Ohio EPA
40 years and moving forward

John R. Kasich, Governor
Mary Taylor, Lt. Governor
Scott J. Nally, Director

Certified Mail

March 19, 2013

Mr. Alexander Casadonte
Red Bag Solutions, Inc.
3431 Benson Avenue, Suite 100
Baltimore, Maryland 21227

Re: Red Bag Solutions, Inc.
Steam Sterilizer Macerator 150

Dear Mr. Casadonte:

The Steam Sterilizer Macerator (SSM) 150 technology was initially approved as a state-wide alternative infectious waste treatment technology for the Antaeus Group, Inc. by Ohio EPA on March 18, 1999. In accordance with Ohio Administrative Code (OAC) Rule 3745-27-38(I), on April 21, 2003, a request was submitted by the WPS Company to revise the approval for the SSM-150 technology to be in the name of the WPS Company because of a recent purchase of the assets of the Antaeus Group, Inc. It was represented at that time that there were no changes in the SSM-150 technology and it would operate in the same manner as outlined in the original March 18, 1999 approval. The request by WPS Company for transfer and approval to use the SSM-150 alternative technology was approved by the Director and journalized on July 18, 2003.

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 expends considerable effort to be responsive to the needs of the community, and in response has promulgated 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.

By way of background, the original request submitted by the Antaeus Group, Inc. for statewide approval of the alternative infectious waste treatment technology was submitted on December 30, 1998. The alternative treatment technology known as SSM-150 operates on the principle 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 recirculation 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 SSM-150 system operates for a minimum total treatment time of thirty (30) minutes per treatment cycle.

Infectious wastes 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.

Following size reduction, the sterilization process is initiated. The SSM-150 utilizes the scientific standard for sterilization which states that sterilization occurs at 250° Fahrenheit sustained for a 15 minute period. If the temperature rises above 250°F, then sterilization occurs in a shorter period of time. Therefore, the degree of sterilization is measured in equivalent minutes (at 250°F) rather than real minutes. The computer records the amount of time the waste has been exposed to temperatures above 250°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°F. 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°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 OAC Rule 3745-27-32 and 3745-32-38, and based upon the previously submitted documents including: 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 SSM-150 was initially approved for statewide use by The Antaeus Group, Inc. in March 1999. The SSM- 150 was transferred and approved for statewide use to WPS Company on July 18, 2003. Red Bag Solutions, Inc. has stated that the technology has not changed since approved in March, 1999. Red Bag Solutions, Inc. supplemented the previously submitted documents by providing Ohio EPA with the most current operating manual: The SSM-150 Operator's Manual, revised November 21, 2012, and the most current Supervisor's Manual revised November 21, 2012. The SSM-150 is herein approved for statewide use by Red Bag Solutions, Inc., provided each statewide installation of the SSM-150 alternative infectious waste treatment technology unit conforms to the following conditions:

1) Each SSM-150 treatment unit shall be operated in accordance with OAC Rule 3745-27-32 and OAC Rule 3745-27-38 and utilizing the following parameters:

   a) The treatment capacity of each SSM-150 unit shall not exceed 75 pounds;

   b) The operator of each unit shall measure and add a minimum of 2 ounces of surfactant such as sodium dodecyl lauryl-sulfate into the process tank prior to starting the treatment cycle;

   c) 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;

   d) The wastes shall be stationary in the superheated water for a minimum time period of one (1) minute;

   e) The shredding shall occur for a minimum of one (1) minute after the injection of steam and addition of superheated water;

   f) The separator shall have a maximum screen opening of one-half (0.5) inch in diameter;

   g) The temperature of the recirculated liquid and waste shall be a minimum of 205°F;

   h) 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 permanently connected recording device printout the minimum water temperature in °F achieved for each treatment cycle and record in the daily log on Attachment B to be kept by the operator at each location with the other operation records for each respective unit;

i) The SSM-150 shall be equipped with a permanently connected recording device. In addition, the permanently connected recording device shall be used during all operation of each treatment unit during infectious waste treatment;

j) The permanently connected recording device shall produce a printout of, at a minimum, the following:

   i) Date

   ii) Time

   iii) Temperature of the water in the process tank

   iv) Accumulative equivalent time at 250°F

k) The equivalent minutes at 250°F shall not be a number less that 30 per treatment cycle;

l) Retain the sterilization report and daily log;

m) The operator of the SSM-150 at each location 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

n) If the SSM-150 fails any monthly quality assurance testing at any location, that 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, 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 OAC Rule 3745-27-32(I)(2).

The FMP 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 Ohio EPA, the operator of each respective unit shall perform quality control testing. This testing must demonstrate the unit's capability to achieve a minimum four $\log_{10}$ reduction of *Bacillus stearothermophilus* spores.

4) The operator of each respective SSM-150 unit 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 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 arranges 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 OAC Rule 3745-27-32; and

   b) Conduct daily and weekly preventative maintenance checks and services as stated in the operating manual: The SSM-150 Operator's Manual, revised November 21, 2012, and Supervisor's Manual revised November 21, 2012.

5) Each operator shall comply with all applicable rules pertaining to infectious waste treatment.

6) Waste contaminated with chemotherapeutic wastes, pathological wastes, cytotoxic agents, hazardous waste as defined in 40 CFR Part 261 and OAC Rule 3745-27-51, 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) Red Bag Solutions, Inc. 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) Red Bag Solutions, Inc. shall provide a copy of this Director's approval letter to each current Operator of the SSM-150 with instructions to insert the Director's approval letter in the front of the November 2012 operating manual of the SSM-150.

10) Red Bag Solutions, Inc. shall present a copy of this letter, prior to purchase, to each prospective purchaser or operator of the SSM-150 during any initial contacts.

11) Red Bag Solutions, Inc. shall provide Ohio EPA with any future updates to the SSM-150 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 1 without approval by the Director.

12) 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 September 2012 and the date of the issuance of this permit to Red Bag Solutions, Inc. should be identified to Ohio EPA in writing within fourteen (14) days of the approval of this authorization.

13) 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.

14) Nothing in this approval should be interpreted to release the owner or operator of each respective SSM-150 unit from responsibility under Chapters 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.

15) This SSM-150 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 or off-site treatment facilities by the Division of Air Pollution Control or the Division of Surface Water.

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 of in a licensed solid waste facility.

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 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

Should you have any questions regarding this authorization, please contact Barry Chapman, 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,

Scott J. Nally,
Director

cc: Barry Chapman, DMWM-CO
Marty Cooper, Legal

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 $\log_{10}$ 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 $\log_{10}$ 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 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 (I)(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.

Attachment B

DAILY LOG

Date	Time	Batch #	Minimum Water Temp. ^{0}F			Operator Name	Comments
				Equivalent Minutes at °F (minutes)	Treatment load weight pounds		