

COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF ENVIRONMENTAL PROTECTION  
BUREAU OF WASTE MANAGEMENT

**General Permit  
For  
Processing/Beneficial Use of Regulated Medical Waste**

Permit No. WMGI015

Date Amended \_\_\_\_\_

Date Issued 06/19/2015

Date Expires 06/19/2025

The Department of Environmental Protection, Bureau of Waste Management, Division of Municipal and Residual Waste hereby approves the:

Beneficial Use

Processing

Other

of: regulated medical waste using technology that involves mechanical processing in combination with ozone to achieve disinfection.

for use as: N/A

This approval is granted to: Clean Waste Systems, LLC

3535 Plymouth Blvd., Suite 112

Plymouth, MN 55447

subject to the attached conditions and may be revoked or suspended for any project which the Department of Environmental Protection determines to have a substantial risk to public health, the environment, or cannot be adequately regulated under the provisions of this permit.

The processing of wastes not specifically identified in the documentation submitted for this approval, or the beneficial use of wastes not approved in this permit, is prohibited without the written permission of the Department.

This permit is issued under the authority of the Solid Waste Management Act (35 P.S. §§6018.101-6018.1003), The Pennsylvania Used Oil Recycling Act (58 P.S. §§471-480), The Clean Streams Law (35 P.S. §§691.1-691.1001), Sections 1905-A, 1917-A and 1920-A of the Administrative Code of 1929 (71 P.S. §§510-5, 510-17 and 510-20) and the Municipal Waste Planning, Recycling and Waste Reduction Act (53 P.S. §§4000.101-4000.1904).

This approval is granted:

By: 

Statewide  Regional

Title: Environmental Program Manager

THIS PERMIT IS NON-TRANSFERABLE

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OZONE AND MECHANICAL PROCESSING OF REGULATED MEDICAL WASTE

**A. Description:**

The statewide permit herein granted is limited to the processing of regulated medical waste using mechanical processing in combination with ozone for disinfection of the regulated medical waste. Regulated medical waste processing shall be carried out in an enclosed system to protect employee and public health, safety, welfare, and the environment. This permit only authorizes the processing of regulated medical waste generated by the permittee.

**B. Registration:**

A person or municipality that proposes to operate under the terms and conditions of this general permit after the date of permit issuance shall obtain a registration from the appropriate Department Regional Office (see attached list) prior to commencing authorized activities under this general permit. A completed application on forms available from the Department must be submitted to the appropriate Department Regional Office. A check in the amount identified in Section A (General Information) of the Form 20RMCW (Application for a Regulated Medical or Chemotherapeutic Waste General Permit) shall be submitted to the appropriate Department Regional Office. A check shall be made payable to the "Commonwealth of Pennsylvania." No activities shall commence unless approved, in writing, by the Department.

**C. Operating Conditions:**

1. All activities conducted under the authorization granted in this permit shall be conducted in accordance with the permittee's application. Except to the extent the permit states otherwise, the permittee shall utilize the processed material as described in the permit application.
2. The permittee shall comply with the fugitive emissions regulations under Title 25 Pa. Code, Chapter 123 (Standards for Contaminants) issued under the Air Pollution Control Act, the Act of January 8, 1960, P.L. 2119, 35 P.S. §4005 and shall comply with all the applicable provisions of the Fugitive Emissions Sections 123.1 and 123.2.
3. Nothing in this permit shall be construed to supersede, amend, or authorize a violation of any of the provisions of any valid and applicable local law, ordinance, or regulation, providing that said local law, ordinance, or regulation is not preempted by the Pennsylvania Solid Waste Management Act, 35 P.S. §6018.101 et seq.; the Municipal Waste Planning, Recycling and Waste Reduction Act of 1988, 53 P.S. §4000.101 et seq.; the Air Pollution

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Control Act, 35 P.S. §4001 et seq.; or the Clean Stream Law, 35 P.S. §691.1 et seq.

