ILLINOIS POLLUTION CONTROL BOARD
January 23, 1992

IN THE MATTER OF:	)	
	)	R91-19
POTENTIALLY INFECTIOUS MEDICAL WASTES: ETIOLOGIC AGENTS	) (Identical in Substance Rules)	

ADOPTED RULE. FINAL ORDER.

OPINION AND ORDER OF THE BOARD (by R.C. Flemal):

The Board reserved this docket on August 9, 1991 and issued an Order on August 26, 1991 stating that we had opened this docket for the purposes of a new legislative mandate contained in H.B. 2491, then awaiting the Governor's signature. The Governor signed H.B. 2491 (now designated P.A. 87-752) on September 26, 1991. It became effective January 1, 1992.

Public Act 87-752 imposes four mandates on the Board, each of which includes a deadline for Board action:

1. The repeal of existing Board regulations relating to medical wastes (new Section 56.2(d), due by January 1, 1992, the subject of docket R91-18);

2. The adoption of rules identical in substance to the etiologic agents in Class 4 in a 1974 federal Centers for Disease Control, Office of Biosafety listing: Classification of Etiologic Agents on the Basis of Hazard (new Section 56.2(e), due January 1, 1992, the subject of this docket);

3. The adoption of rules setting forth the standards for facilities treating, storing, and transferring potentially infectious medical wastes (new Section 56.2(a), due January 1, 1993, the subject of docket R91-20); and

4. The adoption of rules setting forth standards for transportation, packaging, segregation, labelling, and marking of potentially infectious medical wastes (new Section 56.2(c), due January 1, 1993, the subject of docket R91-21).

The Board proposed rules for public comment in furtherance of a portion of that mandate by its Opinion and Order of November 7, 1991. A Notice of Proposed Rules appeared in the Illinois Register on December 2, 1991, at 15 Ill. Reg. 17016. The Board today adopts those rules pursuant to that mandate.

PUBLIC COMMENTS

As of this date, the Board has received two public comments in this matter. The Board received PC #1 on September 18, 1991

from Van Allen Anderson, Ph.D., of the University of Illinois at Urbana-Champaign, Division of Environmental Health and Safety. Further, Dr. Anderson and others made pertinent comments regarding this proceeding during the course of the September 18, 1991 public hearing in companion dockets, R91-20 and R91-21. The appropriate segment of the following discussion considers the comments of Dr. Anderson and those made at the public hearing. **All references to the hearing transcript ("Tr. at --") in the following discussion are to the transcript of the consolidated inquiry hearing held September 18, 1991 in dockets R91-20: Potentially Infectious Medical Waste: Treatment, Storage, and Transfer Facilities and R91-21: Potentially Infectious Medical Waste: Treatment, Packaging, and Labeling.** Many portions of that hearing testimony directly relate to the subject of this docket.

The Board received PC #2 on December 9, 1991 from the Administrative Code Division of the Office of the Secretary of State. This comment suggests a small number of Code format correction. These are mentioned in the end of the following discussion.

DISCUSSION

The action taken today in this docket adopts a listing of Class 4 Agents based on the U.S. Department of Health and Human Services, Centers for Disease Control, Office of Biosafety publication entitled "Classification of Etiologic Agents on the Basis of Hazard," (4th edition, July 1974). This action is pursuant to new Section 56.2(e) of the Environmental Protection Act (to be codified as Ill. Rev. Stat. 1989 ch. 111½, par. 1056.2(e), effective January 1, 1992).

P.A. 87-752 (H.B. 2491), particularly new Section 56.1 (of new Title XV: Potentially Infectious Medical Waste), includes various prohibitions against the improper disposal, delivery, transport, storage, treatment, transfer, and packaging of potentially infectious medical wastes (PIMWs). This Section and Sections 56.3 and 56.4 also include permitting, manifesting, and reporting requirements for various activities related to PIMWs.

Section 56.2(e) mandates that the Board adopt a listing of Class 4 etiologic agents by identical-in-substance procedures:

> No later than January 1, 1992, the Board shall adopt rules that are identical in substance to the list of etiologic agents identified as Class 4 agents as set forth in "Classification of Etiological Agents on the Basis of Hazard, 1974", published by Centers for Disease Control. If the Centers for Disease Control amends the listing of etiologic agents identified as Class 4 agents as set forth in "Classification of

> Etiological Agents on the Basis of Hazard, 1974", the Board shall adopt rules that are identical in substance to the amended list within 180 days after the Centers for Disease Control amendment. The provisions and requirements of Title VII of this Act shall not apply to rules adopted under this subsection (e). Section 5 of the Illinois Administrative Procedure Act relating to the procedures for rulemaking shall not apply to rules adopted under this subsection (e).
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> P.A. 87-752, § 56.2(e) (to be codified as Ill. Rev. Stat. 1989 ch. 111½, par. 1056.2(e)).

