

SPECIAL CONDITIONS
GENERAL PERMIT NUMBER WMGI005

Rev. 3/2009

Description:

The approval herein granted is limited to the processing of infectious waste, as defined in Section 271.1 of the Municipal Waste Management Regulations (25 Pa. Code Chapter 271), generated in the production and research and development of pharmaceuticals, as referred to in the Appendix, using chemical and/or thermal inactivation to satisfy the disinfection requirements of Condition 3.

Only the following types of infectious wastes shall be processed in the treatment facility: live, attenuated vaccines; liquid wastes from the production of biologicals; laboratory stocks and cultures of potentially infectious agents; cell lines from humans and primates.

Application Requirements:

Persons or municipalities that propose to operate under the terms and conditions of this general permit after the date of permit issuance must apply for a determination of applicability to the Waste Management Program at the Department's appropriate Regional Office. At a minimum, the following information must be provided on forms available from the Department's Bureau of Waste Management:

1. Name and street address of the applicant.
2. Location of the processing equipment.
3. Contact person (name and title).
4. The applicant must have documented ownership interest in the waste processing equipment. The applicant may contract with an independent contractor to construct, operate, and maintain the equipment.
5. Total volume of infectious waste to be processed on a daily or monthly basis.
6. A map clearly showing the location of any processing facility to be operated by the applicant under this permit.
7. Number and title of the general permit.
8. Documentation that the categories of infectious waste to be processed are consistent with the general permit.
9. Site-specific facility operation plan including ongoing equipment maintenance and employee training plan, in accordance with the Department's municipal waste management regulations.
10. A signed and notarized statement by the applicant that the applicant accepts all the terms and conditions included in the general permit.
11. A application fee payable to the "Commonwealth of Pennsylvania."
12. Proof that copies of the application have been submitted to each municipality in which the infectious waste processing facility will be located.
13. Documentation that the applicant has legal rights to enter the land and operate the facilities approved under this permit. The applicant shall identify any and all pending litigations contesting their rights where the processing equipment will be operated.
14. An irrevocable written consent from the landowner giving Department permission to enter upon the land where the applicant will be conducting infectious waste processing activities under this general permit.
15. A Preparedness, Prevention, and Contingency (PPC) plan for the facility prepared in accordance with the most recent edition of the Department's "Guidelines for the Development and Implementation of Environmental Emergency Response Plans".

SPECIAL CONDITIONS
GENERAL PERMIT NUMBER WMGI005

Rev. 3/2009

16. Documentation of compliance history of the applicant.
17. Documentation of the compliance history of any independent contractor, retained to operate or construct the facility, as specified in Condition 13 below.
18. Submission of a disinfection monitoring protocol, for Departmental approval, consistent with Condition 3 of this permit.
19. Submission of specific parameters for the facility found in the Appendix.
20. Additional information the Department believes is necessary to make a decision.

Operating Conditions:

1. No other solid wastes (i.e., hazardous, municipal, residual, chemotherapeutic, commingled infectious and chemotherapeutic, and regulated radioactive waste or wastes containing elemental mercury) are to be stored, processed, treated or disposed within the units and/or processes listed in the Appendix under the provisions or conditions of this permit.
2. All activities conducted under the authorization granted in this permit shall be conducted in accordance with the permittee's application and subsequent approval by the Department afterwards. Except to the extent that the permit states otherwise, the permittee shall operate the facility as described in the approved application.
3. The effectiveness of all thermal inactivation systems shall be demonstrated through initial testing in accordance with generally accepted industry standards and the destruction standard in Condition 23. The Department may require additional testing for modifications made to inactivation systems. Copies of these testing procedures are to be maintained on site, and are to be made available for inspection.

For production scale chemical inactivation operations, effectiveness will be demonstrated through initial kill kinetic studies based on chemical concentration and mixing time. The studies may be performed by the chemical manufacturer or the permittee. The Department may require additional testing for modifications made to inactivation systems. Copies of these procedures are to be maintained on site, and are to be made available for inspection.

Chemical inactivation of laboratory waste and research and development material shall be conducted in accordance with generally acceptable industry practices for the inactivation of infectious waste. These practices shall be consistent with guidelines developed by the Association of Analytical Communities (AOAC), Centers for Disease Control & Prevention (CDC), the National Institutes of Health (NIH) and/or other scientifically accepted protocols.

Verification that the thermal inactivation process continues to provide satisfactory inactivation must be demonstrated by use of one of the following methods:

- a. Testing of the system, using the challenge method listed in the Appendix, shall be performed at least every twelve months to demonstrate that the process operates as originally demonstrated and continues to provide satisfactory inactivation. Records of results of this testing shall be kept for 3 years and made available to the Department, upon request.

SPECIAL CONDITIONS
GENERAL PERMIT NUMBER WMGI005

Rev. 3/2009

b. Design of the automated system, meeting the specifications in Condition 25b.