4. As a condition of this general permit and of the permittee's authority to conduct the activities authorized by this general permit, the permittee hereby authorizes and consents to allow authorized employees or agents of the Department, without advance notice or search warrant, upon presentation of appropriate credentials and without delay, to have access to and to inspect all areas on which solid waste management activities are being, will be, or have been conducted. This authorization and consent shall include consent to collect samples of waste, soils, water, or gases; take photographs; to perform measurements, surveys, and other tests; inspect any monitoring equipment; to inspect the methods of operation and to inspect and/or copy documents, books, and papers required by the Department to be maintained. This permit condition is referenced in accordance with §608 and §610(7) of the Solid Waste Management Act, 35 P.S. §6018.608 and §6018.610(7). This condition in no way limits any other powers granted under the Solid Waste Management Act.
5. Any independent contractors or agents retained by the permittee in the completion of activities authorized under this general permit shall be subject to compliance history review by the Department prior to performance of any activities, as specified by the Pennsylvania Solid Waste Management Act of 1980.
6. Failure of the permittee to comply with the applicable laws, rules, and regulations and terms of this permit, for any reason, shall be grounds for the revocation or suspension of the permittee's approval to conditions of this permit, or of the measures herein approved to perform as intended or operate under this permit.
7. The activities authorized by this general permit shall not harm or present a threat of harm to the health, safety, or welfare of the people or environment of this Commonwealth. The Department may modify, suspend, revoke, and reissue the authorization granted in this general permit if it deems necessary to prevent harm or the threat of harm to the public health, and the environment or if they cannot be adequately regulated under the conditions of this general permit.
8. The permittee shall comply with the terms and conditions of this general permit and with the environmental protection acts to the same extent as if

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the activities were covered by an individual permit. The Department may require an individual permit be obtained if the permittee cannot comply with the conditions of this general permit or is conducting an activity that harms or presents a threat of harm to the health, safety, or welfare of the public or the environment of this Commonwealth.

9. This permit does not authorize and shall not be construed as an approval to discharge any waste, wastewater, or runoff from the site of storage to the land or waters of the Commonwealth.
10. The permittee shall maintain in force and affect a general liability insurance policy in accordance with 25 Pa. Code, Chapter 287, Subchapter E (relating to bonding and insurance requirements) to provide continuous coverage during operation of the facility and until the Department issues a final closure certification.
11. This permit does not authorize a person or municipality to operate a commercial regulated medical waste processing facility, as defined in 25 Pa. Code § 271.1.
12. The permittee shall locate the regulated medical waste processing system equipment at the waste generating facility, in an area where unauthorized access by the employees, patients, patrons of the facility, and the general public is restricted. Warning signs shall be clearly visible with respect to the type of waste and the processing equipment.
13. Except for regulated medical waste, this permit does not authorize the storage, processing, treatment, or disposal of solid waste.
14. The regulated medical waste processing equipment, under this general permit, shall be operated in accordance with all of the conditions established by its manufacturer.
15. In the event of a system shutdown or failure, the load of waste being processed shall be reprocessed after the equipment is repaired. No additional regulated medical waste shall be loaded into the processing equipment, until after the cause of the shutdown or failure is fully investigated, corrected, and confirmed by the operator.

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16. During periods of extended equipment failure or shutdown, regulated medical waste may be stored for no more than the time limits indicated in 25 Pa. Code § 284.415, relating to Duration of Storage of Regulated Medical and Chemotherapeutic Waste for Generators. During such periods, the onsite generated regulated medical waste shall be manifested and transported by a licensed regulated medical waste transporter to a permitted regulated medical waste processing facility, in accordance with the Department's rules and regulations.
17. The storage standards in 25 Pa. Code § 284.401-419, which are applicable to regulated medical waste processing facilities relative to the storage of regulated medical waste and the processed residue, shall be met.
18. Equipment used for the storage and processing of regulated medical waste shall be maintained in good operating condition. Daily inspection of the facility, its equipment, and surrounding area are to be conducted to determine its operating status and any evidence of equipment failure.
19. The storage and processing of regulated medical waste at the processing facility and its transportation, when applicable, shall be carried out in a manner which prevents the harborage or breeding of vectors, spills, leaks, or other releases, and the creation of nuisances which may be harmful to the public health, welfare, safety, or the environment.
20. The permittee shall notify the Department within 24 hours of any spills or accidental discharges which may enter the environment or which may have an adverse impact on public health.
21. The regulated medical waste processing system shall meet the following performance standards:
  - a. All waste shall be thoroughly shredded and exposed to ozone at a minimum rate of 1,500 ppm for a period of time no shorter than one hour.
  - b. All waste shall be treated to meet the disinfection standards in 25 Pa. Code § 284.321, relating to Regulated Medical Waste Monitoring Requirements.
22. Shredding of the regulated medical waste, prior to disinfection, must occur within a continuous and enclosed disinfection processing unit.

