

TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE M: BIOLOGICAL MATERIALS
CHAPTER I: POLLUTION CONTROL BOARD
SUBCHAPTER b: POTENTIALLY INFECTIOUS MEDICAL WASTES

PART 1420
GENERAL PROVISIONS

Section

1420.101	Scope and Applicability
1420.102	Definitions
1420.103	Incorporations by Reference
1420.104	Prohibitions
1420.105	Permit and Manifest Requirements and Exceptions
1420.106	Penalty Factor
1420.107	Cleaning and Disinfection
1420.120	Severability

AUTHORITY: Implementing Section 56.2 and authorized by Section 27 of the Environmental Protection Act [415 ILCS 5/56.2 and 5/27].

SOURCE: Adopted in R91-19, at 16 Ill. Reg. 2594, effective February 3, 1992; amended in R91-20, at 17 Ill. Reg. 9947, effective June 21, 1993; amended in R18-29 at 43 Ill. Reg. 10044, effective August 30, 2019; amended in R20-17 at 44 Ill. Reg. _____, effective _____.

Section 1420.101 Scope and Applicability

This Subtitle establishes standards for and applies to all persons who generate, transport, treat, store, or dispose of potentially infectious medical waste within the State of Illinois.

(Source: Amended at 43 Ill. Reg. 10044, effective August 30, 2019)

Section 1420.102 Definitions

All definitions in this Section have the following meanings throughout this Subtitle, unless specifically stated otherwise. Words and terms not defined have the meanings stated in the Act.

"6-log reduction" means a 6-decade reduction or a one millionth (0.000001) survival probability in a microbial population.

"Act" means the Environmental Protection Act [415 ILCS 5].

"Agency" means the Illinois Environmental Protection Agency.

"ATCC" means American Type Culture Collection.

"Board" means the Pollution Control Board.

"CFU" means colony forming unit.

"Chemical treatment" means using disinfectants or chemicals as the primary means to eliminate the infectious potential of PIMW. Examples include treatment with ethylene oxide, chlorine, and ozone.

"Class 4 etiologic agent" means a pathogenic agent that is extremely hazardous to laboratory personnel or that may cause serious epidemic disease. Class 4 etiologic agent includes the following viral agents:

Alastrim, Smallpox, Monkey pox, and Whitepox (when used for transmission or animal inoculation experiments);

Hemorrhagic fever agents (including Crimean hemorrhagic fever (Congo), Junin, and Machupo viruses, and others not yet defined);

Herpes virus simiae (Monkey B virus);

Lassa virus;

Marburg virus;

Tick-borne encephalitis virus complex (including Absettarov, Hanzalova, HYPR, Kumlinge, Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses);

Venezuelan equine encephalitis virus (epidemic strains, when used for transmission or animal inoculation experiments);

Yellow fever virus (wild, when used for transmission or animal inoculation experiments);

Guanarito virus;

Sabia;

Ebola virus; and

Equine Morbillivirus.

BOARD NOTE: The definition of Class 4 agent is adopted under Section 56.2(e) of the Act to help define an "isolation waste" for Section 3.360(a)(6) of the Act and this Subtitle. This listing is derived from the CDC document "Classification of Etiologic Agents on the Basis of Hazard, 1974", and is supplemented from the CDC/NIH document "Biosafety in Microbiological and Biomedical Laboratories", December

2009, and "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)", April 2019._

"Container" means a receptacle that does not contain PIMW.

"Detergent" means a cleansing substance that contains surface-active agents for rapid wetting, penetration, and emulsification of fats and oils, plus a sequestering agent.

"Detergent-sanitizer cleaner" means an agent that is both a detergent and sanitizer registered by the United States Environmental Protection Agency (USEPA), as identified on its label.

"Discharge" means the accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of waste into or on any land or water. This does not include the normal loading and unloading of PIMW from a vehicle.

