



State of Ohio Environmental Protection Agency

STREET ADDRESS:

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

TELE: (614) 644-3020 FAX: (614) 644-3184

MAILING ADDRESS:

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

JUL 18 2003

Mr. Sanford A. Glazer, Ph. D Ed.  
Director of Technology  
WPS Company  
Suite B  
3052 Washington Blvd.  
Baltimore, MD 21230

OHIO E.P.A.  
JUL 18 2003  
RECEIVED DIRECTOR'S JOURNAL

**RE: Approval of the Steam Sterilizer Macerator (SSM) 150  
Infectious Waste Treatment Technology**

Dear Dr. Glazer:

The Antaeus Group, Inc. Steam Sterilizer Macerator (SSM) 150 technology was previously approved as a state-wide alternative infectious waste treatment technology by Ohio EPA on March 18, 1999. In accordance with Ohio Administrative Code (OAC) Rule 3745-27-38 (I), the WPS Company submitted a request on April 21, 2003 to revise the approval in the name of the WPS Company for the SSM 150 technology because of a recent purchase of the assets of the Antaeus Group, Inc. There have been no changes in the SSM 150 technology and it will operate in the manner as outlined in the approval. 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. The Ohio EPA expends considerable effort to be responsive to the needs of the community for an alternative method for the treatment of infectious wastes, and in response has promulgated OAC Rule 3745-27-38. OAC Rule 3745-27-38 specifies Ohio's alternative infectious waste treatment technology approval process. Ohio EPA's current approval process allows for either statewide or site-specific approval of an alternative infectious waste treatment technology based on the submission of data that demonstrates the successful achievement of the performance standard.

The request by the Antaeus Group, Inc. for statewide approval was submitted on December 30, 1998. The Steam Sterilizer Macerator (SSM) 150 operates on the principal of steam and superheated water inactivation of the microorganisms. Superheated water relies on exposure of the surface area of the waste load to boiling water. Steam relies on penetration of the steam into the waste load. The grinding and re-circulation performed by this unit increases both the surface area of the waste load for exposure to the superheated water and the penetration of the steam. Thus, inactivation of the microorganisms is achieved through a two-fold exposure of the waste load to: 1) a minimum exposure time of superheated water; and 2) a minimum exposure time and temperature to steam. The Antaeus Group, Inc. SSM-150 system operates for a minimum total treatment time of thirty (30) minutes per treatment cycle.

Bob Taft, Governor  
Jennette Bradley, Lieutenant Governor  
Christopher Jones, Director

Verify this to be a true and accurate copy of the official document as filed in the records of the Ohio Environmental Protection Agency

By: [Signature] Date: 7/18/03

Infectious wastes, that have been properly packaged in accordance with OAC Rule 3745-27-34, are loaded into a stainless steel process tank. The process tank is injected with steam and superheated water. There is a soaking period of approximately 60 seconds. The infectious wastes are mixed with the added liquids and are drawn through the cutting system with the activation of the macerator pump located beneath the process tank. The wastes submerged in the superheated water are continuously in motion. The shredded material passes through the macerator pump for further size reduction. Next, the sterilization process is initiated. The SSM-150 utilizes the scientific standard for sterilization which states that sterilization occurs at 250<sup>0</sup> Fahrenheit sustained for a 15 minute period. If the temperature rises above 250<sup>0</sup>F, then sterilization occurs in a shorter period of time. Therefore, the degree of sterilization is measured in equivalent minutes (at 250<sup>0</sup>F) rather than real minutes. The computer records the amount of time the waste has been exposed to temperatures above 250<sup>0</sup>F and calculates the equivalent minutes. Recirculation of waste is still occurring during the sterilization phase. After completion of the sterilization process, water is added to the process tank to cool the waste and to achieve a minimum temperature of 195<sup>0</sup>F. Next, the air inside the process tank is vented to depressurize the process tank. The waste and liquid mixture is discharged into the separator unit where additional water is added to further cool the waste liquid mixture to a minimum temperature of 125<sup>0</sup>F. The process tank is rinsed with water to remove any residual material. The waste liquid mixture is filtered through a 5 micron filter prior to the entry of the separator unit. The waste (solid and liquid) exits the treatment unit through the sanitary sewer system or the solid waste stream. The liquid is drained into the sanitary sewer system, and the solids are collected into bags located in the separator unit.

Pursuant to Rule 3745-27-32 of the Ohio Administrative Code, and based upon the submitted documents: 1) the "Evaluation of Infectious Waste Treatment Technology Information Request Form" and request for approval, submitted January 22, 1996; 2) microbiological testing submitted by BBI Clinical Laboratories, Inc., August 24, 1998 and University of Maryland, Department of Oral and Craniofacial Biological Sciences, August 14, 1998; and 3) The SSM-150 Operator's Manual and Supervisor's Manual revised September 22, 1998. The WPS Company, SSM-150 is approved statewide, provided each statewide installation conforms with the following conditions:

1. Each SSM-150 treatment unit shall be operated in accordance with Rule 3745-27-32 of the Ohio Administrative Code and utilizing the following parameters:
  - a. Only infectious wastes properly packaged in accordance with Rule 3745-27-34 of the Ohio Administrative Code are to be processed in the SSM-150 unit;
  - b. The treatment capacity shall not exceed 75 pounds;