The ultimate effect of fulfilling this mandate is to add definition to one segment of the broader universe of PIMWs. Section 3.81(a) of this legislation (to be codified as Ill. Rev. Stat. 1989 ch. 111½, par. 1003.81(a)) defines "potentially infectious medical waste". Subsection 3.81(b)(6) includes "isolation waste" as part of the definition, as follows:

> Isolation waste. This waste shall include but not be limited to discarded waste materials contaminated with blood, excretions, exudates, and secretions from humans that are isolated to protect others from highly communicable diseases. "Highly communicable diseases" means those diseases identified by the Board in rules adopted under subsection (e) of Section 56.2 of this Act.
>
> P.A. 87-752, § 3.81(b)(6) (to be codified as Ill. Rev. Stat. 1989 ch. 111½, par. 1003.81(b)(6)).

The 1974 document referred to by P.A. 87-752 defines five classes of etiologic agents:

> Class 1: Pathogenic agents of no or minimal hazard under ordinary conditions of handling. Class 1 Agents include all agents not classified as any of Classes 2 through 5 Agents.
>
> Class 2: Pathogenic agents of ordinary potential hazard. Class 2 Agents include those which may produce disease from accidental inoculation or injection or other means of cutaneous penetration but which are contained by ordinary laboratory techniques.
>
> Class 3: Pathogenic agents involving special hazard, or pathogenic agents derived outside the U.S. which require a federal permit for importation, unless the pathogenic agent is specified for higher classification. Class 3 Agents include those for

which special conditions for their containment are required.

Class 4: Pathogenic agents that are extremely hazardous to laboratory personnel or that may cause serious epidemic disease. Class 4 Agents include Class 3 Agents derived from outside the U.S. when they are employed in entomological experiments or when other entomological experiments are conducted in the same laboratory area. Class 3 Agents include those that require the most stringent conditions for their containment.

Class 5: Pathogenic agents that are excluded from the U.S. by law or U.S. Department of Agriculture administrative policy.

"Classification of Etiological Agents on the Basis of Hazard," U.S. Department of Health, Education, and Welfare, Centers for Disease Control (4th ed. 1974) at 3-4.

Aside from the narrative description of what falls within each class, the 1974 document includes listings of the Class 2, Class 3, Class 4, and Class 5 agents. The listings are divided into separate sublistings of bacterial agents; fungal agents; parasitic agents; and viral, rickettsial, and chlamydial agents. The listing for Class 4 agents includes the following:

Bacterial agents: no pathogenic agents specifically listed.

Fungal agents: no pathogenic agents specifically listed.

Parasitic agents: no pathogenic agents specifically listed.

Viral, Rickettsial, and Chlamydial 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)

Herpesvirus simiae (Monkey B virus)

Lassa virus

Marburg virus

> Tick-borne encephalitis virus complex (including 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)

"Classification of Etiological Agents on the Basis of Hazard" at 9.

Thus, the Class 4 listing of etiologic agents is limited to a very small number of viral agents.

The intent of the CDC classification is to "define[] minimal safety conditions for their management without restricting or hampering bona fide microbiological investigations." "Classification of Etiological Agents on the Basis of Hazard" at 1. The purpose is to foster safety for work using these agents in the laboratory setting.

In 1986, the Department of Health and Human Services (successor to the Department of Health, Education, and Welfare), National Institutes of Health published "Guidelines for Research Involving Recombinant DNA Molecules" in the Federal Register. 51 Fed. Reg. 16958 (May 7, 1986). This set of guidelines applied to all institutions engaged in recombinant DNA research that received funding from the National Institutes of Health. It used the Class 1 through Class 5 system established by the CDC in the 1974 document "Classification of Etiological Agents on the Basis of Hazard." The NIH revised the list for the purposes of the Guidelines. 51 Fed. Reg. 16965 & 16967-68. Class 4 no longer included Alastrim, Smallpox, and Whitepox. These are all prohibited from study in the United States except at specified facilities, and a note indicated that all activities relating to variola (smallpox) and whitepox were restricted to a single facility. 51 Fed. Reg. 16968 & note 4; see also Tr. 61-62 (testimony re the deletion of agents prohibited from use).

