ILLINOIS POLLUTION CONTROL BOARD
April 2, 1981

In The Matter Of:	)	
Hazardous Hospital Wastes,	)	R80-19
Sections 3(jj) and 21(h) of	)	
the Environmental Protection Act	)	

PROPOSED RULE. SECOND NOTICE.

PROPOSED OPINION OF THE BOARD (by J. Anderson):

This proposed Opinion is written in support of the proposed new Part 9 to Chapter 9: Special Waste, second notice of which was authorized to be sent to the Joint Committee on Administrative Rules by the Board's Order of March 19.

The purpose of this rulemaking is the implementation of Section 21(h) of the Environmental Protection Act (Act), which absolutely prohibits the deposit of "hazardous hospital waste" in any landfill, and mandates that it be incinerated, sterilized or otherwise properly disposed of pursuant to regulations of the Board. Section 3(jj) defines hazardous hospital waste as:

> "wastes generated in connection with patient care that is contaminated with or may be contaminated with an infectious agent that has the potential of inducing an infection and has not been rendered innocuous by sterilization or incineration."

Much of the history of this rulemaking was explained in detail in the Board's Opinion of December 24, 1980, written in explanation of the emergency rules (Chapter IX, Part 9) adopted December 18, 1980 after two inquiry hearings on November 14 and 17, 1980. That Opinion is incorporated by reference herein as if fully set forth.

Also on December 18, 1980, the Board ordered publication of the First Notice of proposed rules identical, but for one provision, to the emergency rules. These proposed rules were published in the Environmental Register #330, January 6, 1981 and in the Illinois Register, Vol 5, pp. 14-17, January 2, 1981. Hearings were held on January 26, 1981 (Springfield) and January 28, 1981 (Chicago), at which testimony concerning the language of the proposed rules was received.

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*The Board wishes to express its appreciation for the excellent work done in this matter by Kathleen M. Crowley, Administrative Assistant to the Board and Hearing Officer herein, and by William Withrow, Technical Assistant to the Board.

Having considered the testimony presented at hearing, as well as all of the written comments received since publication of the first notice,* the Board has made some revisions. Prior to discussion of the specific language changes, it is necessary to present an overview of the regulatory and statutory framework concerning infectious wastes in which hospitals currently operate, as an aid to understanding the slightly different direction the Board has taken in the drafting of Part IX.

OTHER EXISTING REGULATIONS AND LEGISLATION

As a general statement, the Board believes that these proposed rules reflect the legislative intent to require hospitals to more carefully manage the same infectious waste stream that hospitals currently are expected to isolate in their facilities under other applicable regulations.

Illinois Department of Public Health

The first set of applicable regulations, which affect every hospital, are those of the Illinois Department of Public Health (IDPH), promulgated in the exercise of its statutory mandate and authority under the Hospital Licensing Act Ill. Rev. Stat. Ch. 111½, Sec. 142 et seq. IDPH requires that each hospital create an Infection Control Committee which must establish, inter alia, "policies and procedures for the handling of infectious cases." IDPH further requires that the "handling and disposal of contaminated material shall be in a manner designed to prevent the transmission of the infectious agents." IDPH Hospital Licensing Requirements, Part IX, Section D "Infection Control," Illinois Register, Vol 5., pp. 553-554 (January 9, 1981). Waste is to be "collected, stored, and disposed of in a manner that will not permit the transmission of a contagious disease;" "potentially hazardous waste must be double-bagged and identified." Part XIV, Section B "Garbage, Refuse and Solid Waste Handling and Disposal" Illinois Register, Vol. 5, pp. 571-572. New hospitals are required to provide incinerators for "the complete destruction of pathological and infectious waste. Infectious waste shall include, but shall not be limited to, dressings and material

