

**GENERAL PERMIT NUMBER WMGI010**  
**Infectious Waste Processing**  
**Using Potassium Hydroxide and/or Sodium Hydroxide** Rev.  
12/2007

**A. 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) using chemical and thermal digestion using sodium and/or potassium hydroxide to satisfy the disinfection requirements of Condition C27.

Infectious waste which may be processed under this permit is limited to the following types: animal carcasses, bedding, feces, and body parts. The following types of residual wastes may also be processed in the waste management facility: noninfectious animal carcasses, bedding, feces, and body parts.

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, the environment, or if the activities cannot be adequately regulated under the conditions of this permit.

**B. Registration Requirements:**

Persons or municipalities that propose to process waste by operating under the terms and conditions of this general permit after the date of permit issuance must register with the appropriate Regional Office of the Department that has jurisdiction for waste-related activities in the county where the waste will be processed at least 30 days prior to commencing processing of infectious waste. Completed Forms 20IC (Application for a Infectious/Chemotherapeutic Waste Processing), 2540-PM-BWM0515 (General Information Form for a Residual or Municipal Waste General Permit), HW-C (Compliance History), L (Contingency Plan), E - GP (Contractual Consent of Landowner), B (Professional Certification), and 27M (Acceptance of General Permit Conditions) along with a registration fee in the amount specified in the regulations must be submitted to the appropriate Regional Office. Checks shall be made payable to the "Commonwealth of Pennsylvania."

**C. Operating Conditions**

1. No other solid wastes (i.e., hazardous, municipal, chemotherapeutic, commingled infectious and chemotherapeutic, wastes containing elemental mercury or residual waste) other than those identified in Section A (Description) are to be stored, processed, or treated 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, except to the extent that the permit states otherwise or the application conflicts with the regulations or governing statutes.

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3. 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.
4. The permittee shall locate the waste processing facility, at the waste generating facility, in an area where unauthorized access by employees and the general public is restricted. If the waste processing 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.
5. In the event of system shutdown or failure, the load of waste being processed shall be reprocessed after the equipment is repaired. 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 by the permittee or the manufacturer of the processing equipment.
6. 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.
7. The storage of infectious waste and the processed residue shall comply with all applicable requirements of Chapter 284 (Municipal Waste Regulations), Subchapter E (Storage).
8. 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. Nothing in this permit shall be construed to supersede, amend, or authorize a violation of any of the provisions of any valid and applicable federal law or regulation.
9. 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). This condition in no way limits any other powers granted under The Solid Waste Management Act.

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10. 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.
11. 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.
12. 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.
13. 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.
14. 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.
15. The permittee shall notify the Department within 24 hours of any spills or accidental discharges which enter the environment or which may have an adverse impact on public health.
16. 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.
17. 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, the Infectious and Chemotherapeutic Waste Disposal Act, and other environmental protection acts, and the regulations promulgated thereunder.

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18. The permittee shall prepare and follow written Standard Operating Procedures (SOPs). SOPs shall be used to guarantee and document that each infectious waste process cycle is operated properly. Each time the inactivation systems are operated, critical parameters must be measured to demonstrate that the cycle operated consistently and achieved the digestion conditions. Copies of SOPs 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.
19. 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 expand the existing operation by providing notification to the appropriate Regional Office of the Department. The notification shall contain the following:
- a. For expansion of the existing operation, submission of information on the total volume of infectious waste to be processed on a daily or monthly basis and documentation that the categories of infectious waste to be processed are consistent with the general permit is mandatory, whereas documentation that the applicant has the legal right to enter the land and operate the facilities approved under this permit and an irrevocable written consent from the landowner giving the Department permission to enter upon the land where the applicant will be conducting infectious waste processing activities under this general permit are required only when the information related to land ownership by the permittee has changed. The notification shall be submitted at least 30 days prior to starting the expanded operation.
  - b. If processing equipment is to be utilized which is different than the equipment permitted under the existing application, submission of a detailed description of the processing technology and equipment to be utilized and a digestion monitoring protocol, for Departmental approval, consistent with Condition C27 of this permit is required. The notification shall be submitted at least 30 days prior to starting the expanded operation.
  - c. For a new operation at a new location, Completed Forms 20IC (Application for a Infectious/Chemotherapeutic Waste Processing), 2540-PM-BWM0515 (General Information Form for a Residual or Municipal Waste General Permit), L (Contingency Plan), E - GP (Contractual Consent of Landowner), B (Professional Certification) must be submitted. The notification shall be submitted at least 30 days prior to starting the new operation.
20. Any person that operates under the provisions of this permit shall immediately notify the appropriate Regional Office of the Department 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.

