ILLINOIS POLLUTION CONTROL BOARD
December 3, 2020

IN THE MATTER OF:	)	
	)	
AMENDMENTS TO DEFINITION OF	)	R20-17
"CLASS 4 ETIOLOGIC AGENT", 35 ILL.	)	(Identical-in-Substance Rulemaking -
ADM. CODE 1420.102	)	Biological Materials)

Adopted Rule. Final Order.

OPINION AND ORDER OF THE BOARD (by A. Palivos):

The General Assembly found in the early 1990s that potentially infectious medical waste (PIMW), if not handled properly, may constitute an environmental or public health problem. 415 ILCS 5/56(a) (2018). To reduce these potential risks, the General Assembly enacted Title XV of the Environmental Protection Act (Act), establishing requirements for handling PIMW responsibly. 415 ILCS 5/56(b) (2018). Title XV mandated that the Board adopt regulations prescribing design and operating standards for all PIMW treatment, storage, and transfer facilities. 415 ILCS 5/56.2(a) (2018). Following this mandate, the Board in 1992 and 1993 adopted regulations applicable to all persons who generate, transport, treat, store, or dispose of PIMW. *See* 35 Ill. Adm. Code 1420, 1421, 1422

In 1992, the Board adopted the definition of "Class 4 etiologic agent" as required by Public Act 87-752, which added, among other provisions, Section 56.2(e) to the Act. That legislation mandated that the Board adopt "rules identical in substance to the etiologic agents in Class 4 in a 1974 Centers for Disease Control [CDC], Office of Biosafety listing: Classification of Etiologic Agents on the Basis of Hazard." Potentially Infectious Medical Wastes: Etiologic Agents, R91-19, slip op. at 1 (Jan. 23, 1992). Revising the definition of "Class 4 etiologic agent" requires amending 35 Ill. Adm. Code 1420.102 under Section 56.2(e) of the Act (415 ILCS 5/56.2(e) (2018)). On December 19, 2019, the Board found that the 1974 CDC listing of Class 4 etiologic agents was updated by the 2019 guidelines, warranting amendments to the Board's definition of "Class 4 etiologic agent." Amendments to Definition of "Class 4 etiologic agent", 35 Ill. Adm. Code 1420.102, R20-17, slip op. at 4-5 (Dec. 19, 2019).

Today, the Board adopts final amendments to update its definition of "Class 4 etiologic agent," which bears on the definition of PIMW. The Act requires these amendments to reflect the addition of four viral agents, as the Board discussed in detail in its proposal for public comment. *See* Amendments to Definition of "Class 4 etiologic agent", 35 Ill. Adm. Code 1420.102, R20-17 (Dec. 19, 2019).

In this opinion, the Board first provides the procedural history of the rulemaking and then discusses the final amendments. In the order following this opinion, the Board directs the Clerk to file the amendments with the Secretary of State. The amendments themselves appear in the order.

PROCEDURAL HISTORY

On December 19, 2019, the Board issued an opinion and order proposing amendments to update its definition of "Class 4 etiologic agent." The Board also directed its Clerk to enter into this record two public comments that had been filed in a related proceeding. *See* Amendments to Definition of "Class 4 etiologic agent", 35 Ill. Adm. Code 1420.102, R20-17, slip op. at 3-4 nn.2-3 (Dec. 19, 2019). The proposed amendments were published in the *Illinois Register* on January 24, 2020 (44 Ill. Reg. 1768 (Jan. 24, 2020)).

In its December 19, 2019 opinion and order, the Board welcomed public comment on any aspect of the proposed amendments, but specifically requested comments on the following: (1) "Should any other etiologic agents listed in CDC, NIH [National Institute of Health], or BMBL [Biosafety in Microbiological and Biomedical Laboratories] documents be added to the definition of '[C]lass 4 etiologic agent'?"; and (2) "Should any agents from the Federal Select Agents and Toxins list be added to the definition of '[C]lass 4 etiologic agent'?" Amendments to Definition of "Class 4 etiologic agent", 35 Ill. Adm. Code 1420.102, R20-17, slip op. at 6 (Dec. 19, 2019). On September 24, 2020, the Illinois Environmental Protection Agency (IEPA) filed a public comment responding "[n]o" to each of the Board's questions. No other public comments were filed.

On September 16, 2020, the oearing officer issued an order scheduling two hearings, each to be held by videoconference between the Board's Chicago office and Springfield office, as well as by WebEx due to COVID-19. The first hearing was held on October 16, 2020, and the second on November 5, 2020. No participant offered testimony or comment at either hearing.

DISCUSSION

Section 56.2(e) of the Act (415 ILCS 5/56.2(e) (2018)) requires that the Board adopt rules that are identical in substance to the listing of Class 4 etiologic agents in "Classification of Etiological Agents on the Basis of Hazard, 1974," as amended. As discussed below, the Board finds that the 1974 CDC listing of Class 4 etiologic agents was updated by the 2019 NIH guidelines, warranting amendments to the Board's definition of "Class 4 etiologic agent." Accordingly, the Board adopts those amendments.