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*In its Opinion of December 24, 1980, the Board acknowledged receipt of the first eight public comments which were received in 1980 prior to the Board's adoption of specific language. Since then, the Board has received comments from August Lorenz, Abraham Lincoln Memorial Hospital (PC 9); Arthur Lelio, Suburban Medical Center (PC 10); Director William Kempiners, Illinois Department of Public Health (PC 11); Stephen Sokalski, Christ Hospital (PC 12); Donna Koser, St. Joseph Hospital (PC 13); Timothy West, Community Memorial General Hospital (PC 14); Eric Gleason, St. Francis Hospital (PC 15); and Maurice Davenport, Olin Chemicals (PC 16).

from open wounds, laboratory specimens, and all waste material from open wounds." Part XX, Section D(13)(h)(2) "Waste Processing Services," IDPH publication, eff. October 1, 1977. Although existing hospitals are not required to have incinerators, they must provide "space and facilities for the sanitary storage and disposal of... infectious or radioactive waste substances" Part XXI, Section C(13)(h)(2), IDPH publication, eff. May 26, 1978.

Medicare-Medicaid Program and Joint Commission on Accreditation of Hospitals

The second set of regulations are applicable to every hospital which participates in the federal Medicare-Medicaid program. A condition of hospital participation in this federal program is that "proper facilities are maintained and techniques used for incineration of infectious wastes, as well as sanitary disposal of all other wastes" CFR 405.1022(a)(5). It should also be noted that most hospitals belong to a voluntary association called the Joint Commission on Accreditation of Hospitals (JCAH), whose findings during its inspections of hospitals for accreditation purposes may, under the federal law, be used by federal officials when determining compliance with Medicare participation standards. The JCAH has its own detailed standards for the storage and disposal of infectious waste.

Federal and Illinois Environmental Protection Agencies

As discussed in the Board's earlier Opinion, both federal and state legislation [Section 21(h) of the Act aside] address the disposal of hazardous waste. Although the U.S. Environmental Protection Agency has not promulgated regulations for the identification and disposal of waste with "infectious characteristics" to implement the Resource Recovery and Conservation Act of 1976, 42 USC §6901-6987, the Illinois Environmental Protection Agency has adopted final "Criteria for Identification of Hazardous Wastes" to implement Section 22.2 of the Act (otherwise known as H.B. 453, P.A. 81-0856 signed September 21, 1979). Pursuant to Section 22.2 and the Agency criteria, owners or operators of hazardous waste disposal sites must pay hazardous waste disposal fees if they receive "...any pathological specimens and any articles attendant thereto that may be disposed of from humans and animals known to be contaminated with organisms that may produce communicable diseases which must be reported to the Illinois Department of Public Health. Pathological specimens shall include all solid tissue, excreta, and secretions..." (followed by reportable disease list. Illinois Register Vol 4, pp. 133-134). Since Hazardous Hospital (infectious) Waste must be rendered innocuous by sterilization or incineration before going to any landfill, the above criteria for determining fees would no longer appear to apply to hospitals.

CHANGES IN THE RULES AS PROPOSED

The IDPH stated its support of the rules as drafted, but also noted that "[w]hile it may be necessary [to make] additional changes and revisions to this rule, the basic content will provide for the protection of the public's health" (PC 11). The Board has not changed the basic content of the rule, but has made modifications to better fit these rules into the hospitals' existing regulatory and statutory framework in order to avoid unnecessary confusion and duplicative record-keeping. Changes, and the reason for these changes, in each rule are:

Rule 901 Definitions

Hazardous (infectious) Hospital Waste
Infectious Agent

The Board has deleted entirely the definition of infectious agent. The "hazardous (infectious) hospital waste" definition has been divided into subsections for greater readability. The language of the proposed rule has been retained (but with some suggested editorial revisions), and explicitly references IDPH isolation requirements. Lastly, the "includes but is not limited to" language has been deleted, in light of addition of a new subsection giving hospitals the responsibility to classify suspect material as infectious, as already required by the rules of the IDPH.