All inactivation systems shall be operated in accordance with facility specific parameters in the Appendix.

4. This permit does not authorize any person or municipality to operate a commercial infectious waste processing facility, as defined in Section 271.1 of the Municipal Waste Management Regulations.
5. The permittee shall locate the treatment facility, at the waste generating facility, in an area where unauthorized access by employees and the general public is restricted. If the facility is located outside a building, in an open area, steps shall be taken to restrict unauthorized access to the waste processing facility. Warning signs shall be clearly visible with respect to the type of waste processed at the processing facility.
6. In the event of system shutdown or failure, the load of waste being processed shall be reprocessed after the equipment is repaired if adequate kill cannot be proven. Documented scientific justification can be used to prove inactivation of an incomplete batch prior to discharge. If kill cannot be proven, alternate approved processing methods (i.e., chemical inactivation) may be used. No additional infectious waste shall be loaded into the processing equipment, until after the cause of the shutdown or failure is fully investigated, confirmed, and corrected.
7. During periods of extended equipment failure or shutdown, infectious waste may be stored for no more than 30 days from the date infectious waste was first generated.
8. The storage of infectious waste and the processed residue shall comply with all applicable requirements 25 Pa. Code Chapter 284, Subchapter E (relating to the storage of infectious and chemotherapeutic waste).
9. 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 regulations, providing that said local law, ordinance, or regulation is not preempted by The Solid Waste Management Act, 35 P.S. §6018.101 et seq; and the Municipal Waste Planning, Recycling and Waste Reduction Act of 1988, 53 P.S. §4000.101 et seq.
10. 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 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; to perform measurements, surveys, and other tests; to 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 Section 608 and 610(7) of The Solid Waste Management Act, 35 P.S. Section 6018.608 and 6018.610(7), as amended. This condition in no way limits any other powers granted under The Solid Waste Management Act.

SPECIAL CONDITIONS
GENERAL PERMIT NUMBER WMGI005

Rev. 3/2009

11. This permit does not convey any property rights, either in real estate or materials, or in any privileges; nor does it authorize any injury to property or invasion of rights or any infringement of Federal, State, or local laws or regulations.
12. Approval of any plans or facilities herein refers to the functional design, but does not guarantee operational efficiency. Failure of the measures and facilities herein approved to perform as intended, or as designed, shall be grounds for the revocation or suspension of the permittee's approval to operate under this permit.
13. Any independent contractors or agents retained by the permittee to operate these facilities shall be subject to prior compliance history review by the Department as specified by The Solid Waste Management Act of 1980, as amended.
14. 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, otherwise, cannot be adequately regulated under the conditions of this permit.
15. This permit does not authorize and shall not be construed as an approval to discharge any waste, wastewater, or runoff from the site of processing to the land or waters of the Commonwealth unless discharge is authorized under the appropriate pretreatment or NPDES permit.
16. The storage and processing of infectious 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 and the creation of other nuisances which may be harmful to the public health, welfare, safety, or the environment.
17. The permittee shall notify the Department within 24 hours of any spills or accidental discharges into the waters, land, or air of the Commonwealth that may have a potential adverse impact on public health.
18. 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.
19. Upon cessation of operations at the processing facilities, the operator shall remove any infectious waste and structures or other materials which contain or have been contaminated with infectious waste and shall provide for the processing and disposal of the waste or material in accordance with The Solid Waste Management Act, as amended, the Infectious and Chemotherapeutic Waste Disposal Act, and other environmental protection acts, and the regulations promulgated thereunder.

SPECIAL CONDITIONS
GENERAL PERMIT NUMBER WMGI005

Rev. 3/2009

20. The permittee shall prepare and follow standard operating procedures (SOPs) and/or other written procedures. Each time the inactivation systems are operated, critical parameters are measured to demonstrate that the cycle operated consistently and achieved the inactivation conditions. Copies of current procedures and records of critical parameter measurements shall be maintained on site for a minimum of three years and be made available to the Department upon request.
21. Any person or municipality, who is permitted to operate under the provisions of this general permit, may operate infectious waste processing equipment at a new location or to expand the existing operation by providing notification to the Waste Management Program at the Department's appropriate Regional Office. The notification shall contain the following:
- a. For expansion of the existing operation, submission of information, as required in items 5, 8, and 19 of Application Requirements above, is mandatory, whereas items m and n, are required only when the information related to land ownership by the registrant has changed. Similarly, information related to items r and s, of Application Requirements, is required if the processing equipment is different from the equipment permitted under the existing application. The notification shall be submitted at least 10 days prior to starting the expanded operation.
 - b. For a new operation at a new location, the information required in items: 1, 2, 3, 4, 5, 6, 7, 8, 9, 12, 13, 14, 15, 18, and 19 in the "Application Requirements", above, must be submitted. The notification shall be submitted at least 30 days prior to starting the new operation.
22. Any person that operates under the provisions of this permit shall immediately notify the Waste Management Program at the Department's appropriate Regional Office via certified mail of any changes in: the company name, address, owners, operators and responsible officials; 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.
23. Each time a new infectious waste process unit is installed, the equipment shall be tested to demonstrate that it is capable of achieving and maintaining the operational requirements for inactivation. 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. All systems shall be designed and operated to assure destruction of the target organism, or a six log reduction of a more resistant organism, or a four log reduction of *G. stearothermophilus*.
24. The processing unit shall be set up and operated in a manner that prevents spills, leaks, or other releases.
25. Equipment used for the storage and processing of infectious waste shall be maintained in good operating condition. This is assured by use of one of the following methods:
- a. Daily inspections of the facility during periods of waste processing activities, its equipment, and the surrounding area are to be conducted to determine its operating status and for any evidence of equipment failure.