In 1988, the CDC and NIH conjunctively published "Biosafety in Microbiological and Biomedical Laboratories," U.S. Department of Health and Human Services, Public Health Service, Centers for Disease control and National Institutes of Health, (HHS) Publication No. (NIH) 88-8395 (2d ed. 1988). This document "describe[d] combinations of standard and special microbiological practices, safety equipment, and facilities that constitute biosafety levels 1-4, which [were] recommended for working with a variety of infectious agents in various laboratory settings." "Biosafety in

Biomedical and Microbiological Laboratories" at vii. "Classification of Etiological Agents on the Basis of Hazard" "served as the basic format" for this 1988 publication, and the 1988 publication included a revised version of the 1974 document. Id. at 3.

The classification system under the 1988 biosafety recommendation is more elastic than the 1974 Classification. Rather than assign etiologic agents to classes, the 1988 publication assigns them to biosafety levels (Biosafety Level (BL) 1 through BL 4), which can change for any specific agent, depending on the laboratory setting and nature of the experimentation. For example, Herpesvirus simiae, in Class 4 in 1974, is in BL 3 for materials known to contain the virus and in BL 4 for the propagation of the virus or for activities involving infected nonhuman primates. Id. at 74-75. The pox viruses, other than smallpox; yellow fever virus; and one strain of venezuelan equine encephalitis virus, in Class 4 in the 1974 Classification, are in BL 2 for immunized workers. Id. at 78-79 & 82. In the 1988 document, BL 4 includes only Congo-Crimean hemorrhagic fever, tick-borne encephalitis complex (Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian Spring-Summer encephalitis), Marburg, Ebola, Junin, Lassa, and Machupo viruses from the 1974 Class 4 list. Added to BL 4 and not appearing in Class 4 of the 1974 Classification are four tick-borne encephalitis viruses: Absettarov, Hanzalova, Hypr, and Kumlinge. Id. at 92.

At the public hearing and in PC #1, Dr. Anderson stated that he does not believe that the Board should use any document other than the 1974 "Classification of Etiological Agents on the Basis of Hazard." He states that both the 1986 and 1988 documents are updates of the 1974 Classification in two different formats. He asserts that the 1988 document abandoned a classification of agents in favor of assigning biosafety levels based on potential hazard in the laboratory setting. He urges that the 1974 Classification or the 1986 (NIH) Guidelines "more clearly delineate strict classifications and are more complete in their representation of agents." However, he states that the 1986 document "only lists selected agents, not all agents currently identified as requiring biosafety levels 2-4." PC #1 at 4.

Dr. Anderson believed that the Board should add as Class 4 to the 1974 Classification, the newly-listed Absettarov virus, Hanzalova virus, HYPR virus, and Kumlinge virus because these would qualify as Class 4. PC #1 at 3-4; Tr. at 17-22, 51-56, 58-62, 79-84 & 88-90. Larry Von Behren, M.D., of the Southern Illinois University School of Medicine, concurred in Dr. Anderson's observations as to those agents the Board should include. Tr. 48-49, 56-58, 63-68 & 84-88.

In light of the character of the 1974, 1986, and 1988 publications; the public comment; and the testimony elicited at the

R91-20/R91-21 hearing, the Board agrees with Drs. Anderson and Von Behren and concludes that it must base the list of Class 4 agents on the 1974 document with the addition of the four tick-borne encephalitis viruses added in 1988.

Many reasons exist for not relying on the 1986 Recombinant DNA Guidelines and the 1988 Biosafety in Laboratories as updates of the 1974 CDC Classification. First, as to the 1986 Recombinant DNA Guidelines, the NIH is independent of the CDC, and Section 56.2(e) specifically refers to updates by the CDC. This document is not as complete a listing of Class 4 agents, due to the omission of the three pox viruses, for reasons unrelated to their relative hazard. Second, as to the 1988 Biosafety in Laboratories, the classification is largely dependent on factors immaterial to wastes generated in the clinical setting. Third, as to both documents, neither expressly claims to be an update of the 1974 classification (although the 1988 document claims to be an updated system for managing etiologic agents in the laboratory). Finally, the public comment and hearing testimony appears to disfavor use of the more recent 1986 and 1988 listings.