Two minor additions have been made to the general legislative definition in Section 3(jj) of the Act of "hazardous hospital waste," which was repeated verbatim as the first sentence of the proposed rule. The Board has chosen to describe the waste with which the rules deal as "hazardous (infectious) hospital waste," to allow for instant recognition of the hazardous component of this waste. This further identification will counter what the Board has observed to be a popular misconception: that Sections 3(jj) and 21(h) concern themselves with the chemical or low level radioactive wastes generated by hospitals, rather than their infectious waste (See R. 347-363). A similar clarification, as suggested in PC 16, is the specification that the waste at issue is waste "generated by a hospital in connection with patient care." While the Board's December 24 Opinion made it clear that the legislative intent was to exclude non-hospital facilities such as first-aid clinics, the additional language may be useful in dispelling any lingering confusion.

Much of the testimony at hearing concerned the definition of these terms as proposed, with five of the comments (PC 9, 13, 14, 15, 16) specifically questioning the definition of the waste, and two (PC 12, 15) questioning the definition of infectious agent. As these two definitions are so closely related, they will be considered together.

A significant change has been made in the thrust and format of the second sentence of the waste definition, which was drafted to provide the more specific guidance needed by the persons who must actually separate a hospital's infectious "special disposal required" waste stream from its normal "no special handling" waste stream. The hearing participants were in general agreement with the definition as proposed, and indicated that the definition as drafted identified a waste stream which they were already giving special internal handling (e.g. R. 429). However, concern was expressed both at hearing and in the public comments about the proposed rule's statement that hazardous hospital waste "includes but is not limited to" the items specified, the primary concern being that this phrase could lead to arbitrary identification of additional infectious wastes and resulting arbitrary enforcement (e.g. R. 248, 277, 285, 446, PC 9, 14). On the other hand, there was also dissatisfaction with the tie-in of the IDPH reportable disease list with the definition of infectious agent. At least some "reportable" diseases do not transmit infection through waste products, and these patients, therefore, are not isolated (e.g. R. 263, Ex. 1B generally). In this connection, the Board was again reminded that IDPH rules require that isolation policies and procedures be in place, and accepted the suggestion that direct reference be made to "Isolation Techniques for Use in Hospitals," a publication of the Center for Disease Control, U.S. Public Health Services (Ex. 1B). Hearing participants confirmed their own as well as the widespread use of this manual, as yearly amended (e.g. R. 383, 270, 429), and one participant commented that both IDPH and JCAH "beat hospitals over the head with" the manual (R. 288).

Therefore, the Board did not take the "laundry list" approach of listing infectious agents by name which was taken by the USEPA in its original RCRA regulation proposal, 43 Federal Register 58946 et seq. at 58963-64 (December 18, 1978), and to some extent by the Agency in its criteria for implementation of Section 22.2 of the Act (supra p. 3). The Board chose, instead, to rely upon the medical judgment and expertise of the health care professionals to flesh out a general definition. The IDPH new hospital incinerator rule takes this approach (supra, p. 2-3), as does a similar regulation of the Minnesota Pollution Control Agency of which the Board takes official notice.*

*The Minnesota Pollution Control Agency has prohibited the deposit of "special infectious waste" in any landfill, pursuant to its general legislative authorization to control solid waste disposal (Minn. Stat. Ch. 1046, Sec. 11607). Minn. Rule SW6(v)(iii) states that "...special infectious waste..." "shall not be acceptable for deposit in sanitary landfills..." Minn. Rule SW1(12) defines special infectious waste as originating from diagnosis, care or treatment of a person or animal that has or may have been exposed to a contagious or infectious disease. It includes, but is not limited to: (footnote continued on p. 6)

On balance, the Board finds that the latter approach is preferable, particularly since IDPH rules require the development of isolation practices and procedures and references guidelines respected in the health care field, and IDPH and the JCAH already monitor hospital waste stream separation for their licensing and accreditation purposes. Finally, the legislative history of Section 21(h) contains no indication that it was considered that hospitals' in-house identification of waste was faulty; the dissatisfaction lie solely with the holding, transporting and ultimate disposal methods.

Hospital

No change.

Incineration

This definition has been added.

Innocuous Hospital Waste

The Board has added that this waste "is not a special waste." This reflects the Board's original intent as expressed in its December 24 Opinion, and should remove any further doubt.

