



pennsylvania
DEPARTMENT OF ENVIRONMENTAL
PROTECTION

BUREAU OF WASTE MANAGEMENT
DIVISION OF MUNICIPAL and RESIDUAL WASTE

GENERAL PERMIT WMGI007

PROCESSING OF REGULATED MEDICAL WASTE USING A MODULAR
DISINFECTION UNIT

Issued: November 27, 2017
Expires: November 27, 2027

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PROCESSING OF REGULATED MEDICAL WASTE
USING A MODULAR DISINFECTION UNIT

A. Description:

The approval herein granted is limited to the processing of regulated medical waste, as the term is defined in Section 271.1 of the Municipal Waste Management Regulations, 25 Pa. Code, § 271 (relating to definitions), using a modular disinfection unit with the components listed below to satisfy the disinfection requirements of Section 284.321 of the Municipal Waste Management Regulations, 25 Pa. Code, § 284.321 (relating to regulated medical waste monitoring requirements).

- a. A waste feed system to convey regulated medical waste to a feed hopper.
- b. A feed hopper that provides for the initial application of sodium hypochlorite (2500 ppm) and feeds the waste to the shredder.
- c. A shredding system capable of rendering the waste unrecognizable.
- d. A steam disinfection system capable of maintaining the regulated medical waste at 205°F to 212°F for a minimum of 60 minutes.
- e. Final disposal of processed regulated medical waste at a permitted landfill or incinerator.

The following types of regulated medical waste may not be processed under this general permit:

1. human or animal pathological waste including body parts, organs and tissues,
2. chemotherapeutic waste,
3. commingled regulated medical and chemotherapeutic waste,
4. radioactive material, hazardous waste, residual waste, and other types of municipal waste, as the terms are defined in 25.Pa. Code § 271.1 (relating to definitions).

B. Registration Requirements:

A person or municipality that proposes to operate under the terms and conditions of this general permit after the date of permit issuance must obtain a registration from the Department prior to commencing activities authorized under this general permit. A completed application on forms provided by the Department along with the application fee for a registration must be submitted to 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. Checks shall be made payable to the "Commonwealth of Pennsylvania." No activities shall commence unless approved, in writing, by the Department.

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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 exhaust air released into the ambient air, from the air filtration system and the low pressure steam conveyor, shall comply with the fugitive emission standards and the malodor standards adopted under 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 25 Pa. Code §§ 123.1 and 123.2 (relating to prohibition of certain fugitive emissions and fugitive particulate matter)..
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 Solid Waste Management Act, 35 P.S. §6018.101 et seq. (SWMA); the Municipal Waste Planning, Recycling and Waste Reduction Act of 1988, 53 P.S. §4000.101 et seq.; the Air Pollution 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 permit and of the permittee's authority to conduct the activities authorized by this permit, the permittee hereby authorizes and consents to allow authorized employees or agents of the Department, without advanced notice or search warrant, upon presentation of appropriate credentials and without delay, to have access to and 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; to take photographs; perform measurements, surveys, and other tests; inspect any monitoring equipment; inspect the methods of operation; and inspect and/or copy documents, books, and papers required by the Department to be maintained. This permit condition is referenced in accordance with Sections 6018.608 and 6018.610 (7) of the SWMA, 35 P.S. §§ 6018.608 and 6018.610(7). This condition in no way limits any other powers granted under the SWMA.
5. Any independent contractors or agents retained by the permittee in the completion of activities authorized under this general permit shall be subject to a compliance history review by the Department prior to performance of any activities, as specified by the SWMA.
6. Failure of the measures and facilities herein approved to perform as intended, or as designed, or in compliance with the applicable laws, rules, regulations, terms and conditions of this permit, for any reason, shall be grounds for the revocation or suspension of the permittee's approval to operate under this permit.

