



pennsylvania
DEPARTMENT OF ENVIRONMENTAL
PROTECTION

BUREAU OF WASTE MANAGEMENT

DIVISION OF MUNICIPAL and RESIDUAL WASTE

GENERAL PERMIT WMGI005

**CHEMICAL/THERMAL INACTIVATION OF REGULATED MEDICAL
WASTE GENERATED IN THE PRODUCTION AND RESEARCH AND
DEVELOPMENT OF PHARMACEUTICALS**

Issued: July 27, 2017

Expires: July 27, 2027

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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, § 271.1, generated in the production, research and development of pharmaceuticals, as referred to in the Approved Facility Specific Reference Table, using chemical and/or thermal inactivation 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).

The approval herein granted is limited to processing of the following types of regulated medical wastes:

1. Discarded live or attenuated vaccines;
2. Liquid wastes from the production of biologicals;
3. Laboratory stocks and cultures of infectious agents, or those that have been exposed to infectious agents; and
4. Cell lines from humans and primates.

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

1. human body parts including organs,
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. Application 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.

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.

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2. The permittee shall comply with the fugitive emissions regulations 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 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 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; 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 Sections 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 measures herein approved to perform as intended, or as designed, or in compliance 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 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 the activities were

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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 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. Regular inspections of the facility during periods of waste processing activities, the equipment, and the surrounding area shall be conducted to determine compliance with the terms and conditions of this permit and for evidence of equipment failure. Continuous monitoring systems that monitor all waste processing operations and alert personnel of potential equipment failure shall also be implemented on automated processing equipment. Continuous monitoring is not required for simple chemical inactivation.
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. 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.
16. Processing activities authorized under this permit shall be conducted in accordance with 25 Pa. Code §§ 284.301 – 284.322.

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17. 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.
18. The permittee shall locate the regulated medical waste processing system 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.
19. 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.
20. 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 the procedures in 25 Pa. Code § 284.322 (relating to autoclave validation testing requirements) have been successfully performed. 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.
21. 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 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.
22. 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 effectiveness of all thermal processing systems shall be demonstrated initially prior to processing wastes through testing performed in accordance with generally accepted industry standards. Initial testing must demonstrate the absence of anaerobic or aerobic bacterial growth in a composite sample of processing residue or ash. For operators using an autoclave to inactivate regulated medical wastes, the autoclave validation testing requirements contained in 25 Pa. Code § 284.322 (relating to autoclave validation testing requirements) must also be performed prior to the processing of regulated medical wastes.

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23. 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 process is capable of inactivating mycobacteria at 6 log 10 reduction or greater and *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.
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, initial verification testing for thermal inactivation processes must be repeated at the following frequencies to demonstrate that the process operates as originally demonstrated and continues to provide satisfactory inactivation of regulated medical wastes:
- a. Every 12 months, at a minimum, or at an on-going frequency as specified by the equipment manufacturer, whichever is more frequent.
 - b. When a new piece of equipment is installed.
 - c. When the processing equipment is modified, repaired or has experienced a malfunction with respect to hardware, software, controls or ancillary equipment.
- All inactivation systems shall be operated in accordance with the parameters in the Facility Specific Reference Table.
25. 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 an independent contractor for the permittee. The equipment manufacturer shall provide training or training materials 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.
26. Incompatible waste, including but not limited to items that contain elemental mercury, shall be removed from the waste stream, prior to processing the waste.

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27. 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. The PPC Plan shall be retained onsite 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.
28. 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.
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 32. The analytical testing required by this condition is meant to apply only to the initial validation required by Conditions 22 and 23, and the annual testing required by Condition 30.

30. 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, a permittee operating a facility that thermally processes regulated medical waste under this general permit shall perform microbiological analysis of a composite sample of the processing or ash residue, at a minimum, annually during the life of the facility.
31. 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.
32. 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, a permittee operating a facility that disinfects regulated medical waste under this general permit by means other than thermal processing shall perform microbiological confirmation testing of indicators removed from the processed waste. The microbiological confirmation testing shall be conducted, at a minimum, every 40

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hours during the operational life of the facility, unless otherwise approved in writing by the Department. The microbiological confirmation testing shall be conducted in accordance with the testing indicator manufacturer's instructions and Condition 33.