- c. The operator shall measure and add a minimum of 2 ounces of a surfactant such as sodium dodecyl lauryl-sulfate into the process tank prior to starting the treatment cycle;
- d. The treatment unit is initially pressurized with steam followed by the addition of superheated water at a minimum of 212 degrees Fahrenheit (<sup>0</sup>F). The pressure of steam shall be at a minimum of fifteen (15) pounds per square inch (psi) and monitored and maintained during the treatment cycle;
- e. The wastes shall be stationary in the superheated water for a minimum time period of one (1) minute;
- f. The shredding shall occur for a minimum of one (1) minute after the injection of steam and addition of superheated water;
- g. The separator shall have a maximum screen opening of one-half (0.5) inch in diameter;
- h. The temperature of the re-circulated liquid and waste shall be a minimum of 205 <sup>0</sup>F;
- i. The temperature of the superheated water shall be monitored and recorded by the permanently connected recording device. In addition, the operator shall verify from the permanently connected recording device printout the minimum water temperature in <sup>0</sup>F achieved for each treatment cycle and record in the daily log on attachment B;
- j. The SSM-150 shall be equipped 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;
- k. The permanently connected recording device shall produce a printout of, at a minimum, the following;
  - date
  - time
  - temperature of the water in the process tank
  - accumulative equivalent time at 250 <sup>0</sup>F
- l. The equivalent minutes at 250 <sup>0</sup>F shall not be a number less than 30 per treatment cycle;

- m. Retain the sterilization report and daily log;
  - n. 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
  - o. If the SSM-150 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.
2. The operator, if applicable, shall develop and maintain in one area on the premises of the infectious waste treatment unit a Facility Management Plan (FMP) pursuant to Rule 3745-27-32 (I)(2) of the Administrative Code.

The Plan shall also include 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 SSM-150; and
  - b. Information specified in condition 4.
3. 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 log<sub>10</sub> reduction of *Bacillus stearothermophilus* spores.
4. The operator of the SSM-150, shall perform the following daily operational and maintenance activities and maintain permanent records of these activities and their outcome in the Facility Management Plan specified in condition 2:
- 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 SSM-150 treatment unit to that day's daily log. Use of the daily operational log form shall satisfy the daily log requirements of Rule 3745-27-32 of the Administrative Code; and

- b. Conduct daily, weekly preventative maintenance checks and services as stated in the operating manual: The SSM-150 Operator's Manual, revised September 22, 1998 and Supervisor's Manual revised September 22, 1998.
5. The operator shall comply with all applicable rules pertaining to infectious waste treatment.
6. 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 SSM-150.
7. If treatment occurs outside the parameters established in Condition 1 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.
8. WPS Company shall include a copy of the Director's approval letter in the front of each operating manual of the SSM-150 and provide a copy of the monthly quality assurance testing as detailed in Attachment A for the operator to make additional copies as necessary.
9. WPS Company shall present a copy of this letter, prior to purchase, to each prospective purchaser or operator of the SSM-150 during any initial contacts.
10. WPS Company shall provide Ohio EPA with any updates to the operating manuals 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 1 without approval by the Director.
11. WPS Company shall inform the 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.

Mr. Sanford A. Glazer, Ph. D Ed.  
WPS Company  
Page 6

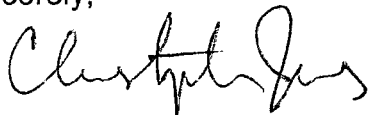
13. Nothing in this approval should be interpreted to release the owner or operator of the unit from responsibility under Chapters 3704. (air pollution control statute), 3734. (solid, infectious, and hazardous waste statute), or 6111. (water pollution statute) of the Ohio Revised Code or rules promulgated thereunder. Additionally, this approval does not release the owner or operator from compliance with all other federal or local laws or regulations.
14. This SSM-150 approval 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.

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 Agency (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  
309 South Fourth Street, Room 222  
Columbus, Ohio 43215

Sincerely,



Christopher Jones  
Director

CJ/AE/kd

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

cc: Joseph Koncelik, Assistant Director  
Daniel Harris, Chief, DSIWM  
Lisa Morris, Chief, DSW

## Attachment A

### Quality Assurance Testing Procedures

Quality Assurance testing is performed to demonstrate the capability of the SSM-150 to achieve the performance standard of a minimum four log<sub>10</sub> reduction of *B. Stearothermophilus* spores. The quality assurance testing for the SSM-150 shall be performed monthly, in accordance with the following provisions:

1. Perform monthly quality assurance testing every calendar month in which the SSM-150 is used for the treatment of infectious wastes to ensure the capability of the SSM-150 to achieve the performance standard of a minimum four log<sub>10</sub> reduction of *B. Stearothermophilus* spores;
2. Use either spore strips with a population of at least  $1.0 \times 10^4$  *Bacillus stearothermophilus* spores, or ampules containing at least  $1.0 \times 10^4$  *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 SSM-150 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 water temperature 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 ampules;
  
- (f) The total weight in pounds of infectious waste used during the quality assurance testing;
  
- (g) The spore strip or ampule containing spores shall be incubated in accordance with the manufacturer's recommendation for optimal growth; and
  
- (h) 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 ampule unless other morphological or metabolic testing indicates that the growth is due to a contaminating microorganism.
  - (i) 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; and
  
  - (ii) 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 this rule, 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.