In addition to the definitions of "class 4 etiologic agent," "highly infectious disease," and "isolation waste," the Board will set forth the definition of "potentially infectious medical waste." The language of each definition tracks the statutory language to the maximum extent possible. Capitalization of those passages highlights this fact pursuant to 1 Ill. Adm. Code 100.380.

The Administrative Code Division suggests two Code format corrections to the text of the proposed rules. The Board adopts the text of the proposed rules with the suggested corrections. The Board uses the word "Section" in the section headings, and we change the reference to the Environmental Protection Act to "ch. 111½."

ORDER

The Board hereby directs the Clerk of the Board cause a Notice of Proposed Amendments reflecting these proposed rules be published in the Illinois Register, and to submit the proposed incorporations by reference to the Joint Committee on Administrative Rules pursuant to Ill. Rev. Stat. 1989 ch. 127, par. 1006.02(b).

The language of the proposed rules follows:

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

AUTHORITY: Implementing and authorized by Section 56.2(e) of the Environmental Protection Act (Ill. Rev. Stat. 1989, ch. 111½, par. 1056.2(e), as added by P.A. 87-752, effective January 1, 1992).

SOURCE: Adopted in R91-19, at 16 Ill. Reg. , effective

Note: Capitalization denotes statutory language.

Section 1420.101 Scope and Applicability

a) This Subtitle applies to all persons who generate, transport, treat, store, or dispose of potentially infectious medical waste. It sets forth standards for such activities occurring in whole or in part within the State of Illinois.

b) This Part sets forth definitions that apply throughou this Subtitle except as specifically provided otherwise.

BOARD NOTE: Section 56.2(d) requires the Board to repeal pre-existing rules for handling medical wastes by January 1, 1992. Section 56.2(e) requires the Board to adopt by January 1, 1992 a list of Class 4 etiologic agents, which lends operative meaning to "isolation waste," as that term is used in the statutory definition of potentially infectious medical waste at Section 3.81. Section 56.2(a) and (c) require the Board to adopt standards for the transportation, packaging, segregation, labelling, and marking of potentially infectious medical waste by January 1, 1993. Section 56.2(f) authorizes additional rules to promote the purposes of Title XV of the Environmental Protection Act (Ill. Rev. Stat. 1989 ch. 111½, par. 1001 et seq., as amended by P.A. 87-752, effective January 1, 1992).

Section 1420.102 Definitions

All definitions set forth in this Section shall have the following meanings throughout this Subtitle, unless specifically provided otherwise:

"Act" means the Environmental Protection Act (Ill. Rev. Stat. 1989 ch. 111½, par. 1001 et seq., as amended by P.A. 87-752, effective January 1, 1992).

"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)
Herpesvirus 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)
BOARD NOTE: A Class 4 Agent helps define an "isolation waste" for the purposes of Section 3.81(a)-(6) of the Act and this Subtitle. This listing derives from the CDC document, "Classification of Etiologic Agents on the Basis of Hazard," and is supplemented from the CDC/NIH document "Biosafety in Microbiological and Biomedical Laboratories."

"HIGHLY COMMUNICABLE DISEASE" MEANS THOSE DISEASES IDENTIFIED AS CLASS 4 ETIOLOGIC AGENTS. (Section 3.81(a)(6) of the Act)

"ISOLATION WASTE" MEANS DISCARDED WASTE MATERIALS CONTAMINATED WITH BLOOD, EXCRETIONS, EXUDATES, AND SECRETIONS FROM HUMANS THAT ARE ISOLATED TO PROTECT OTHERS FROM HIGHLY COMMUNICABLE DISEASES. (Section 3.81(a)(6) of the Act)

"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 PROVISION OR TESTING OF BIOLOGICALS:

CULTURES AND STOCKS;

HUMAN PATHOLOGICAL WASTES;

HUMAN BLOOD AND BLOOD PRODUCTS;

USED SHARPS;

ANIMAL WASTE;

ISOLATION WASTE; AND

UNUSED SHARPS.

POTENTIALLY INFECTIOUS MEDICAL WASTE DOES NOT INCLUDE THE FOLLOWING:

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. (Section 3.81 of the Act)

IT IS SO ORDERED.

I, Dorothy M. Gunn, Clerk of the Illinois Pollution Control Board, do hereby certify that the above Proposed Opinion and Order was adopted on the 23rd day of January, 1992, by a vote of 5-0.

Dorothy M. Gunn

Dorothy M. Gunn, Clerk
Illinois Pollution Control Board