33. The tests to demonstrate inactivation shall include temperature mapping or inactivation studies. Inactivation studies shall include biological testing, using the target organism or a more resistant organism which was qualified using kill kinetic studies. Unless the Department approves another indicator or test in writing, the following indicators shall be used to establish and verify the inactivation of infectious agents:

- a. For autoclaving, spores of *Geobacillus stearothermophilus*.
- b. For dry heat, gas or chemical disinfection, spores of *Bacillus atrophaeus* variety *niger* (globigii). Ethylene oxide may not be used for gas disinfection.
- c. For ionizing radiation, spores of *Bacillus pumilus*.

Indicators used for methods of disinfection other than thermal processing shall be located prior to disinfection at a point within the load where disinfection will be most difficult to achieve.

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.23 above for disinfection processes other than thermal processing.
- b. A microbiological analysis determines that disinfection has occurred in accordance with Condition C.22 above for thermal processing using a test other than an indicator spore.
- c. 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

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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. The regulated medical waste generator or operator of the regulated medical waste processing facility shall dispose of ash or other processing residue from the facility 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.

D. Recordkeeping

- 1. Copies of initial testing performed in accordance with Conditions C.22 and C.23 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. A permittee operating a facility that disinfects regulated medical waste under this general permit by means other than thermal processing shall retain results of microbiological confirmation testing performed in accordance with Condition C.32 of this general 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(if not performed onsite), and name or description of the analytical methodologies employed. Results of these analyses shall be maintained for a minimum of 5 years and made available to the Department upon request.
- 3. A permittee operating a facility that thermally processes regulated medical waste under this general permit shall retain results of microbiological analysis of a composite sample of the processing or ash residue performed in accordance with Condition C.30 of this general 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.

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Results of these analyses shall be maintained for a minimum of 5 years and made available to the Department upon request.

4. Records of individual employee training performed in accordance with Condition C.25 of 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:

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 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 thermally processes regulated medical waste under this general permit shall submit to the appropriate Department Regional Office (see attached list) the results of microbiological analysis of a composite sample of the processing or ash residue. Results shall be submitted no later than March 1 of each year for the preceding calendar year.
4. A permittee operating a facility that disinfects regulated medical waste under this general permit by means other than thermal processing shall submit to the appropriate Department Regional Office (see attached list) a certification that disinfection requirements of Condition C.32 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

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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	Regional Solid Waste Manager:	James Wentzel
Norristown, PA 19401	Facilities Manager:	Mohamad Mazid
Phone: 484-250-5960	Operations Manager:	Robert France
Fax: 484- 250-5961	RW Coordinator:	

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

Northeast Regional Office

2 Public Square	Regional Solid Waste Manager:	Roger Bellas
Wilkes-Barre, PA 18701-1915	Facilities Manager:	Dave Matcho
Phone: 570-826-2511	Operations Manager:	Dean Ritter (Fisher)
Fax: 570-826-5448	RW Coordinator:	Tracey McGurk

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

Southcentral Regional Office

909 Elmerton Avenue	Regional Solid Waste Manager:	Tony Rathfon
Harrisburg, PA 17110-8200	Facilities Manager:	John Oren
Phone: 717-705-4706	Operations Manager:	Carrie Fleming
Fax: 717-705-4930	RW Coordinator:	James Smathers

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

Northcentral Regional Office

208 West 3 rd Street, Suite 101	Regional Solid Waste Manager:	Pat Brennan
Williamsport, PA 17701	Facilities Manager:	Lisa Houser
Phone: 570-327-3636	Operations Manager:	Jason Yufer
Fax: 570-327-3420	RW Coordinator:	

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

Southwest Regional Office

400 Waterfront Drive	Regional Solid Waste Manager:	Mike Forbeck
Pittsburgh, PA 15222-4745	Facilities Manager:	Diane McDaniel
Phone: 412-442-4000	Operations Manager:	Scott Swarm
Fax: 412-442-4194		

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

Northwest Regional Office

230 Chestnut Street	Regional Solid Waste Manager:	Christina Wilhelm
Meadville, PA 16335-3481	Facilities Manager:	Joel Fair
Phone: 814-332-6848	Operations Manager:	Brian Mummert
Fax: 814-332-6117	RW Coordinator:	Mark Cresswell