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7. The activities authorized by this 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, or reissue the authorization granted in this permit if it deems necessary to prevent harm or the threat of harm to the public health or the environment, or if the facility cannot be adequately regulated under the conditions of this 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 the activities were covered by an individual permit. The Department may require the permittee to apply for and obtain an individual permit if the permittee is not in compliance 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.
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 or processing 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. 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 shall be conducted to determine compliance with the terms and conditions of this permit and for evidence of equipment failure. A plan for the alternative storage and processing of regulated medical waste, during periods of equipment breakdown or emergencies, shall be developed and retained at each processing facility location.
12. Storage of regulated medical waste shall be in a manner that complies with the requirements of 25 Pa. Code §§ 284.401 – 419 (relating to the segregation and storage of regulated medical waste) that are applicable to regulated medical waste processing facilities.
13. The activities authorized by this permit shall not cause or allow conditions that are harmful to the environment, public health or safety, including but not limited to odors, noise, or other public nuisances. The permittee shall not cause or allow harborage or breeding of vectors.
14. Regulated medical waste shall not be mixed with other types of solid waste, including hazardous waste, chemotherapeutic waste, municipal waste that is not regulated medical waste, special handling waste, or residual waste, as the terms are defined in 25 Pa. Code § 271.1.
15. The permittee shall develop and implement a Preparedness, Prevention and Contingency (PPC) Plan that is consistent with the Department's most recent guidelines for the development and implementation of environmental emergency response plans.

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The PPC Plan shall be retained onsite and located in close proximity to the processing unit and made available to the Department upon request. The permittee shall update the PPC Plan as necessary and at a minimum of every 5 years.

16. Upon cessation of permitted operations at the facility, the permittee shall remove all waste, including but not limited to regulated medical waste and structures or other materials which contain or have been contaminated with regulated medical waste, and provide for the processing, recycling, beneficial use or disposal of the waste in accordance with the SWMA, the Infectious and Chemotherapeutic Waste Disposal Act, 35 P.S. § 6019.1 et. Seq., the environmental protection acts, and the regulations promulgated thereunder.
17. This permit does not authorize the storage, processing, treatment, or disposal of solid waste, other than regulated medical waste, as the term is defined in 25 Pa. Code § 271.1.
18. Processing activities authorized under this permit shall be conducted in accordance with 25 Pa. Code §§ 284.301 – 284.322.
19. This permit does not authorize a person or municipality to operate a commercial regulated medical waste processing facility, as the term is defined in 25 Pa Code § 271.1.
20. The permittee shall locate the regulated medical waste processing equipment, in an area that prevents unauthorized access to the waste and processing area, including but not limited to unauthorized employees, patients, patrons of the facility, and the public. Enclosures and containers used for storage of regulated medical waste shall also be secured to deny access to unauthorized persons and shall be marked with prominent warning signs indicating the storage of regulated medical waste.
21. Regulated medical waste processing equipment, operated under the authorization granted pursuant to this general permit, shall be operated and maintained in accordance with the conditions specified by its manufacturer.
22. In the event of a system shutdown or failure, 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 a demonstration is made that the equipment is capable of achieving the disinfection required by 25 Pa. Code § 284.321(a)(2) (relating to regulated medical waste monitoring requirements). The load of waste being processed at the time of system shutdown or failure shall be reprocessed after the equipment is repaired, or processed using another approved method.
23. During periods of extended equipment failure or shutdown, regulated medical waste may not be stored longer than the time limits indicated in 25 Pa. Code §§ 284.415 – 284.416 (relating to duration of storage of regulated medical and chemotherapeutic waste for generators and duration of storage of regulated medical and chemotherapeutic waste for processors, respectively), and any regulated medical waste generated onsite shall be transported, in accordance with 25 Pa. Code §§ 284.511 – 284.514 (relating to collection

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and transportation), by a regulated medical waste transporter licensed in accordance with 25 Pa. Code §§ 284.631 – 284.634 (relating to transporter licensing for regulated medical and chemotherapeutic waste). to a permitted regulated medical waste processing facility.