"Enclosed compartment" means a compartment that protects from the elements, prevents spillage and prevents containers from falling off the vehicle. The enclosed compartment cannot be used to meet the packaging requirements of 35 Ill. Adm. Code 1421.Subpart C.

"Equivalent log kill" means the logarithm of the indicator microorganisms that must be killed and correlates to a 6-log reduction of viable test microorganisms.

"Highly communicable disease" means a disease identified as a Class 4 etiologic agent under this Section.

"Indicator microorganisms" means those microorganisms listed in 35 Ill. Adm. Code 1422.Appendix A, Table B, as classified by ATCC.

"International biohazard symbol" means the symbol that is shown in 35 Ill. Adm. Code 1421.Illustration A.

"Irradiation treatment" means using ionizing radiation as the primary means to eliminate the infectious potential of PIMW. Examples include treatment with gamma (cobalt 60) and electron beam.

"Log" means logarithm to the base 10.

"Log kill" means the difference between the logarithms of viable test microorganisms or indicator microorganisms before and after treatment.

"Oversized PIMW" means a single waste item that is too large to be placed into a 33 gallon bag or container.

"Package" means a receptacle that contains PIMW.

"Person" is any individual, partnership, co-partnership, firm, company, corporation, association, joint stock, trust, estate, political subdivision, state agency, or any other legal entity, or their representative, agent, or assigns. (Section 3.315 of the Act)

"PFU" means plaque forming unit.

"Potentially infectious medical waste" or "PIMW" means the following types of waste generated in connection with the diagnosis, treatment (i.e., provision of medical services), or immunization of human beings or animals; research pertaining to the provision of medical services; or the production or testing of biologicals:

Cultures and stocks. This waste shall include but not be limited to cultures and company stocks of agents infectious to humans, and associated biologicals; cultures from medical or pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live or attenuated vaccines; or culture dishes and devices used to transfer, inoculate, or mix cultures.

Human pathological wastes. This waste shall include tissue, organs, and body parts (except teeth and the contiguous structures of bone and gum); body fluids that are removed during surgery, autopsy, or other medical procedures; or specimens of body fluids and their containers.

Human blood and blood products. This waste shall include discarded human blood, blood components (e.g., serum and plasma), or saturated material containing free flowing blood or blood components.

Used sharps. This waste shall include but not be limited to discarded sharps used in animal or human patient care, medical research, or clinical or pharmaceutical laboratories; hypodermic, intravenous, or other medical needles; hypodermic or intravenous syringes; Pasteur pipettes; scalpel blades; or blood vials. This waste shall also include but not be limited to other types of broken or unbroken glass (including slides and cover slips) in contact with infectious agents.

Animal waste. Animal waste means discarded materials, including carcasses, body parts, body fluids, blood, or bedding originating from animals inoculated during research, production of biologicals, or pharmaceutical testing with agents infectious to humans.

Isolation waste. This waste shall include discarded materials contaminated with blood, excretions, exudates, and secretions from

humans that are isolated to protect others from highly communicable diseases, as defined in this Section.

Unused sharps. This waste shall include but not be limited to the following unused, discarded sharps: hypodermic, intravenous, or other needles; hypodermic or intravenous syringes; or scalpel blades.

Potentially infectious medical waste does not include:

Waste generated as general household waste;

Waste (except for sharps) for which the infectious potential has been eliminated by treatment; or

Sharps that meet both of the following conditions:

The infectious potential has been eliminated from the sharps by treatment; and

The sharps are rendered unrecognizable by treatment.

Sharps that are managed in accordance with the following requirements:

The infectious potential is eliminated from the sharps by treatment at a facility that is permitted by the Agency for the treatment of PIMW;

The sharps are certified by the treatment facility as non-special waste in accordance with Section 22.48 of the Act;

The sharps are packaged at the treatment facility the same as required under Board rules for PIMW;

The sharps are transported under the custody of the treatment facility to a landfill permitted by the Agency under Section 21 of the Act to accept municipal waste for disposal; and

The management of sharps is authorized in, and conducted in accordance with, a permit issued by the Agency to the treatment facility. (Section 3.360 of the Act)

"Putrescence" means the partial decomposition of organic matter by microorganisms that causes malodors, gases, or other offensive conditions, or that can provide food for vectors.

