plan (FMP) pursuant to OAC Rule 3745-27-32.

The FMP shall also include the following information and documentation:

- a. A statement signed by all treatment unit operators certifying that training has been provided to them regarding the operation and maintenance of the Tissue Digester unit;
- b. Information specified in condition 5.
4. Upon written request of the Ohio EPA, the operator of each unit shall perform quality control testing. This testing must demonstrate the unit's capability to achieve a minimum four log₁₀ reduction of *Bacillus stearothermophilus* spores. If so directed, the owner or operator shall use twice as many spore strips in the same location in the heating chamber and allow the Ohio EPA or approved Health Department to remove and separately incubate one-half of the spore strips.
5. The operator of the WR² Tissue Digester, shall perform the following daily operational and maintenance activities and maintain permanent records of these activities and their outcome in the FMP specified in condition 3:
 - a. Each operator shall utilize a daily operating log form (Attachment B) 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. The operator shall attach the permanently connected recording device printout as produced by the Tissue Digester treatment unit to that day's daily log. Use of the daily operational log form, (Attachment B) shall satisfy the daily log requirements of OAC Rule 3745-27-32;
 - b. Conduct daily and weekly preventative maintenance checks and services as stated in: WR² Tissue Digester Hazard Analysis, revised November 11, 1999.
6. The operator shall comply with all applicable rules pertaining to infectious waste treatment.

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7. Wastes contaminated with organic solvents, explosive substances, aluminum, hazardous waste as defined in 40 CFR Part 261 and OAC Chapter 3745-37-51, or radioactive waste shall not be introduced into the WR² Tissue Digester unit.
8. If treatment occurs outside the parameters established in Condition 2 as a result of a malfunction of the unit (such as jamming, overloading, electrical, or mechanical reasons), all waste contained within the treatment unit shall be managed as infectious waste. 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.
9. WR² Waste Reduction by Waste Reduction, Inc. shall include a copy of the Director's approval letter in the front of each operating manual of the WR² Tissue Digester and provide a copy of the monthly quality assurance testing procedure (Attachment A) for the operator to make additional copies as necessary.
10. WR² Waste Reduction by Waste Reduction, Inc. shall present a copy of this letter, prior to purchase, to each prospective purchaser or operator of the WR² Tissue Digester during any initial contacts.
11. WR² Waste Reduction by Waste Reduction, Inc. shall provide Ohio EPA with any updates to the operating manual that significantly impact the use or operation of the system 30 days prior to the manual change. Operating manual changes shall not alter any of the parameters specified in Condition number 2 without approval by the Director.
12. WR² Waste Reduction by Waste Reduction, Inc. shall inform the Ohio EPA in writing of all new installations in the state of Ohio of the WR² Tissue Digester treatment unit a minimum of seven (7) days prior to installation.
13. This approval is not a substitute for a Permit-to-Install and license required by the Division of Solid and Infectious Waste Management as cited in Sections 3734.02, 3734.05, and 3734.06 of the Ohio Revised Code for off-site infectious waste treatment facilities or on-site treatment facilities that treat infectious wastes not generated on the premises operated by the generator. On-site treatment facilities that treat only infectious waste generated on the premises operated by the generator are not required to obtain a permit-to-install and a license under Sections 3734.02, 3734.05, and 3734.06 of the Ohio Revised Code.
14. Nothing in this approval should be interpreted to release the owner or operator of the unit from responsibility under Chapters 3704. (air pollution control statute), 3734. (solid, infectious, and hazardous waste statute), or 6111. (water pollution statute) of the Ohio Revised Code or rules promulgated thereunder. Additionally, this approval does not release the owner or operator from compliance with all other federal or local laws or regulations.

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15. This approval is not a substitute for any Permit(s)-To-Install or Permit(s)-To-Operate required for any on-site or off-site treatment facilities by the Division of Air Pollution Control or the Division of Water Pollution Control.

Upon compliance with the conditions stated herein, infectious waste treated by this unit is to be: (1) handled in the same manner as solid waste, provided the material meets the definition of "solid waste" in paragraph (B) of rule 3745-27-01 of the Ohio Administrative Code for free liquids, and (2) disposed of in a licensed solid waste facility.

