



John R. Kasich, Governor  
Mary Taylor, Lt. Governor  
Craig W. Butler, Director

**OHIO EPA**  
**FEB 18 2016**

**ENTERED DIRECTOR'S JOURNAL**

**FEB 18 2016**

Dr. Sanford Glazer  
Red Bag Solutions, Inc.  
3431 Benson Avenue, Suite 100  
Baltimore, Maryland 21227

RE: RBS SSM  
Director's Authorization  
Approval  
Infectious Waste Treatment  
IWT021285

Re: Red Bag Solutions, Inc.  
Steam Sterilizer Macerator

Dear Dr. Glazer:

On March 18, 1999, the Ohio EPA approved the Steam Sterilizer Macerator (SSM) 150 technology as a state-wide alternative infectious waste treatment technology for the Antaeus Group, Inc., in accordance with Ohio Administrative Code (OAC) Rule 3745-27-38(I). On April 21, 2003, the WPS Company submitted a request to revise the approval for the SSM-150 technology because it recently purchased the assets of the Antaeus Group, Inc. WPS Company represented that there were no changes in the SSM-150 technology, and the unit would operate in the same manner as outlined in the original March 18, 1999 approval. On July 18, 2003, the director approved the request by WPS Company for transfer and approval to use the SSM-150 alternative technology. On March 19, 2013, the director reauthorized the approval because of the purchase of the SSM-150 technology by Red Bag Solutions, Inc. On November 10, 2015, Red Bag Solutions request approval for the SSM-150 technology to change the operating parameters and the name of the unit. The current request indicates that the re-designed unit no longer needs surfactant, can treat 120 pounds of waste per treatment cycle (an increase from the original 75 pounds), and is now known as the RBS SSM.

Pursuant to Section 3734.021 of the Revised Code, the Director of Ohio EPA has the authority to adopt rules for the handling and treatment of infectious waste. The Ohio EPA has adopted OAC Rule 3745-27-38 in order to review and approve an alternative technology for the treatment of infectious wastes. 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 as set forth in the rule.

Pursuant to OAC Rule 3745-27-32 and 3745-32-38, the review and recommendation for approval of the technology is based upon the previously submitted documents including:

- The "Evaluation of Infectious Waste Treatment Technology Information Request Form" and request for approval, submitted January 22, 1996;
- Microbiological test submitted by BBI Clinical Laboratories, Inc., August 24, 1998 and University of Maryland, Department of Oral and Craniofacial Biological Sciences, August 14, 1998";
- The SSM-150 Operator's Manual and Supervisor's Manual revised September 22, 1998;
- The SSM-150 Operator's Manual, revised November 21, 2012, and the current Supervisor's Manual revised November 21, 2012;
- The RBS SSM Operator's/Services Manual dated December 2014; and
- Section Seven Appendix B of The RBS SSM Operator's/Service Manual dated December 2014.

The RBS SSM is hereby approved for statewide use by Red Bag Solutions, Inc., provided each statewide installation of the RBS SSM alternative infectious waste treatment technology unit conforms to the following conditions:

1. Each RBS SSM treatment unit shall be operated in accordance with OAC Rule 3745-27-32, and the requirement outlined in The RBS SSM Operator's/Service Manual dated December 2014, which are summarized below:
  - a) The treatment capacity of each RBS SSM unit shall not exceed 120 pounds of waste;
  - b) The treatment unit is initially pressurized with steam followed by the addition of superheated water at a minimum of 212°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;
  - c) The waste shall be stationary in the superheated water for a minimum time period of one (1) minute;
  - d) The shredding shall occur for a minimum of one (1) minute after the injection of steam and addition of superheated water;
  - e) The separator shall have a maximum screen opening of one-half (0.5) inch in diameter;
  - f) The temperature of the recirculated liquid and waste shall be a minimum of 250°F;
  - g) The temperature of the superheated water shall be monitored and recorded by the permanently connected recording device. In addition, the operator of each

unit shall verify from the connected recording device printout the minimum water temperature in °F achieved for each treatment cycle and maintain the recorded information at each location with the other operation record for each respective unit.