"Registered professional engineer" means a person registered under the Illinois Professional Engineering Practice Act [225 ILCS 325].

"Reusable container" means a receptacle that complies with 35 Ill. Adm. Code 1421.121(a) and (b); is made and repaired with materials that are corrosion resistant and non-absorbent; and designed and constructed to easily permit cleaning and disinfection in compliance with Section 1420.107.

"Sanitizer" means an antimicrobial agent that is intended for application to inanimate objects or surfaces for reducing the microbial count to safe levels and that is registered by USEPA, as identified on its label.

"Sharps" mean unused sharps and used sharps as stated in the definition of PIMW with or without residual fluids.

"Significant mechanical change" means the substitution or addition of mechanical parts that result in different operating conditions. A significant mechanical change does not mean the replacement of a part that meets the same specifications as the original.

"Single-use container" means a container intended by the manufacturer for one use only (e.g., biohazard bags).

"Site" means any location, place, tract of land, and facilities, including but not limited to buildings, and improvements used for purposes subject to regulation or control by the Act or regulations thereunder. (Section 3.460 of the Act) For this Subtitle, every educational institution's campus is a single site.

"Storage" means the containment of waste, either on a temporary basis or for a period of years, in such a manner as not to constitute disposal. (Section 3.480 of the Act)

"Storage site" means a site at which waste is stored. "Storage site" includes transfer stations. (Section 3.485 of the Act)

"Test microorganisms" means those microorganisms listed in 35 Ill. Adm. Code 1422.Appendix A, Table A, as classified by ATCC.

"Thermal treatment" means using elevated temperatures as the primary means to eliminate the infectious potential of PIMW. Examples of thermal treatment are incineration, steam sterilization, microwaving, radiowaving, infrared heating, pyrolysis, plasma systems, and laser treatments.

"Transfer station" means a site or facility that accepts waste for temporary storage or consolidation and further transfer to a waste disposal, treatment or

storage facility. "Transfer station" includes a site where waste is transferred from:

a rail carrier to a motor vehicle or water carrier;

a water carrier to a rail carrier or motor vehicle;

a motor vehicle to a rail carrier, water carrier or motor vehicle;

*a rail carrier to a rail carrier, if the waste is removed from a rail car; or
a water carrier to a water carrier, if the waste is removed from a vessel.
(Section 3.500 of the Act)*

*"Treatment" means any method, technique or process, including neutralization, designed to change the physical, chemical, or biological character or composition of any waste so as to neutralize it or render it nonhazardous, safer for transport, amenable for recovery, amenable for storage, or reduced in volume. Such term includes any activity or processing designed to change the physical form or chemical composition of hazardous waste so as to render it nonhazardous.
(Section 3.505 of the Act)*

"Unrecognizable" means relating to a sharp that has undergone physical alteration (e.g., melting, charring, corroding, or grinding) so that the sharp may no longer be used for its intended purpose.

"Vector" means any living agent, other than human, capable of transmitting, directly or indirectly, an infectious disease.

"Vehicle" means any device used to transport special waste in bulk or in packages, tanks or other containers.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 1420.103 Incorporations by Reference

The following materials are incorporated by reference. This Section incorporates no later editions or amendments.

Standard Methods for the Examination of Water and Wastewater, American Public Health Association et al. (1015 Fifteenth Street, N.W., Washington, D.C. 20005) (23rd Edition, 2017).