You are hereby notified that this action of the Director of Environmental Protection (Director) is final and may be appealed to the Environmental Review Appeals Commission (ERAC) 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. It must be filed with the Board within thirty (30) days after notice of the Director's action. A copy of the appeal must be served on the Director within three (3) days of filing with ERAC. An appeal may be filed with ERAC at the following address:

Environmental Review Appeals Commission
236 East Town Street
Columbus, Ohio 43215

Sincerely,



Christopher Jones
Director

cc: Barbara Brdicka, Assistant Director
Sharon Gbur, Acting Chief, DSIWM
Lisa Morris, Chief, DSW

Attachments: Attachment A - Quality Assurance Testing Procedure
Attachment B - Daily Log

CJ/AE/dk

Attachment A

Quality Assurance Testing Procedures

Quality Assurance testing is performed to demonstrate the capability of the Tissue Digester unit to achieve the performance standard of a minimum four log₁₀ reduction of *B. Stearothermophilus* spores. The quality assurance testing for the Tissue Digester unit shall be performed monthly, in accordance with the following provisions:

1. Perform monthly quality assurance testing every calendar month in which the Tissue Digester unit is used for the treatment of infectious wastes to ensure the capability of the Tissue Digester unit to achieve the performance standard of a minimum four log₁₀ reduction of *B. Stearothermophilus* spores;
2. Use either spore strips with a population of at least 1.0×10^4 *Bacillus stearothermophilus* spores, or ampules containing at least 1.0×10^4 *Bacillus stearothermophilus* spores per milliliter;

[comment: For quality assurance testing, the Ohio EPA has set the performance standard for the treatment of infectious waste by an approved treatment technology to be a four log reduction of *Bacillus stearothermophilus* spores. The quality assurance is designed to be a qualitative (growth/no growth) system. If the owner or operator uses strips or ampules with a greater spore population, then the treatment unit must still achieve a complete kill of all spores.]

3. The majority of the waste load may consist of infectious waste. The contents shall be representative of normal or anticipated use for the treatment unit. A spore strip or ampule shall be placed in each of the three vial holders located inside the process tank.
4. Treat the waste load containing the challenging population of spores in the same manner as the daily operation of the Tissue Digester treatment of infectious waste. This would include the same temperature, pressure, time, and total treatable volume.
5. During the monthly quality assurance testing the following information shall be recorded:
 - (a) The date;
 - (b) The time the treatment cycle started;
 - (c) The time the treatment cycle ended;
 - (d) The temperature of the liquid inside the vessel produced by the permanently connected recording device;

Attachment A

Quality Assurance Testing Procedures (Cont.)

- (e) The name of the person who loaded the treatment unit and the name of the person performing laboratory analysis of the spore strips or ampules;
 - (f) The total weight in pounds of infectious waste used during the quality assurance testing;
6. The spore strip or ampule containing spores shall be incubated in accordance with the manufacturer's recommendation for optimal growth; and
7. Record daily, for a period of seven days, the results of spore growth during incubation. The results of spore growth shall be recorded as indicated by the development of turbidity in the growth media. The development of turbidity in the growth media is indicative of growth of the spores present on the strip or in the ampule unless other morphological or metabolic testing indicates that the growth is due to a contaminating microorganism.
- (a) If any of the spore strips or ampules used to perform the testing are positive for growth at any time during the seven day incubation period, the unit has failed to achieve the performance standard required for treatment. Infectious waste placed within the unit during and after the spore testing that remains on the facility site is not treated and shall be handled as infectious waste. The treatment unit shall not be used for further treatment of infectious waste until the problem has been determined and rectified and another successful quality assurance test performed. The rectification may require the operator to increase the minimum temperature and/or pressure requirements or cycle time;
 - (b) Upon request by, and in the presence of, the director or his authorized representative or the board of health or its authorized representative the treatment facility owner or operator shall perform the quality assurance testing to verify that the posted written operating procedures, as required by paragraph (1)(5) of Paragraph (1)(5) of Rule 3745-27-32 are sufficient to meet the performance standard of a four log (base ten) reduction in *Bacillus stearothermophilus* spores. If so directed, the owner or operator shall use twice as many spore strips or ampules in the same location in the treatment unit and permit the director or his authorized representative or the board of health or its authorized representative to remove and separately incubate one-half of the spore strips or ampules.