Normal Hospital Waste

The Board has also added that this "is not a special waste." It was suggested that there was an overlap between the definition of infectious agent, now deleted, and the first sentence of the definition of "hazardous (infectious) hospital waste" (PC 12). In light of the redefinition of "hazardous (infectious) hospital

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a. All wastes originating from persons in isolation for control and treatment of an infectious disease.
b. Bandages, dressings, casts, catheters, tubing and similar disposal items, which have been in contact with wounds, burns, anatomical tracts or surgical incisions, and which are suspect or have been medically identified as infectious and potentially hazardous.
c. All anatomical waste, including human and animal parts or tissues removed surgically or at autopsy.
d. Laboratory and pathology waste of an infectious nature which has not been autoclaved.
e. Any other waste, as defined by the Minnesota Department of Health, which, because of its hazardous infectious nature, requires special handling and disposal in the manner prescribed for (a) through (d).

waste," the first sentence of this "normal" definition has been deleted to leave only the illustrative examples.

Sterilization

There were no comments concerning this requirement, so there has been no change.

Rule 902 Disposal methods for hospital waste

Rule 902 has been changed only by addition in subsection (b) of the requirement that the incinerator used be one "for which the Agency has issued a permit." This language had been included in 902(c) and was not included in 902(b) through oversight.

Rule 903 Rendering hazardous (infectious) hospital waste innocuous by sterilization

The Rule has been internally renumbered, due to deletion of former rule 903(b) which would have required segregation and identification of sterilized hospital waste. Deletion of this segregation requirement was suggested in PC 9, 10, 13, 14, and 15, and by several hearing participants (e.g. R. 251, 404, 446).

The purpose of this requirement, which had been included to provide an indication to waste haulers and landfill operators that such waste could be lawfully accepted, has been fulfilled in other ways. First, the process of autoclaving material enclosed in a "biohazardous" bag gives a visual indication that it has been rendered innocuous, as it warps the bag (R. 391-392). Secondly, some landfill operators have required hospitals to sign indemnification agreements which warrant that their waste is all "non-hazardous" (R. 398, 421-423).

Rule 904 Incinerator Permit Issuance
Rule 905 Agency Criteria

Both of these rules have been deleted in their entirety. While the Agency has not commented on these or any of the other proposed rules, it did, through attorney Richard Warrington, present testimony that:

> "The Agency permits incinerators based on two criteria. One is particulates and the other is carbon monoxide. *** The problem of developing the criteria to permit or not to permit a particular incinerator for the infectious nature of ... air emissions will be unique in the United States, as far as I know.

> In order to do that, we would have to develop a test procedure that would be objective and verifiable. As such, we do not have one. And, I believe there is a literature search going on right now" (R. 319, 321).

The Agency could give no estimate as to when its "objectively verifiable and scientific" test procedure might be developed.

In reply, James Ahrens of the Illinois Hospital Association (IHA) pointed out that:

> "hospitals are making capital expenditures, some of them very major, based upon the assumption that the Agency will permit these incinerators *** people are out there buying incinerators and assuming that the current manufacturing standards ... will be adequate to meet the needs of this piece of legislation. So, delay or change [in regulations] later on is just going to add to the cost of a lot of things" (R. 331-332).

Similar ideas were expressed in written comments (PC 9, 10).

Rules 904 and 905 were originally drafted to address the twin problem of infectious material going up the incinerator stack or remaining in the incinerator ash to be transported for disposal in a landfill. The Board is aware that some infectious agents are very resistant to heat; however, it would seem that the greatest potential for problem would stem from improper operation of the incinerator and resulting lack of combustion sufficient to completely reduce all the waste to innocuous ash. Given the apparent lack of stack or incinerator ash testing procedures for infectious material, the Board believes the prudent approach at this time is to delete Chapter 9 permitting requirements. If an incinerator is improperly charged (loaded), so that combustion is incomplete, and material is forced up the stack, this will result in a violation of the Board's Chapter 2 particulate emission standards, and will trigger enforcement under those rules. Also, the Board has drafted new Rule 904 to require proper operation, and has incorporated a flexible incinerator record keeping requirement into Rule 905 (which details will be discussed below). Enforcement can proceed under these two rules if necessary.