Test Methods for Evaluating Solid Waste. Physical/Chemical Methods, EPA Publication SW-846 (Third Edition, Final Updates I (1993), II (1995), IIA (1994), IIB (1995), III (1997), IIIA (1999), IIIB (2005), IV (2008), and V (2015)). SW-

846 and updates are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, (202) 783-3238.

(Source: Amended at 43 Ill. Reg. 10044, effective August 30, 2019)

Section 1420.104 Prohibitions

No person shall:

- a) *Cause or allow the disposal of any PIMW. Sharps may be disposed of in any landfill permitted by the Agency under Section 21 of the Act to accept municipal waste for disposal, if both:*
 - 1) *The infectious potential has been eliminated from the sharps by treatment; and*
 - 2) *The sharps are packaged in accordance with 35 Ill. Adm. Code 1421.*
- b) *Cause or allow the delivery of any PIMW for transport, storage, treatment or transfer except in accordance with 35 Ill. Adm. Code 1421.Subpart C and Subpart E.*
- c) *Cause or allow the delivery of any PIMW to a person or facility for storage, treatment, or transfer that does not have a permit issued by the Agency to receive PIMW under Section 39 of the Act, unless no permit is required under Section 1420.105(c).*
- d) *Cause or allow the delivery or transfer of any PIMW for transport unless:*
 - 1) *The transporter has a permit issued by the Agency to transport PIMW, or the transporter is exempt from the permit requirement under Section 1420.105(b).*
 - 2) *A PIMW manifest is completed for the waste unless no manifest is required under Section 1420.105(e).*
- e) *Cause or allow the acceptance of any PIMW for purposes of transport, storage, treatment, or transfer except in accordance with 35 Ill. Adm. Code 1421.Subpart C and 35 Ill. Adm. Code 1422.Subpart B.*
- f) *Conduct any PIMW transportation operation:*
 - 1) *Without a permit issued by the Agency to transport PIMW, unless no permit is required under Section 1420.105(b).*

- 2) *In violation of any condition of any permit issued by the Agency under the Act.*
 - 3) *In violation of any regulation adopted by the Board.*
 - 4) *In violation of any order adopted by the Board under the Act.*
- g) *Conduct any PIMW treatment, storage, or transfer operation:*
- 1) *Without a permit issued by the Agency that specifically authorizes the treatment, storage, or transfer of PIMW under Section 39 of the Act, unless no permit is required under Section 1420.105(c).*
 - 2) *In violation of any condition of any permit issued by the Agency under the Act.*
 - 3) *In violation of any regulations adopted by the Board.*
 - 4) *In violation of any order adopted by the Board under the Act.*
- h) *Transport PIMW unless the transporter carries a completed PIMW manifest, unless no manifest is required under Section 1420.105(e).*
- i) *Offer for transportation, transport, deliver, receive, or accept PIMW for which a manifest is required, unless the manifest indicates that the fee required under Section 56.4 of the Act has been paid.*
- j) *Conduct a PIMW treatment operation at an incinerator in existence on January 1, 1992 in violation of emission standards established for these incinerators under section 129 of the Clean Air Act (42 USC 7429), as amended. (Section 56.1 of the Act)*
- k) Cause or allow the discharge of PIMW from a vehicle.
- l) Cause or allow the discharge of PIMW into a sanitary or combined sewer except in compliance with 35 Ill. Adm. Code Subtitle C.-

BOARD NOTE: Interested persons should note that units of local government can regulate discharges to sewer systems.

- m) Cause or allow the discharge of inert or solid PIMW, or inert or solid materials resulting from PIMW treatment, into any sanitary sewerage system, combined sewerage system, or storm sewerage system directly or indirectly tributary to waters of the State. This prohibition applies to absorbents, aluminum, or other metallic foils, ash, bone, bedding materials, cellulose, culture dishes, garments

and other cloth materials, gauze, glass, pads, plastic, sharps, shavings, straw, and syringes.