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23. All regulated medical waste, **except the following**, may be processed by the regulated medical waste processing system: human body parts including organs, chemotherapeutic waste, and commingled infectious and chemotherapeutic waste. In addition, radioactive waste, hazardous waste, residual waste, and other types of municipal waste shall not be processed in the processing unit.
24. The entire regulated medical waste processing unit shall be cleaned using the system shutdown procedures established by the manufacturer after processing of the final waste load and shall be disinfected prior to conducting any routine, preventative, or emergency maintenance. Daily, weekly, monthly, and annual preventative maintenance checks and services shall be conducted in accordance with the manufacturer's specifications and instructions. All modifications or amendments to those specifications relative to the cleaning and maintenance time frames and procedures must be approved in writing by the Department prior to implementation.
25. Only trained and designated personnel shall operate the unit. Such personnel shall be employees of the permittee or of the independent contractor. Protocols used for training employees shall be those recommended and documented by the manufacturer of the equipment. The equipment manufacturer shall provide training for the individuals responsible for operating the equipment. Individual employee training records shall be maintained on the processing unit.
26. Incompatible waste, such as thermometers, metallic items, and other waste items that contain elemental mercury, shall be removed from the waste stream, prior to charging waste into the processing unit.
27. A Contingency Plan, consistent with the Department's most recent guidelines, shall be maintained alongside the processing unit and updated as necessary or, at least, every five years.
28. The regulated medical waste generator or operator of the regulated medical waste processing unit shall dispose of all properly disinfected processed residue from the processing unit in a landfill or incinerator that is permitted by the Department, and has been approved to accept the waste. If the processed waste is disposed outside the Commonwealth, the receiving State's requirements shall be met.

**D. Recordkeeping:**

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1. Daily records shall be maintained of weight or volume of regulated medical waste charged into the equipment. The load charged shall not exceed the recommended capacity of the equipment.
2. A log shall be maintained to record the time and date of the ozone concentrations reached 1,500 ppm, the duration of time for which ozone concentrations were greater than or equal to 1,500 ppm, and operator name and title. The results of the disinfection monitoring, including any equipment calibration shall also be recorded. A copy of the log shall be maintained alongside the unit, where the processing took place.
3. Records of equipment servicing during routine maintenance and emergency situations shall be maintained.
4. The permittee shall maintain all records for five (5) years, and make the records available to the Department upon request.

**E. Renewal:**

A person or municipality that plans to continue the operations authorized under this general permit, after the expiration date indicated on the approval for coverage page, shall file a complete application for permit renewal at least 180 days before the expiration date of this general permit unless permission has been granted by the Department for submission at a later date. The renewal application shall be submitted to the appropriate Department Regional Office. A check shall be made payable to the "Commonwealth of Pennsylvania." A copy of the renewal application shall also be sent to the attention of the Department's Bureau of Waste Management, Division of Municipal and Residual Waste, Rachel Carson State Office Building, 400 Market Street, P.O. Box 69170, Harrisburg, PA 17106-9170.

In the event that a timely and complete application for renewal has been submitted and the Department is unable, through no fault of the permittee, to reissue the general permit or approval for coverage before its current coverage expiration date, the terms and conditions of the approved coverage will automatically continue and will remain fully effective and enforceable pending the issuance or denial of the renewal for permit coverage, provided the permittee is, and has been, operating in compliance with the terms and conditions of the general permit.

**Department of Environmental Protection  
Regional Offices  
(and Counties Served)**

- I. Bucks, Chester, Delaware, Montgomery, Philadelphia.

**Southeast Regional Office**

2 East Main Street  
Norristown, PA 19401  
Phone: (484) 250 - 5960

- II. Carbon, Lackawanna, Lehigh, Luzerne, Monroe, Northampton, Pike, Schuylkill, Susquehanna, Wayne, Wyoming.

**Northeast Regional Office**

2 Public Square  
Wilkes-Barre, PA 18711-0790  
Phone: (570) 826 - 2516

- III. Adams, Bedford, Berks, Blair, Cumberland, Dauphin, Franklin, Fulton, Huntingdon, Juniata, Lancaster, Lebanon, Mifflin, Perry, York.

**Southcentral Regional Office**

909 Elmerton Avenue  
Harrisburg, PA 17110-8200  
Phone: (717) 705 - 4706

- IV. Bradford, Cameron, Centre, Clearfield, Clinton, Columbia, Lycoming, Montour, Northumberland, Potter, Snyder, Sullivan, Tioga, Union.

**Northcentral Regional Office**

208 West 3<sup>rd</sup> Street - Suite 101  
Williamsport, PA 17701  
Phone: (570) 327 - 3653

- V. Allegheny, Armstrong, Beaver, Cambria, Fayette, Greene, Indiana, Somerset, Washington, Westmoreland.

**Southwest Regional Office**

400 Waterfront Drive  
Pittsburgh, PA 15222-4745  
Phone: (412) 442 - 4000

- VI. Butler, Clarion, Crawford, Elk, Erie, Forest, Jefferson, Lawrence, McKean, Mercer, Venango, Warren.

**Northwest Regional Office**

230 Chestnut Street  
Meadville, PA 16335-3481  
Phone: 814-332-6848