SPECIAL CONDITIONS
GENERAL PERMIT NUMBER WMGI005

Rev. 3/2009

- b. Continuous monitoring systems to monitor all waste processing operations and alert personnel of potential equipment failure.
26. A plan for the alternative storage and processing of infectious waste, during periods of equipment breakdown or emergencies, shall be developed and retained at each processing facility.
27. Only trained and designated personnel shall operate the equipment. Such personnel shall be employees of the permittee or of the independent contractor. Individual employee training records shall be maintained at the processing facility.
28. Should measured critical parameters of a written procedure indicate that the cycle has not operated consistently or achieved the inactivation conditions, the waste shall be reprocessed to meet the requirements of the written procedure or transported, under the Department's manifesting procedures, to an approved waste processing facility.
29. Disposable infectious waste containers shall be managed as infectious waste. Reusable containers shall be cleaned in accordance with the Department's most recent Policy and Procedure on "Container/Vehicle Decontamination and Small Spill Clean-up."
30. The permittee shall maintain at the permitted facility an updated copy of a Preparedness, Prevention, and Contingency (PPC) plan for the facility prepared in accordance with the most recent edition of the Department's "Guidelines for the Development and Implementation of Environmental Emergency Response Plans". The PPC plan shall be updated every 5 years or more frequently.
31. For manually operated systems, a log shall be maintained to record the time and date of inactivation, operator name or initials, waste identification, waste volume, processing time, concentration or temperature used. A copy of the log shall be maintained at the facility for three years and shall be made available to the Department upon request.
- For automated systems, preventive maintenance (PMs) and calibrations must be maintained to verify all parameters are met.
32. Records of equipment servicing during shall be kept for 3 years and made available to the Department, upon request.

SPECIAL CONDITIONS
GENERAL PERMIT NUMBER WMGI005

Rev. 3/2009

APPENDIX
FACILITY SPECIFIC PARAMETERS
WMGI005

| Product/Operation | Inactivation System | Set Point Temperature | Concentration | Set Point Time | Challenge Method |
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**DEP Regional Offices
(and Counties Served)**

Southeast Regional Office

Bucks, Chester, Delaware, Montgomery, Philadelphia
2 East Main Street
Norristown, PA 19401
Phone: 484-250-5960
Fax: 484-250-5961

Northeast Regional Office

Carbon, Lackawanna, Lehigh, Luzerne, Monroe, Northampton, Pike, Schuylkill, Susquehanna, Wayne, Wyoming
2 Public Square
Wilkes-Barre, PA 18711-0790
Phone: 570-826-2516
Fax: 570-826-5448

Southcentral Regional Office

Adams, Bedford, Berks, Blair, Cumberland, Dauphin, Franklin, Fulton, Huntingdon, Juniata, Lancaster, Lebanon, Mifflin, Perry, York
909 Elmerton Avenue
Harrisburg, PA 17110-8200
Phone: 717-705-4706
Fax: 717-705-4930

Northcentral Regional Office

Bradford, Cameron, Centre, Clearfield, Clinton, Columbia, Lycoming, Montour, Northumberland, Potter, Snyder, Sullivan, Tioga, Union
208 West 3rd Street, Suite 101
Williamsport, PA 17701
Phone: 570-327-3653
Fax: 570-327-3420

Southwest Regional Office

Allegheny, Armstrong, Beaver, Cambria, Fayette, Greene, Indiana, Somerset, Washington, Westmoreland
400 Waterfront Drive
Pittsburgh, PA 15222-4745
Phone: 412-442-4000
Fax: 412-442-4194

Northwest Regional Office

Butler, Clarion, Crawford, Elk, Erie, Forest, Jefferson, Lawrence, McKean, Mercer, Venango, Warren
230 Chestnut Street
Meadville, PA 16335-3481
Phone: 814-332-6848
Fax: 814-332-6117