In taking this approach, the Board believes that it has struck the proper balance between the need to protect public health and the need to avoid any unnecessary health care expenditures to comply with Section 21(h) of the Environmental Protection Act. The Board also wishes to note its concern that any increase in volume of waste which must be incinerated could lead to improper charging and overloading of incinerators; the Board assumes that the Agency will consider this factor in developing Chapter 2 monitoring and inspection schedules.

Rule 904 Rendering hazardous (infectious) hospital waste innocuous by incineration

The reasons for this new rule are as discussed above.

Rule 905 Recordkeeping requirements for generators of hazardous (infectious) hospital waste

The comments of the IHA and others expressed concern that the originally proposed Rule 905 would require unnecessary and costly recordkeeping (R. 252, PC 9, 10, 13).

The rule has been rephrased to reflect the Board's intent, which is as follows:

a. The records describing approximate amounts of waste are required primarily to assure that a sufficient amount of isolation waste, consistent with the type of patient care offered by a particular hospital, is actually being incinerated and/or sterilized.

The revised rule calls for an approximation of the amount of incinerated or sterilized waste. The purpose of the rule is to aid in detection of unauthorized deposit of waste in a landfill. For example, if no infectious waste is incinerated, and none autoclaved, enforcement action would seem to be needed, since it is reasonable to expect that every hospital will generate some infectious waste. Precise weighing is therefore not required, nor is precise calculation of volume; the requirement is of a good faith estimate. Obviously, if all waste generated in a hospital is sterilized or incinerated, the records need only to indicate that fact.

b. The requirement to show proper equipment operation reflects the need to provide assurance that the statutory mandate to render the the waste innocuous is being met. If records are already kept to comply with existing air pollution, special waste regulations, and good hospital practice and these, singly or combined show proper handling and equipment operation, then these would suffice.

Sterilizer Operation Records. The spore assay tests are similar to procedures already in use by hospitals in conjunction with their processing of products to be used for patient care, and both the IDPH and the JCAH currently provide close oversight in this area (see IDPH Hospital Licensing Requirements, Part IX, Section C "Sterilization and Processing of Supplies," Illinois Register Vol. 5, pp. 548-49, R. 302-304, 307, 310). If a sterilizer is operated improperly, waste is not rendered innocuous as required by Section 21(h). Biological spore assay can indicate only that the sterilizer is functioning on that particular day (R. 305): the Board has required only weekly tests for the commonly used autoclaves. To be certain each load was rendered

innocuous, the Board could require that "sterile tape" be put on each biohazard bag, but at approximately $.16 per bag this would not be cost effective (see R. 391). Another option would be to require that a spore assay test be put in every sterilizer load (at $1.00 per load), and then to require that the sterilized waste be stored for the 24-48 hour period until the spore assay had incubated and complete sterilization had been confirmed. Waste storage and biological monitoring would of course impose additional costs (R. 309-311).

The Board does concur that there is no need to duplicate reporting forms, particularly as it is not required that the records be submitted to the Agency, only that they be available for Agency inspection at reasonable times in reasonable manners. Accordingly new subsection (b) explicitly provides that records kept for IDPH or JCAH purposes may be used to satisfy this requirement.

Incinerator Operation Records. The Board is aware that while hospital sterilization procedures are currently monitored by IDPH, hospital incineration procedures are not (R. 308). The Board is also aware that incinerators vary in type and cost, and that the highly automatic "Cadillac" of incinerators may well have monitoring equipment which is not to be found on the older incinerators. It is not the Board's intent in drafting this rule to cause a hospital to needlessly "trade-up" in incinerator class, or to retrofit with expensive monitoring equipment. The Board does intend that each hospital develop as good a system of housekeeping practices for incinerator use as for sterilizer use. Written operating and maintenance instructions shall be maintained (cf. IDPH Hospital Licensing Requirements, Part XVI, "Maintenance," Illinois Register, Vol. 5, p. 579), as well as records appropriate to the type of incinerator of its use.

