



State of Ohio Environmental Protection Agency

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AUG 11 2009 P.O. Box 1049
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AUG 11 2009

Daniel B. Marks
Progressive Recovery, Inc.
700 Industrial Dr
Dupo, IL 62239

ENTERED DIRECTOR'S COPY OF THE 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: [Signature] Date: 8-11-09

RE: Approval of the Caustic Digester Unit as an Alternative Infectious Waste Treatment Technology

Dear Mr. Marks:

On October 24, 2008, Progressive Recovery, Inc. requested statewide approval of the Caustic Digester Unit (CDU) as an alternative infectious waste treatment technology. At this time, Progressive Recovery, Inc. submitted the operation and maintenance manual, a sample Batch Data Report and microbial testing data for the CDU. Pursuant to Rule 3745-27-38 of the Ohio Administrative Code (OAC), the Ohio Environmental Protection Agency (Ohio EPA) requested that Progressive Recovery, Inc submit the Evaluation of Infectious Waste Treatment Technology Information Request Form, which was received on May 14, 2009. On July 2, and July 16, 2009, Ohio EPA received an updated sample Batch Data Report and an updated operation and maintenance manual, respectively.

Ohio EPA has reviewed the Evaluation of Infectious Waste Treatment Technology Information Request Form, the microbial testing data, the operation and maintenance manual, and the sample Batch Data Report submitted by Progressive Recovery, Inc. The CDU infectious waste treatment technology uses sodium hydroxide (NaOH) or potassium hydroxide(KOH), high temperatures and pressures for a minimum of three hours to treat pathologic waste, including human remains, whole or portions of animal carcasses, organs and/or tissue, animal bedding and blood.

The inactivation of potentially infectious microorganisms in such pathologic materials as noted above is achieved in the CDU through their exposure to a minimum operating temperature of 275⁰ F (to within +2⁰ F) at a minimum of thirty pounds per square inch (30 psi) pressure for a minimum of three hours (3 hr). Water is combined with NaOH or KOH in a ratio dependent upon the weight of the load (18% minimum concentration for KOH). When this is completed, the vessel is closed to create a pressure-tight seal. The waste is submerged in the chemical solution and heated under pressure. The alkaline chemical solution is continuously in motion around the waste and is employed to "digest" all organic components of the load. However, the treatment of the waste is solely effected by prolonged exposure to high temperature and thereby is independent of the caustic solution. After a cooling period, the pH of the liquid is neutralized, and the liquid waste exits the

Ted Strickland, Governor
Lee Fisher, Lieutenant Governor
Chris Korleski, Director

treatment unit. The bone shadows remaining in the retainer basket inside the digester may be removed prior to the next treatment cycle.

Pursuant to Section 3734.021 of the Revised Code, the Director of Ohio EPA has the authority to approve the use of alternative technologies for the treatment of infectious waste based on the submission of data that demonstrates the successful achievement of the performance standard. Ohio EPA has determined that the CDU is capable of achieving the performance standard of a minimum four log₁₀ reduction of bacterial spores and a five log₁₀ reduction of mycobacterium.

The CDU infectious waste treatment system is hereby granted statewide approval provided that Progressive Recovery, Inc., and the owner or operator of each installed unit conforms to the following conditions:

1. The CDU shall be operated in accordance with written documentation submitted on October 24, 2008, and subsequent addendum submitted on May 14, 2009, July 2, 2009, and July 16, 2009.
2. Liquid infectious waste, pathological waste and animal carcasses as identified in OAC Rule 3745-27-01 (l)(6)(c), (e), and (f) may be processed in the CDU. In addition the following types of noninfectious wastes may also be processed in the CDU; noninfectious whole or portions of animal carcasses, organs or tissue, blood, and animal bedding.
3. Wastes contaminated with explosive substances, volatile chemicals, aluminum, magnesium, tin, copper, zinc, non-degradable plastics such as sharps, vinyl, glass, latex gloves, wood, hazardous waste as defined in 40 CFR Part 261 and OAC Chapter 3745-37-51, or radioactive waste shall not be introduced into the CDU.
4. The CDU shall be operated utilizing the following parameters:
 - a. Each treatment load shall not exceed the weight capacity for the model.
 - b. Prior to each treatment cycle, an Integrity Test of the CDU shall be performed for 20 minutes at 5 psi. Water shall then be added to the CDU (based on tissue weight to 150%), alkali (18% of tissue weight), with the introduction of steam, as needed to elevate the mass temperature to the set point (50% of tissue weight).
 - c. The heated and pressurized alkaline chemical solution shall be re-circulated over the wastes for the minimum time required to dissolve all fleshy material, using the minimum operational parameters of 275 °F and 30 psi.