24. Except as provided in 25 Pa. Code § 284.321(p) for facilities engaged in the production or research and development of vaccines or other biologics that are classified under the NAICS as code 325414 – biological protocol (except diagnostic) manufacturing, the permittee shall monitor regulated medical waste during the waste processing using spores of *Bacillus atrophaeus* variety niger (globigii), as required by 25 Pa. Code § 284.321(e)(2). The permittee shall perform microbiological analysis of indicators removed from the processed waste, at a minimum, every 40 hours of the equipment operation, in accordance with 25 Pa Code § 284.321(d). The disinfection monitoring procedures shall be based on an established protocol, designed using standard microbiological testing procedures, to ensure disinfection. The protocol shall be submitted for approval, as part of the registration for coverage under this general permit. Monitoring of the processing method conducted in accordance with this paragraph must indicate that the waste processing meets the disinfection standard of 25 Pa Code § 284.321(a)(2), and Condition C.25 of this general permit. The test articles used shall be of the American Type Culture Collection (ATCC) variety.
25. Except as provided in 25 Pa. Code § 284.321(p) for facilities engaged in the production or research and development of vaccines or other biologics that are classified under the NAICS as code 325414 – biological protocol (except diagnostic) manufacturing, for production scale chemical inactivation operations, effectiveness shall be demonstrated initially prior to processing wastes through kill kinetic studies based on chemical concentration and mixing time and conducted in accordance with generally acceptable industry practices for the inactivation of regulated medical waste. Initial testing must demonstrate that the processing equipment or method is capable of the following in accordance with 25 Pa Code § 284.321(a)(2):
- a. Inactivation of mycobacteria at a 6 log 10 reduction or greater; and
 - b. Inactivation of *Geobacillus stearothermophilus* spores, *Bacillus pumilus* or *Bacillus atrophaeus* spores at a 4 log 10 reduction or greater.

These practices shall be consistent with guidelines developed by the Association of Analytical Communities (AOAC), Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and/or other scientifically accepted protocols. The studies may be performed by the chemical manufacturer or the permittee.

26. Only designated personnel who have been trained in the proper operation of the processing equipment shall be permitted to process regulated medical waste using the processing equipment. 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 or owner shall provide training for the individuals responsible for operating the equipment at the time the equipment is purchased. Thereafter, protocols used for training employees shall be those specified by the manufacturer of the equipment.

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27. Incompatible waste, including but not limited to thermometers, metallic items, or items that contain elemental mercury, shall be removed from the waste stream prior to processing.
28. The tests to demonstrate inactivation shall include temperature mapping or inactivation studies. Inactivation studies shall include biological testing, using the target organism identified in Condition C.25 of this permit, or a more resistant organism, which was qualified using kill kinetic studies. Indicators shall be located prior to disinfection at a point within the load where disinfection will be most difficult to achieve.
29. Analytical testing requirement by this general permit shall be performed by a laboratory accredited under the Pennsylvania Environmental Laboratory Accreditation Act, Act of 2002, 27 Pa. C.S.A. §§ 4101-4113.