The NIH guidelines were revised in April 2019.[1] 84 Fed. Reg. 17858 (Apr. 26, 2019). These 2019 NIH guidelines classify human etiological agents under four risk groups. "Risk Group 4" consists of agents that "are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are *not usually* available." NIH Guidelines at 48. This risk group is analogous to the 1974 CDC Class 4 etiologic agent definition.

Risk Group 4 of the 2019 NIH guidelines includes all listed 1974 CDC Class 4 etiologic agents except for Alastrim, Small pox, Monkey pox, White pox, Venezuelan equine encephalitis

[1] NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)," Department of Health and Human Services, National Institute of Health, April 2019 (NIH Guidelines). Available at https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

virus, and yellow fever virus. NIH Guidelines at 48. Again, Alastrim, Small pox, and White pox are restricted to pox viruses that "may not be studied in the United States except at specified facilities," while Monkey pox, Venezuelan equine encephalitis virus, and yellow fever virus fall into Risk Group 3. *Id.* at 39, 46, 47. The Board retains these six viruses in its definition of "Class 4 etiologic agent" when they are used for transmission or animal inoculation experiments. *See id.* at 14 ("[Risk Group 3] agents such as Venezuelan equine encephalomyelitis and yellow fever viruses should be handled at a higher containment level for animal inoculation and transmission experiments."). In addition, Risk Group 4 also adds Guanarito virus, Sabia, Ebola virus, and Equine Morbillivirus to the 1974 CDC listing of Class 4 etiologic agents. *Id.* at 48. The Board adopts the proposal adding these four viral agents to its definition.

Risk groups in the NIH guidelines differ from "biosafety levels" in the CDC/NIH BMBL. Risk groups are "the result of a classification of microbiological agents based on their association with, and resulting severity of, disease in humans." Biosafety in Microbiological and Biomedical Laboratories, 5th Ed., Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention of National Institutes of Health, December 2009 at 24.[2] On the other hand, in determining the biosafety levels in which work will be conducted, "[t]he risk group of an agent should be *one factor* considered in association with mode of transmission, procedural protocols, experience of staff, and other factors." *Id.* (emphasis added). As the Board found, due to this elasticity in the BMBL, biosafety levels can vary for a given viral agent based on the laboratory setting and the nature of the experiment. Potentially Infectious Medical Wastes: Etiologic Agents, R19-19, slip op. at 6. Moreover, the most recent CDC/NIH BMBL, 2009, does not assign "Biosafety Level 4" to all viral agents in the Board's Class 4 definition or the NIH's Risk Group 4.

The Board adopts amendments updating the list of viral agents in its definition of "Class 4 etiologic agent" by adding the following Risk Group 4 agents from the 2019 NIH guidelines: Guanarito virus; Sabia; Ebola virus; and Equine Morbillivirus. The amendments also reflect non-substantive changes suggested by the Joint Committee on Administrative Rules.

ORDER

The Board directs the Clerk to submit the final amendments to the Secretary of State for publication in the *Illinois Register* and codification in the Illinois Administrative Code. All additions are underlined; all deletions appear with strikethroughs.

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

PART 1420
GENERAL PROVISIONS

[2] Available at https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF.

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 1420.102 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); ~~and~~

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 ~~A Class 4 Agent helps~~define an "isolation waste" for ~~the purposes of~~ Section 3.360(a)(6) of the Act and this Subtitle. This listing is derived from the CDC document "Classification of ~~Human~~ 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 company, 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 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.

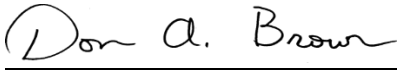
"Vehicle" means any device used to transport special waste in bulk or in packages, tanks or other containers.

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

IT IS SO ORDERED.

Section 41(a) of the Environmental Protection Act provides that final Board orders may be appealed directly to the Illinois Appellate Court within 35 days after the Board serves the order. 415 ILCS 5/41(a) (2018); *see also* 35 Ill. Adm. Code 101.300(d)(2), 101.906, 102.706. Illinois Supreme Court Rule 335 establishes filing requirements that apply when the Illinois Appellate Court, by statute, directly reviews administrative orders. 172 Ill. 2d R. 335. The Board's procedural rules provide that motions for the Board to reconsider or modify its final orders may be filed with the Board within 35 days after the order is received. 35 Ill. Adm. Code 101.520; *see also* 35 Ill. Adm. Code 101.902, 102.700, 102.702. Filing a motion asking that the Board reconsider this final order is not a prerequisite to appealing the order. 35 Ill. Adm. Code 101.902.

I, Don A. Brown, Clerk of the Illinois Pollution Control Board, certify that the Board adopted the above opinion and order on December 3, 2020, by a vote of 4-0.



Don A. Brown, Clerk
Illinois Pollution Control Board