- 1. 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), to shred and disinfect the infectious waste using the *DIDECYLDIMETHYL AMMONIUM CHLORIDE*; ALKYLDIMETHYL BENZYL AMMONIUM CHLORIDE prior to processing/disposal at an approved/permitted municipal waste management facility.
- 2. a. Use of *didecyldimethyl ammonium chloride and alkyldimethyl benzyl ammonium chloride* is limited to the processing only of infectious waste including: cultures and stocks, human blood and blood products, used sharps, animal waste, isolation wastes, plastic tubes in different diameters, polyethylene bags, paper and cardboard, latex gloves, rubber parts, bandages, cotton pads, non-woven cloth, small metal parts, glass jars, test tubes and bottles, wooden spatulas, polyethylene containers up to maximum of 7 liters, electric wires and various probes, full used sharps containers up to maximum of 7 liters, filters from dialysis. The use of this disinfecting chemical solution is contingent upon the process being used in accordance with the manufacturer's specifications.
 - b. Total elapsed time for the processing of infectious waste and the concentration of the disinfecting chemical solution in (a) above shall be sufficient to ensure complete disinfection of the waste. In no case, shall the contact time between the infectious waste and the chemical solution in (a) above be less than 12 minutes as described in the general permit application.
- 3. Use of *didecyldimethyl ammonium chloride* and *alkyldimethyl benzyl ammonium chloride* is not approved for the processing of infectious waste such as human or animal tissue, organs, and body parts.
- 4. 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 under the provisions or conditions of this permit.
- 5. 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, the permittee shall operate the facility as described in the approved application.
- 6. At a minimum of once every 40 hours of operation, Bacillus subtilis variety niger (globigii) or other microorganisms, if approved by the Department, shall be placed in with the infectious waste prior to the start of the disinfection cycle. The contents of the waste shall be sampled and monitored using appropriate standard microbiological testing procedures. Should testing indicate that the adequate destruction was not obtained during the disinfection process, the permittee/registrant shall conduct an investigation into the cause. Should testing indicate that adequate destruction was not obtained during two disinfection

process cycles, the permittee/registrant shall modify operating conditions and the Standard Operating Procedure (SOP) to produce total destruction in subsequent cycles.

- 7. 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.
- 8. Any person that operates under the provisions of this permit shall locate the processing system, at the waste generating facility, in an area where unauthorized access by employees and the general public is restricted. If the system is located outside a building, in an open area, steps shall be taken to restrict unauthorized access to the waste processing system. Warning signs shall be clearly visible with respect to the type of waste processed at the facility.
- 9. In the event of system shutdown or failure, the load(s) 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 disinfection of an incomplete batch prior to disposal. No additional infectious waste shall be loaded into the processing system, until after the cause of the shutdown or failure is fully investigated, confirmed, and corrected.
- 10. During periods of extended equipment failure or shutdown, infectious waste may be stored no more than 30 days from the date infectious waste was first generated.
- 11. The storage of infectious waste and the processed residue shall comply with all applicable requirements of Municipal Waste Regulations.
- 12. 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.
- 13. As a condition of this permit and of the permittee's/registrant'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.

- 14. 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.
- 15. Approval of the process ingredient herein refers to the functional design, but does not guarantee operational efficiency. Failure of the process ingredient 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.
- 16. 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.
- 17. This permit does not authorize and shall not be construed as an approval to discharge any waste, wastewater, or runoff contained the process ingredient, from the site of processing, to the land, or surface waters in the Commonwealth.
- 18. Any person that operates under the provisions of this permit shall notify and receive a written approval from the local sewer authority, prior to, any waste, wastewater or runoff containing the process ingredient may be discharged into the sewer system.
- 19. 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 of the Commonwealth.
- 20. Any person that operates under the provisions of this permit shall notify the Department within 24 hours of any spills or accidental discharges into surface waters, land, or air of the Commonwealth which may have a potential adverse impact on public health.
- 21. The permittee/registrant 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/registrant to apply for, and obtain, an individual permit if the permittee/registrant 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 of the Commonwealth.