Analytical testing in this condition does not refer to the microbiological confirmation testing referenced in Condition 24. The analytical testing required by this condition is meant to apply only to the initial validation required by Conditions C.25 and C.28.
30. Containers of regulated medical waste shall comply with 25 Pa Code §§ 284.413 – 284.414. The reuse of containers must comply with 25 Pa Code § 284.417.
31. The regulated medical waste treatment facility shall meet the following performance standards:
 - a. All regulated medical waste shall be thoroughly heated and maintained at 205 °F or above, for a minimum of 60 minutes.
 - b. All regulated medical waste shall be thoroughly wetted with a solution of no less than 0.25% (2500ppm) sodium hypochlorite with a contact period of no less than 10 minutes.
32. In accordance with 25 Pa Code § 284.321(k), compactors, grinders or similar devices may not be used to reduce the volume of regulated medical waste before the waste has been rendered noninfectious. If the volume reduction device is within a continuous, enclosed disinfection process and part of one processing system, then the reduction device may be used.
33. An air filtration system shall be installed to extract air from the infeed hopper and shall consist of a HEPA (High Efficiency Particulate Air) filter capable of passing a maximum particulate size of 0.3 µm (microns). The HEPA filter shall have a removal efficiency not less than 99.95% for 0.3 micron particles. Filters shall be installed, validated prior to equipment operation, and inspected daily, in accordance with the manufacturer's installation guidelines. Discarded HEPA filters shall be managed, processed and disposed as regulated medical waste. A continuous differential pressure meter shall be installed for monitoring and recording the pressure drop across the HEPA filter. The differential pressure meter shall be replaced when the pressure drop across the filter reaches 6.0 inches in H₂O (0.22 pounds per square inch).

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34. Regulated medical waste will be considered to be infectious unless one of the following has occurred:
- a. Indicator spores are determined by microbiological analysis to have been destroyed in accordance with Condition C.27.
 - b. The facility is engaged in the production or research and development of vaccines or other biologics that are classified under the NAICS as Code 325414 –biological protocol (except diagnostic) manufacturing, and the following have occurred:
 - i. Disinfection has been conducted by inactivating all waste material in accordance with the practices, methods and minimum parameters for biological kill established by the facility's Institutional Biosafety Committee (IBC) or Independent Certified Biosafety Professional (ICBP), or both, consistent with CDC and NIH guidelines or scientifically accepted protocols, or both.
 - ii. Efficacy of the inactivation operations has been demonstrated through review of decontamination cycle data by trained technicians or other testing methods or studies specified by the IBC or ICBP, or both present in the waste. The procedures for demonstrating the efficacy of the inactivation operations must be set forth in SOP's or other written procedures maintained at the facility, or both.
 - iii. Preventative maintenance and calibration programs for decontamination equipment consistent with generally accepted industry standards as specified by the IBC or ICBP, or both, have been established and routinely implemented.
35. Any time the disinfection monitoring standard is not met, that waste load shall be reprocessed to meet the standard, or transported, in accordance with 25 Pa Code §§ 284.501 – 284.513 (relating to collection and transportation), to a permitted regulated medical waste processing facility.
36. Reduced-pressure backflow preventers shall be installed on all water supply lines providing water to the equipment. Each backflow preventer shall be installed to prevent damage from vandals or freezing weather and shall be inspected and tested, at least annually.
37. The entire waste processing equipment, including the shredder and hopper assembly shall be disinfected daily, or after completion of processing of the final load and prior to conducting any routine or emergency maintenance, in accordance with the manufacturer's specifications and standards.
38. Fire extinguishers shall be maintained in working condition on the processing unit.

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39. The regulated medical waste generator or operator of the modular disinfection unit shall dispose of residue from the processing unit in a landfill or incinerator that has been approved by the Department to accept the waste. If the processed waste is disposed outside the Commonwealth, the receiving State's requirements shall be met.
40. The permittee shall prepare and follow standard operating procedures (SOPs) and/or other written procedures that describe proper procedures for operation of the processing equipment, including procedures for measuring and documenting critical parameters or results of indicators demonstrating that the cycle operated consistently and achieved satisfactory inactivation of infectious agents. Critical parameters shall be measured each time the processing equipment is operated and demonstrate that the cycle operated consistently and achieved satisfactory inactivation.