- d. The temperature shall not be less than 275 °F during the digest/sterilize cycle. The liquid effluent shall be cooled to a temperature below 140 °F prior to draining.
 - e. The pH of the liquid effluent shall be neutralized by the injection of carbon dioxide and discharged pursuant to state and local requirements and design requirements of the owner or operator.
 - f. The CDU shall be rinsed first with heated water and then rinsed with cold water for a set time, prior to the odor suppressant being injected into the headspace of the vessel.
 - g. The Batch Data Report generated by the CDU may be used to meet all of the requirements of paragraph (I)(4) of OAC Rule 3745-27-32, in that it provides the following information on each treatment cycle:
 1. date
 2. total treatment time
 3. amount of alkaline chemical concentration added
 4. weight of load
 5. amount of water
 6. temperature
 - h. The operator shall 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; and
 - i. If the CDU 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.
5. All owners and operators of an infectious waste treatment facility shall comply with all general infectious waste treatment facility requirements pursuant to OAC Rule 3745-27-32(I).
 6. Upon written request by 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 *Geobacillus stearothermophilus* spores.

7. The operator of the CDU shall perform daily operational and maintenance activities and maintain permanent records of these activities.
8. If prior to the sealing of the lid of the unit there is a malfunction of the CDU, such as electrical or mechanical failure, which would prevent the treatment of the waste in accord with Condition 4, 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. Progressive Recovery, Inc. shall include a copy of this approval letter in the front of each operating manual of the CDU and provide a copy of the monthly quality assurance testing procedure (Attachment A) for the operator to make additional copies as necessary.
10. Progressive Recovery, Inc. shall provide Ohio EPA with any updates to the operating manuals that significantly impact the use or operation of the system thirty (30) days prior to the manual change.
11. Progressive Recovery, Inc. shall inform Ohio EPA in writing of all new installations in the State of Ohio of the treatment unit a minimum of seven (7) days prior to installation.
12. 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 premises operated by the generator. On-site treatment facilities that treat only infectious waste generated on 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.
13. 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, state, or local laws or regulations.
14. This approval for Progressive Recovery, Inc. is not a substitute for any required Permit(s)-To-Install or Permit(s)-To-Operate to be issued for on-site or off-site treatment facilities by the Division of Air Pollution Control or the Division of Water Pollution Control.

Mr. Daniel Marks
Progressive Recovery, Inc.
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15. 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 notified that this action of the Director is final and may be appealed to the Environmental Review Appeals Commission (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. It 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. A copy of the appeal must be served to the Director of the Ohio Environmental Protection Agency 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
309 South Fourth Street
Room 222
Columbus, Ohio 43215

Sincerely,



Chris Korleski
Director

CK/MF/sw

cc: Ira F. Salkin, Progressive Recovery, Inc.

attachments: Attachment A - Quality Assurance Testing Procedure

Attachment A

Quality Assurance Testing Procedures

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

1. Perform monthly quality assurance testing every calendar month in which the CDU is used for the treatment of infectious wastes to ensure the capability of the CDU to achieve the performance standard of a minimum four log₁₀ reduction of *G. stearothermophilus* spores;
2. Use spore strips with a population of at least 1.0×10^4 *G. stearothermophilus* 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 shall be placed inside the process tank in a nylon histology bag and this then placed into a nylon mesh bag. The latter will be attached within the treatment unit above the liquid level, in the head space.
4. Treat the waste load containing the challenging population of spores in the same manner as the daily operation of the CDU for 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;
 - 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 ampoules;
 - f. The total weight in pounds of infectious waste used during the quality assurance testing;
6. The spore strip containing spores shall be incubated in accordance with the manufacturer's recommendation for optimal growth; and
7. Record daily, 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.
 - a. If any of the spore strips 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; and
 - 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 (l)(5) of Paragraph (l)(5) of Rule 3745-27-32 are sufficient to meet the performance standard of a four log₁₀ reduction in *G. stearothermophilus* spores.