- 22. 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.
- 23. The permittee/registrant shall prepare a written Standard Operating Procedure (SOP) on the proper operation, use and maintenance of system. Each time the disinfection system is operated, critical parameters are measured to demonstrate that the cycle operated consistently and achieved the disinfection conditions. Copies of current SOPs and records of critical parameter measurements shall be maintained on site for a minimum of 3 years and be made available to the Department upon request.
- 24. 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 registration to the Department's Bureau of Land Recycling and Waste Management, Division of Municipal and Residual Waste, P.O. Box 8472, Harrisburg, PA 17105-8472. At a minimum, 30 days prior to unit installation, the following information must be provided on forms available from the Department's Bureau of Land Recycling and Waste Management:
 - a. Name and street address of the registrant.
 - b. Location of the processing equipment.
 - c. Contact person (name and title).
 - d. The applicant must have documented ownership interest in the waste processing equipment. The registrant may contract with an independent contractor to construct, operate, and maintain the equipment.
 - e. Total volume of infectious waste to be processed on a daily or monthly basis.
 - f. A diagram clearly showing the location of any processing facility to be operated by the registrant under this permit.
 - g. Number and title of the general permit.
 - h. Documentation that the categories of infectious waste to be processed are consistent with the general permit.
 - i. Site-specific facility operation plan including ongoing equipment maintenance and employee training plan, in accordance with the Department's municipal waste management regulations.
 - j. A signed and notarized statement by the registrant that the registrant accepts all the terms and conditions included in the general permit.
 - k. A registration fee payable to the "Commonwealth of Pennsylvania."

- 1. Proof that copies of the registration have been submitted to each municipality in which the infectious waste processing facility will be located.
- m. 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".
- n. Documentation of compliance history of the registrant.
- o. Submission of a disinfection monitoring protocol, for Departmental approval, consistent with Condition 6 of this permit.
- p. Additional information the Department believes is necessary to make a decision.
- 25. Any person or municipality, who registers 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 Department (see address in Condition 24). The notification shall contain the following:
 - a. For expansion of the existing operation, submission of information, as required in items e and h of Condition 24 above, is mandatory. Information related to item (o) of Condition 24, 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: a, b, c, d, e, f, g, h, i, 1, m, and o of Condition 24, above, must be submitted. The notification shall be submitted at least 30 days prior to starting the new operation.
 - 26. Any person that operates under the provisions of this permit shall immediately notify the Department(See address in Condition 24) via certified mail of any changes in: the company name, address, owners, operators and responsible officials; the system used to process infectious waste; and the status of any permit issued by the Department or federal government under the environmental protection acts.
 - 27. 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 disinfection. All systems shall be designed and operated to assure destruction of the target organism: a six-log reduction of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria; and a four-log reduction of Bacillus subtilis variety niger (globigii).
 - 28. The processing unit shall be set up and operated in a manner that prevents spills, leaks, or other releases.
 - 29. 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.

- 30. 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.
- 31. Should measured critical parameters of a SOP indicate that the cycle has not operated consistently or achieved the disinfection 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.
- 32. 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.
- 33. 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).
- 34. Residues from processing of infectious waste shall be stored and managed in a manner that complies with Municipal Waste Regulations.
- 35. A log shall be maintained to record the time and date of disinfection, operator name and title, waste identification, quantity of waste, volume of water used, and the results of microbiological testing as specified in Condition 6. Any follow-up action to microbiological testing which indicated that destruction was not obtained during disinfection process shall be recorded on the log. It shall also be noted on the log if the equipment does not operate properly or any signs of improper disinfection is observed. A copy of the log shall be maintained at the facility for three years and shall be made available to the Department upon request.
- 36. Records of equipment serving during routine maintenance and emergency situations shall be kept for three years and made available to the Department upon request.
- 37. Except for persons that process less than 220 pounds per month of infectious waste, any person that operates under this permit, shall obtain the Department's approval (i.e.,

Form 35) to dispose of treated infectious waste at an approved/permitted municipal waste disposal facility.