- h) The RBS SSM shall be equipped with a connected recording device. In addition, the connected recording device shall be used during all operation of each treatment unit during infectious waste treatment;
  - i) The connected recording device shall produce a printout for every treatment cycle. The printout shall contain, at a minimum, the following:
    - Date
    - Time
    - Temperature of the water in the process tank
    - Accumulative equivalent time at 250°F
  - j) The equivalent minutes at 250°F shall not be a number less than 30 per treatment cycle;
  - k) The operator shall retain the sterilization report and daily log for a minimum of three (3) years, unless otherwise instructed by Ohio EPA;
  - l) The operator of the RBS SSM at each location shall perform monthly quality assurance spore testing. Testing results from the monthly quality assurance testing shall be maintained for three years; and
  - m) If the RBS SSM fails any monthly quality assurance testing at any location, the operator of that unit 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 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(l)(2).
  3. Upon written request of the Ohio EPA, the operator of each respective unit shall perform quality assurance testing. This testing must demonstrate the unit's capability to achieve a minimum four log<sub>10</sub> reduction of *Geobacillus stearothermophilus* spores.
  4. Waste contaminated with chemotherapeutic wastes, pathological wastes, cytotoxic agent, hazardous waste as defined in 40 CFR Part 261 and OAC Rule 3745-27-51, or radioactive waste shall not be introduced into the RBS SSM unit.

5. If the unit fails to operate within 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.
6. Red Bag Solutions, Inc. shall include a copy of this Director's approval letter in the front of each operating manual of the RBS SSM.
7. Red Bag Solutions, Inc. shall provide a copy of this Director's approval letter to each current Operator of the RBS SSM with instructions to inset the Director's approval letter in the front of the December 2014 operating manual for the RBS SSM.
8. Red Bag Solutions, Inc. shall present a copy of this Director's letter, prior to purchase, to each prospective purchaser and operator of the RBS SSM during any initial contacts.
9. Red Bag Solutions, Inc. shall provide Ohio EPA with any revisions to the operating manual, intended for use in Ohio, thirty (30) days prior to the manual change. Upon concurrence by Ohio EPA that the operational parameters as specified in Condition 1 of the Director's authorization have been maintained, Red Bag Solutions, Inc. shall supply operating manuals to all operating units in Ohio.
10. Red Bag Solutions, 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. Any new installations that occurred between December 2015 and the date of the issuance of this authorization to Red Bag Solutions, Inc. should be identified to Ohio EPA in writing within fourteen (14) days following the approval of this authorization.
11. This approval is not a substitute for a Permit-to-Install and license required by the Division of Materials and Waste Management as cited in Sections 3734.02, 3734.05, and 3734.06 of the Revised Code for off-site infectious waste treatment facilities or on-site treatment facilities that treat infectious waste 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 Revised Code.
12. Nothing in this approval should be interpreted to release the owner or operator of each respective RBS SSM unit from responsibility under Chapter 3704. 3734., or 6111. of the 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.

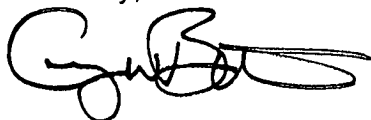
13. This RBS SSM alternative technology approval for Red Bag Solutions, Inc. is not a substitute for any required permit(s)-to-Install or Permit(s)-to-Operate to be issued for on-site treatment facilities by the Division of Air Pollution Control or the Division of Surface Water.
14. Upon compliance with 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 OAC Rule 3745-27-01(S)(23), and 2) disposed in a licensed solid waste facility in this state or in a solid waste facility located in another state that is operating in accordance with that state's laws.

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 a filing fee of \$70.00 made payable to "Treasurer, State of Ohio." The Commission, in its discretion may reduce the fee if by affidavit 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 request 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, 17<sup>th</sup> Floor  
Columbus, Ohio 43215

Should you have any questions regarding this authorization, please contact Holly Hillyer, Ohio EPA, Division of Materials and Waste Management Central Office, 50 West Town Street, Suite 700, Columbus, Ohio or by phone at 614-644-2621.

Sincerely,



Craig W. Butler  
Director

ec: Michelle Ackenhausen, DMWM SWDO  
Kenton Domer-Shank, Public Health of Dayton and Montgomery County