



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

OHIO E.P.A.

MAR 13 2015

ENTERED DIRECTOR'S JOURNAL

MAR 13 2015

Mr. Samuel Vitello  
Triumvirate Environmental, Inc.  
200 Inner Belt Road  
4<sup>th</sup> Floor  
Somerville, MA 02143

Re: Triumvirate Environmental, Inc.  
Director's Authorization  
Approval  
Infectious Waste  
Out of State  
IWT020763

**RE: Approval of the PIWS 3000 Medical Waste Treatment System**

Dear Mr. Vitello:

The PIWS 3000 Medical Waste Treatment System (PIWS 3000), by Positive Impact Waste Solutions, LLC, is currently approved, in Ohio, as an alternative infectious waste treatment technology, in accordance with Ohio Administrative Code (OAC) Rule 3745-27-38. Medical Waste Recovery, Inc. received statewide approval of the PIWS 3000 as an alternative infectious waste treatment technology on April 4, 2008 and on June 21, 2013, Medical Waste Recovery, Inc. received approval to treat infectious waste mixed with up to 8% pathological waste. In 2014 Medical Waste Recovery, Inc. was acquired by Triumvirate Environmental, Inc. On August 26, 2014, the Ohio Environmental Protection Agency (Ohio EPA) received a request from Triumvirate Environmental, Inc. to revise the alternative infectious waste treatment technology approval of the PIWS 3000 to include the treatment of 100% pathological waste. At this time, Triumvirate Environmental, Inc. submitted new microbial testing data which demonstrates the treatment of 100% pathological waste using the PIWS 3000.

The PIWS 3000 is designed to treat infectious waste types routinely generated by hospitals. The PIWS 3000 is a continuous feed treatment system that uses a dry chemical, Cold-Ster<sup>®</sup>, and a grinder to treat infectious waste, including pathological waste. The two-stage process cuts the waste while simultaneously mixing it with the dry chemical, Cold-Ster<sup>®</sup>. The volume of waste is reduced by up to 70%. The Cold-Ster<sup>®</sup> is activated by a water spray, which creates an alkaline environment that renders the waste non-infectious. As the treated waste exits the PIWS 3000, a pH probe ensures that proper treatment conditions are maintained. The PIWS 3000 has a computer control system which creates a permanent treatment record by documenting the quantity and pH of the treated waste and the length of time required for treatment.

The microbial testing data submitted by Triumvirate Environmental, Inc., demonstrates that the PIWS 3000 is capable of achieving a minimum six log<sub>10</sub> reduction of bacterial

spores in the presence of 100% pathological waste. Pathological wastes are human and animal tissues, organs, body parts, and body fluids and excreta that are contaminated with or are likely to be contaminated with infectious agents or zoonotic agents.

In addition, Triumvirate Environmental, Inc. submitted a request for an exemption from OAC Rule 3745-27-38(G)(5), for quality assurance testing requiring a minimum four  $\log_{10}$  reduction of bacterial spores. Due to the impracticality and enormous expense of biological spore testing, Triumvirate Environmental, Inc. has proposed the use of parametric monitoring for quality assurance testing, in lieu of bacterial spore testing.

Pursuant to OAC Rule 3745-27-38, Triumvirate Environmental, Inc. is granted statewide approval for the PIWS 3000 to treat infectious waste, including 100% pathological waste. As part of this authorization, Triumvirate Environmental, Inc. and the operator of each installed PIWS 3000 unit owned by Triumvirate Environmental, Inc. is subject to the following conditions:

A. Triumvirate Environmental, Inc. shall provide the following:

1. A copy of the Director's approval letter (this letter) shall be included in the front of each operating manual of the PIWS 3000 that is owned by Triumvirate Environmental, Inc. and operated in the State of Ohio.
2. An updated operating manual that significantly impacts the use or operation of the system shall be provided to Ohio EPA thirty (30) days prior to the operating manual change.
3. A written notification shall be provided to Ohio EPA a minimum of seven (7) days prior to all new installations of the PIWS 3000 by Triumvirate Environmental, Inc. in the State of Ohio.

B. The operator of a PIWS 3000 owned by Triumvirate Environmental, Inc. shall comply with the following operational requirements and conditions:

1. Operate the PIWS 3000 at a pH between 11 and 12.5 for each treatment cycle with a minimum of 7.5% Cold-Ster<sup>®</sup> chemical per load of waste loaded into the PIWS 3000 to insure adequate treatment of infectious waste.
2. Record and maintain a copy of the Program Logic Control System's continuous monitoring of pH, raw weight waste measurement, and waste through-put.
3. Perform the following quality assurance measures to demonstrate the PIWS 3000 meets the performance standards:

- a. Clean and calibrate the pH monitoring equipment as stated in the operating manual, daily, prior to beginning start-up procedures for the PIWS 3000; and
  - b. Collect three samples of treated infectious waste that has exited the PIWS 3000, on a daily basis, and verify the pH of those samples using pH monitoring equipment independent of the PIWS 3000.
  - c. Test the effectiveness of the Cold-Ster<sup>®</sup> dry chemical as stated in the operating manual each time a shipment is received.
4. Keep quality assurance records and the daily log of operations on site for a minimum of three years.
5. Develop and maintain in one area on the premises of the infectious waste treatment unit a Facility Management Plan (FMP) that includes 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 PIWS 3000.
  - b. A statement signed by each person loading the PIWS 3000 with infectious waste certifying that the operator of the treatment unit has provided instruction on the use of the PIWS 3000 and the types of infectious waste the unit is approved to treat.
  - c. A daily operating log form for each unit for each day that infectious waste is treated in the unit.
  - d. A list of preventative maintenance checks and services as stated in the operating manual.
6. Perform the quality assurance testing upon request by, and in the presence of, Ohio EPA or an approved health department representative to verify that the written operating procedures located in the facility management plan are sufficient to meet the performance standard.
7. Comply with all applicable infectious waste treatment requirements in OAC Rule 3745-27-32.
8. Utilize a daily operating log form for each operator 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.