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21. Each time a new infectious waste process unit is installed or physical changes are made to a unit which alters design parameters or significant changes are made in SOPs, the equipment shall be tested to demonstrate that it is capable of achieving and maintaining the manufacturer's operational requirements for digestion. Qualification shall include, but is not limited to, testing cycle temperature, pressure, pH, fluid circulation, and instrumentation. Qualification records shall be maintained on the premises for the life of the unit.
22. The processing unit shall be set up and operated in a manner that prevents spills, leaks, or other releases.
23. Equipment used for the storage and processing of infectious waste shall be maintained in good operating condition. Daily inspections of the facility during periods of waste processing activities, its equipment, and surrounding area are to be conducted to determine its operating status and for any evidence of equipment failure. 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.
24. 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.
25. The digestion process will consist of the addition of water and sufficient sodium or potassium hydroxide to the infectious waste to cover the waste and produce a minimum hydroxide concentration of 0.7 N. This solution shall be circulated over the infectious waste at the operating temperature for a minimum of:

<b><u>Operating Temperature (°F)</u></b>	<b><u>Minimum Duration (hours)</u></b>
300	3
275	4
250	7

26. Should measured critical parameters of a SOP indicate that the cycle has not operated consistently or achieved the digestion conditions, the waste shall be reprocessed to meet the requirements of the SOP or transported, under the Department's manifesting procedures, to an approved waste processing facility.

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27. a. For the first six months of operation and a minimum of twenty digestion cycles, a sealed ampoule containing *Bacillus stearothermophilis* or other microorganism, if approved by the Department, shall be placed in with the infectious waste prior to the start of the digestion cycle. The contents of the ampoule shall be sampled and monitored using appropriate standard microbiological testing procedures. Should testing indicate that total destruction was not obtained during the digestion process, the permittee shall conduct an investigation into the cause. Should testing indicate that total destruction was not obtained during two digestion process cycles in any 30-day period, the permittee shall modify operating conditions and the SOP to produce total destruction in subsequent cycles.
- b. After the unit has been operated for six months and a minimum of twenty digestion cycles without any indication through testing that total destruction was not obtained during any of the digestion process cycles during that period, a sealed ampoule containing *Bacillus stearothermophilis* or other microorganism, if approved by the Department, shall be placed in with the infectious waste prior to the start of one digestion cycle every six months. The contents of the ampoule shall be sampled and monitored using appropriate standard microbiological testing procedures. Should testing indicate that total destruction was not obtained during the digestion process, the permittee shall conduct an investigation into the cause. Sealed ampoules shall be added to each of the next 10 cycles prior to the start of the digestion cycle and sampled and monitored after the cycle has been completed. Should testing indicate that total destruction was not obtained during any digestion process cycle of these 10 cycles, the permittee shall modify operating conditions and the SOP to produce total destruction in subsequent cycles. The permittee shall continue to add sealed ampoules to each cycle prior to the start of the digestion cycle and sample and monitor them after the cycle has been completed until the operating conditions and the SOP have been modified such that total destruction occurs in 10 successive cycles.
28. Any air or solution vapor vented from the unit shall be captured in a vapor trap containing a sufficient quantity of a disinfectant solution, such as sodium hypochlorite, to ensure destruction of any microorganisms present.
29. A probe shall be installed in the effluent line of the processing unit to monitor the pH of the effluent from the unit during discharge.
30. 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."
31. 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 if necessary (e.g., if changes in phone numbers, equipment, or regulatory requirements occur).

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32. Residues from processing of infectious waste shall be stored and managed in a manner that complies with 25 Pa. Code, Chapters 271 through 285.
33. A log shall be maintained to record the time and date of digestion, operator name and title, waste identification, quantity of waste, quantities of water and sodium or potassium hydroxide used, processing time, temperature used, effluent pH, and the results of microbiological testing as specified in Condition C27. A copy of the log shall be maintained at the facility for three years and shall be made available to the Department upon request.
34. Records of equipment servicing during routine maintenance and emergency situations shall be kept for 3 years and made available to the Department upon request.
35. A person or municipality that plans to continue to process infectious waste 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 made using the Forms 201C (Application for a Infectious/Chemotherapeutic Waste Processing), 2540-PM-BWM0515 (General Information Form for a Residual or Municipal Waste General Permit), HW-C (Compliance History), L (Contingency Plan), E - GP (Contractual Consent of Landowner), B (Professional Certification), and 27M (Acceptance of General Permit Conditions).

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.

**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 3<sup>rd</sup> 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  
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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  
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Fax: 814-332-61171