The Board continues to believe that maintenance of some records is a necessary enforcement tool, and that the records to be kept under Rule 905 add little, if any new costs. (In fact, hospitals who choose to sterilize their waste before depositing it in a landfill will be required to keep less complex records than would be required under H.B. 453, as disposal of a hazardous waste requires use of the Chapter 9 manifest system.)

Rule 906 Defense to enforcement action

No change.

ECONOMIC IMPACT ISSUES

The Illinois Institute of Natural Resources (Institute) is currently in the process of developing an economic impact study.

Therefore, no hearings have been held pursuant to Section 27(b) of the Environmental Protection Act to receive comments concerning this economic impact study. The Board is promulgating these regulations in advance of completion of the study because a) the economic impact flows from the statute and not the regulations, and b) the same public health issue that generated the adoption of the emergency rules remains.

Section 27(b) of the Act charges the Board when adopting regulations to:

> "consider those elements detailed in the Institute's study and... in [the Board's] written opinion, make a determination, based upon the Institute's study and other evidence in the public hearing record, as to whether the proposed regulation has any adverse economic impact on the people of the State of Illinois." (emphasis added)

The hearing record clearly shows that requiring disposal of infectious waste by means other than deposit in sanitary landfills will increase costs to at least some hospitals, at least in the short run.* Some hearing participants seriously questioned whether there were benefits to weigh against the costs (e.g. R. 347-389). While the Institute's study could, considering all relevant factors, suggest that the net economic effect of the regulations is adverse, any such finding by the Board would be irrelevant in the unique circumstances of this rulemaking.

Were this a proceeding before the Board pursuant to Section 22(h) to determine whether land burial of this waste should be prohibited, taking into account the technical feasibility, economic reasonableness and environmental soundness of all available disposal options, the Institute's study would be of considerable assistance to the Board in its deliberations. However, in passing Section 21(h), the legislature has already determined the economic reasonableness and environmental soundness of the landfill prohibition. The primary economic impacts therefore flow from the legislation, and not from the regulations. The Board's regulatory mandate was to fill in the fine details of the broad legislative enactment. To the extent that the Board has had discretionary choices as to how to implement this legislation, for instance in determining whether to require simple or complex recordkeeping, the Board has, as is evident, considered the relative economics in relation to the relative benefits. It is therefore the Board's

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*For example, one administrator of a 340 bed hospital testified that, based on capital investment of $15,000 to $200,000 for an incinerator, and an annual operating expense in energy and manhours of $37,000, that compliance would cost his hospital in excess of $77,000 per year (R. 441-442). However, another hospital, with 318 beds, is considering purchase of a $14,000 sterilizer (no operating costs computed) (R. 431).

opinion and finding that it has, under the unique circumstances of this rulemaking, satisfied the requirements of Section 28(b) of the Act.

Even had the Board not made this finding pursuant to Section 28(b), Section 28(c) would authorize promulgation of these rules pending completion of the Institute's study. The emergency rules which these rules replace expire May 31, 1981. Lack of regulations to implement Section 21(h) will create the same severe threat to public health which prompted promulgation of the emergency rules adopted December 18, 1980. The variance granted by the Board in Mercy Hospital Medical Center and Illinois Hospital Association v. IEPA, PCB 80-218 (December 18, 1980, and January 22, 1981) was from its regulations implementing Section 21(h). If regulations are not in place, the variance is rendered meaningless. Landfill operators will no longer be able to accept hazardous (infectious) hospital waste lawfully, with the resulting likelihood of improper storage, faulty incineration, or surreptitious dumping of hospital wastes by their generators.

This Opinion constitutes the Board's findings of fact and conclusions of law in this matter.

Mr. Werner concurred.

IT IS SO ORDERED.

I, Christan L. Moffett, Clerk of the Illinois Pollution Control Board, hereby certify that the above Opinion and Order were adopted by the Board on the ____ day of _____, 1981 by a vote of ____.

Christan L. Moffett, Clerk
Illinois Pollution Control Board