9. Conduct preventative maintenance checks and services as stated in the operating manual (include dates and name of person completing the checks and services).
10. Manage as infectious waste all wastes contained inside the treatment unit, if the PIWS 3000 fails any parametric monitoring for any reason. In the event of such failure, the operator shall cease to use the treatment unit until such time that the treatment unit is repaired or calibrated and passes a quality assurance test. 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.
11. Operate the PIWS 3000 containing infectious waste, pathological waste, and infectious sharps from medical offices, similar to that for which the treatment technology has been tested.
12. Ensure that wastes containing hazardous waste as defined in 40 CFR Part 261 and OAC Chapter 3745-51 or radioactive material as defined in Chapter 3748 of the Ohio Revised Code (ORC) shall not be introduced into the PIWS 3000 unit.

#### **END OF CONDITIONS**

#### **EXEMPTION FROM OAC RULE 3745-27-38(G)(5)**

On August 26, 2014, Triumvirate Environmental, Inc. submitted a request for an exemption from OAC Rule 3745-27-38(G)(5), which requires monthly quality assurance testing using bacterial spores. Quality assurance testing is an on-going monitor of the treatment technology's ability to attain the performance standard for treatment of infectious waste. The performance standard is the achievement of a minimum four log<sub>10</sub> reduction of bacterial spores immediately upon exit of the wastes from the treatment unit. Triumvirate Environmental, Inc. proposes to use parametric monitoring of pH for quality assurance testing.

An integral part of the PIWS 3000 system is the continuous pH monitoring of the treated waste as it exits the system. This pH is captured continuously through the on-board computer system and stores the readings for quality assurance purposes. This continuous parametric monitoring provides real-time data acquisition to demonstrate compliance with the performance standard. The computer system also weighs the amount of waste loaded into the treatment unit and automatically calculates the amount of Cold-Ster<sup>®</sup> to introduce into the PIWS 3000.

Triumvirate Environmental, Inc. has requested the use of parametric monitoring because the PIWS 3000 is a continuous feed system that shreds the waste as it is

treated. For initial confirmation testing of 100% pathological waste, Triumvirate Environmental, Inc. conducted a spore test by introducing 100 sheets of letter size fluorescent paper coated with bacterial spores into the waste stream. At the end of the treatment cycle, the treated waste was spread out in a dark room with black lights and workers sorted through the waste with tweezers to pick out enough pieces of fluorescent paper to calculate the number of bacterial spores that were destroyed. It would be physically impracticable to conduct such spore testing on a continual basis.

Pursuant to ORC Section 3734.02(G), the director, by order, may exempt any person generating, collecting, storing, treating, disposing of, or transporting solid wastes, infectious wastes, or hazardous waste, or processing solid wastes that consist of scrap tires, in such quantities or under such circumstances that, in the determination of the director, are unlikely to adversely affect the public health or safety or the environment from any requirement to obtain a registration certificate, permit, or license or comply with the manifest system or other requirements of ORC Chapter 3734. Such an exemption shall be consistent with and equivalent to any regulations adopted by the administrator of the United States environmental protection agency under the "Resource Conservation and Recovery Act of 1976," 90 Stat. 2806, 42 U.S.C.A. 6921, as amended, except as otherwise provided in ORC Chapter 3734.

Based upon review of the exemption request and associated information, Ohio EPA has determined that granting an exemption to allow the proposed use of parametric monitoring of pH for quality assurance testing is unlikely to adversely affect the public health or safety or the environment.

Therefore, pursuant to ORC Section 3734.02(G), Triumvirate Environmental, Inc. is hereby exempted from the requirement to perform bacterial spore testing for quality assurance testing, as required in OAC Rule 3745-27-38(G)(5), during operation of the PIWS 3000 infectious waste treatment unit. Triumvirate Environmental, Inc. shall continue to conduct parametric monitoring of pH during operation of the PIWS 3000 infectious waste treatment unit as proposed in the August 26, 2014 exemption request.

#### **END OF EXEMPTION**

Upon compliance with the conditions stated herein, infectious waste treated by this unit is to be handled in the same manner as solid waste and must be disposed in a licensed solid waste facility. Additionally, this approval does not release the owner or operator from compliance with all other federal or local laws or regulations. This approval is not a substitute for a Permit-to-Install and license as cited in ORC Chapter 3734.

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 which the Commission, in its discretion, may reduce if by affidavit it

Mr. Samuel Vitello  
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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, 17<sup>th</sup> Floor  
Columbus, Ohio 43215

If you have any questions concerning this authorization, please contact Scott Hester of Ohio EPA, Division of Materials and Waste Management at (614) 644-2621.

Sincerely,

A handwritten signature in black ink, appearing to read "CWB", with a stylized flourish extending to the right.

Craig W. Butler  
Director

CWB/MF