(Source: Amended at 43 Ill. Reg. 10044, effective August 30, 2019)

Section 1420.105 Permit and Manifest Requirements and Exceptions

- a) The permit and permit appeal provisions in Sections 39 and 40 of the Act and Board regulations adopted thereunder apply to this Subtitle.
- b) A person who transports PIMW must obtain a PIMW hauling permit from the Agency, except:
 - 1) *A person transporting PIMW generated solely by that person's activities;*
 - 2) *Noncommercial transportation of less than 50 pounds of PIMW at any one time; or*
 - 3) *The U.S. Postal Service.* (Section 56.1(f)(1)(A) through (C) of the Act)
- c) A person who conducts a PIMW treatment, storage, or transfer operation must obtain a permit from the Agency, except:
 - 1) *Any person conducting a PIMW treatment, storage, or transfer operation for PIMW generated by the person's own activities that are treated, stored, or transferred within the site where the PIMW is generated;*
 - 2) *Any hospital that treats, stores, or transfers only PIMW generated by its own activities or by members of its medical staff.* (Section 56.1(g)(1) of the Act) No storage permit is required under Section 56.1(g) of the Act if PIMW transportation is interrupted. For example, transportation of PIMW interrupted by vehicle repairs or inclement weather is not storage.
- d) A person applying for a permit for a PIMW treatment, storage, or transfer operation must file an application, on forms provided by the Agency, with the Agency in compliance with 35 Ill. Adm. Code 1422.105 through 1422.107.
- e) Any person who transports PIMW must carry a completed PIMW manifest except for the transportation of:
 - 1) *PIMW being transported by generators who generated the waste by their own activities, when the PIMW is transported within or between sites or facilities owned, controlled, or operated by that person;*
 - 2) *Less than 50 pounds of PIMW at any one time for a noncommercial transportation activity; or*

- 3) *PIMW by the U.S. Postal Service.* (Section 56.1(h) of the Act)

(Source: Amended at 43 Ill. Reg. 10044, effective August 30, 2019)

Section 1420.106 Penalty Factor

In making its orders and determinations relative to penalties, if any, to be imposed for violating Section 56.1(A)(a) of the Act, the Board, in addition to the factors in Sections 33(c) and 42(h) of the Act, or the court shall take into consideration whether the owner or operator of the landfill reasonably relied on written statements from the person generating or treating the waste that the waste is not PIMW. (Section 56.1(B) of the Act)

(Source: Amended at 43 Ill. Reg. 10044, effective August 30, 2019)

Section 1420.107 Cleaning and Disinfection

- a) Cleaning and disinfection includes:
- 1) Washing with a solution of detergent used in compliance with manufacturer's instructions and agitation to remove visible contamination from each surface, followed by a clean water rinse; and
 - 2) One of the following methods of low-level disinfection:
 - A) Exposure to hot water of at least 82 degrees Celsius (180 degrees Fahrenheit) for a minimum of 15 seconds;
 - B) Rinsing with, or immersion in, a chemical disinfectant registered by USEPA, as identified on its label and used in compliance with the manufacturer's instructions;
 - C) Rinsing with, or immersion in, a hypochlorite solution at a concentration of 50 parts per million. For example, 1/8 cup of common household bleach (5.25% sodium hypochlorite) per gallon of tap water (31 milliliters bleach to 3.78 liters of water); or
 - D) Other disinfection processes as approved by the Agency in writing as an equivalent to one of the methods in subsections (a)(2)(A) and (B).
- b) A detergent-sanitizer used in conjunction with agitation to remove visible contamination may be substituted for the methods in subsection (a), if used in compliance with the manufacturer's instructions.

(Source: Amended at 43 Ill. Reg. 10044, effective August 30, 2019)

Section 1420.120 Severability

If any provision of this Part or its application to any person is adjudged invalid, the adjudication does not affect the validity of this Part as a whole or of any portion not adjudged invalid.

(Source: Amended at 43 Ill. Reg. 10044, effective August 30, 2019)