D. Recordkeeping:

1. Copies of initial testing performed in accordance with Conditions C.25 and C.28 of this permit, including but not limited to, the dates of sampling and testing, description of the procedures used to collect samples, name of individual who collected the sample and performed testing, the volume or weight of the sample, the parameter tested, the result of the testing, the name of the analytical laboratory used, and name or description of the analytical methodologies employed. Records must be maintained on site for at least three years and made available to the Department for inspection upon request.
2. The permittee shall retain results of disinfection monitoring testing performed in accordance with Condition C.24 of this general permit, including but not limited to the date of testing, name of individual who performed testing, the total number of test and control samples used, the minimum time samples remain in the disinfection unit and holding sections of the unit, minimum temperature of the thermal section during waste disinfection, and the final results. The results of disinfection monitoring, including equipment calibration must also be recorded. A copy of the log shall be maintained on the unit for 3 years and made available to the Department, upon request.
3. Records of equipment servicing during routine maintenance and emergency situations shall be kept for 3 years and made available to the Department, upon request.
4. Records of individual employee training performed in accordance with this general permit shall be maintained onsite for a minimum of 5 years and made available to the Department upon request.
5. Daily records of weight or volume of regulated medical waste processed, and daily records of weight or volume and destination of regulated medical waste processing residue shall be maintained onsite for at least 3 years and made available to the Department upon request. The load charged into regulated medical waste processing equipment shall not exceed the recommended capacity of the equipment.

E. Reporting Requirements:

1. Any person that operates under the provisions of this permit shall immediately notify the Waste Management Program at the Department's Central Office via certified mail of any

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changes in: the company name, address, owners, operators and responsible officials; compliance status; land ownership and the right to enter and operate on any land occupied by a facility; the system used to process waste; and the status of any permit issued by the Department or federal government under the environmental protection acts.

2. The permittee shall immediately notify the Department's Emergency Hotline by telephone at 800-541-2050 and the waste management program in the appropriate DEP regional office (see attached list) of any accidental spills and shall take appropriate immediate action to protect the health and safety of the public and the environment.
3. A permittee operating a facility that processes regulated medical waste under this general permit shall submit to the Department a certification that disinfection requirements of Condition C.7 were satisfied for wastes processed in the preceding calendar year. The certification shall be submitted no later than March 1 of each year for the preceding calendar year.

F. Renewal:

A regulated medical waste processor 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 original renewal application, along with 2 hard copies and 1 electronic copy, shall be submitted to 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, and include, at a minimum, the following:

- (i) General Information Form (Authorization Application for a Residual or Municipal Waste General Permit Application),
- (ii) Form B (Professional Certification,
- (iii) Form 20 (Application for a Municipal or Residual Waste General Permit),
- (iv) Form 27R (Acceptance of General Permit Conditions), and
- (v) Renewal application fee in the amount identified in Section A (General Information) of the Form 20. A check shall be made payable to the "Commonwealth of Pennsylvania."

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, provide 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
Fax: 484-250-5961

Regional Solid Waste Manager:
Facilities Manager:
Operations Manager:
RW Coordinator:

James Wentzel
Mohamad Mazid
Robert France

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
Fax: 570-826-5448

Regional Solid Waste Manager:
Facilities Manager:
Operations Manager:
RW Coordinator:

Roger Bellas
Dave Matcho
Dean Ritter
Tracey McGurk

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
Fax: 717-705-4930

Regional Solid Waste Manager:
Facilities Manager:
Operations Manager:
RW Coordinator:

Tony Rathfon
John Oren
Carrie Fleming
James Smathers

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

Northcentral Regional Office

208 West 3rd Street, Suite 101
Williamsport, PA 17701
Phone: 570-327-3653
Fax: 570-327-3420

Regional Solid Waste Manager:
Facilities Manager:
Operations Manager:
RW Coordinator:

Pat Brennan
Lisa Houser
Jason Yufer

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
Fax: 412-442-4194

Regional Solid Waste Manager:
Facilities Manager:
Operations Manager:
RW Coordinator:

Mike Forbeck
Diane McDaniel
Scott Swarm
John Ley

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
Fax: 814-332-6117

Regional Solid Waste Manager:
Facilities Manager:
Operations Manager:
RW Coordinator:

John Guth
Joel Fair
Brian Mummert
Mark Cresswell