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SEP 05 2007

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

STATE OF ILLINOIS
Pollution Control Board

IN THE MATTER OF:

PETITION OF STERICYCLE, INC.
FOR AN ADJUSTED STANDARD
FROM Ill. Admin. Code tit. 35 § 1422.111(B)(1);
§ 1450.105(A)-(B); § 1450.200(E);
AND CONDITION 15 OF PERMIT NO. 1997-264-DE/OP,
SUPPLEMENTAL PERMIT NO. 2005-182-SP

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AS 08-2
Adjusted Standard

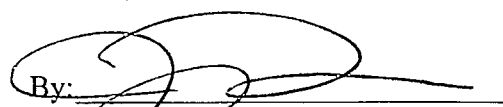
NOTICE OF FILING

To: Dorothy Gunn
Clerk of the Board
Illinois Pollution Control Board
100 West Randolph Street
James R. Thompson Center, Suite 11-500
Chicago, Illinois 60601-3218

Division of Legal Counsel
Illinois Environmental Protection Agency
1021 North Grand Avenue East
Springfield, Illinois 62794-9276

PLEASE TAKE NOTICE, that on Sept. 4, 2007, we filed with the Office of the Clerk of the Illinois Pollution Control Board an original and ten copies of the attached Petition for Adjusted Standard of Stericycle, Inc., and Waste Management, Inc., a copy of which is hereby served upon you.

STERICYCLE, INC.

By: 

Jessica E. DeMonte, Esq. (Ill. No. 6288817)
Squire, Sanders & Dempsey L.L.P.
Three First National Plaza
70 W. Madison, Suite 2015
Chicago, IL 60602
(312) 781-1123
jdemonte@ssd.com

STATE OF ILLINOIS
DEPARTMENT OF REVENUE

SALES TAX

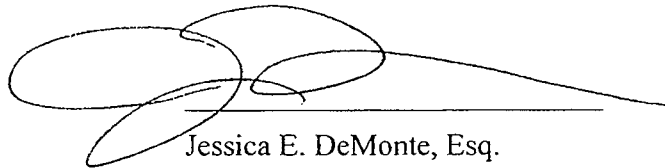
SALES TAX REPORT
FOR THE QUARTER ENDED

CERTIFICATE OF SERVICE

I, the undersigned, on oath state that I have served on the date of SEP. 4, 2007, the attached Petition for Adjusted Standard, via U.S. mail, upon the following:

Division of Legal Counsel
Illinois Environmental Protection Agency
1021 North Grand Avenue East
Springfield, Illinois 62794-9276

Peter Orlinksy
Assistant Counsel, Northern Region
Illinois Environmental Protection Agency
9511 West Harrison Street
Des Plaines, Illinois 60016



Jessica E. DeMonte, Esq.
Squire, Sanders & Dempsey L.L.P.
Three First National Plaza
70 W. Madison, Suite 2015
Chicago, IL 60602
(312) 781-1123
jdemonte@ssd.com

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AS 08-2
Adjusted Standard

PETITION FOR ADJUSTED STANDARD

Stericycle, Inc., as operator, ("Stericycle") petitions the Illinois Pollution Control Board (the "Board") for an adjusted standard pursuant to Ill. Admin. Code 35 § 104.400 *et seq.*, and 415 Ill. Comp. Stat. 5/28.1. Stericycle requests the Board grant an adjusted standard for Ill. Admin. Code tit. 35 § 1422.111(b)(1); § 1450.105(a)-(b); § 1450.200(e); and Condition 15 of Permit No. 1997-264-DE/OP, Supplemental Permit No. 2005-182-SP.

Stericycle requests an adjusted standard from Illinois' requirement that Stericycle manually weigh and record the weight of each load of Potentially Infectious Medical Waste ("PIMW") at its transfer station at 3801 S. Laramie Street, Cicero, Illinois 60804 (the "Facility"). Stericycle weighs all PIMW that is received at the Stickney transfer station at Stericycle's facilities in Clinton, Illinois, or Sturtevant, Wisconsin. The PIMW weight data collected at the Clinton and Sturtevant facilities is more accurate, is made contemporaneously with the receipt of the PIMW at each facility, is recorded daily and is transmitted daily to Stericycle's corporate headquarters in Illinois.

Granting the requested adjusted standard will not result in any potential or actual harm to human health or the environment or any loss in PIMW transporter fee revenue to the State of Illinois. This petition for adjusted standard is submitted pursuant to Section 35(a) of the Illinois Environmental Protection Act (the "Act") (415 ILCS 5/35(a)) and Part 104 of the Board's procedural rules (35 Ill. Admin. Code § 104.100 *et seq.*).

I. PARTIES TO THE PROCEEDING

1. Stericycle has operated the Stickney PIMW transfer facility at the above-stated address since November 4, 1997. In addition to operation of the Stickney facility, Stericycle maintains its corporate headquarters in Bannockburn, Illinois. Stericycle was founded in 1989 and now operates 45 treatment and collection facilities supported by 105 transfer stations throughout North America. It is the largest and only full-service medical waste provider in the United States, and the company has a growing presence in Asia, Australia, the United Kingdom, Ireland and South America, serving more than 339,000 customers worldwide.

2. Waste Management has owned the Facility since the 1970s.

II. STANDARD FROM WHICH RELIEF IS SOUGHT - § 104.406(a)

3. Stericycle requests an adjusted standard for Ill. Admin. Code tit. 35 § 1422.111(b)(1), § 1450.105(a)-(b), and Permit Section 15, which require each load of PIMW arriving at the Facility to be weighed on an Illinois-certified scale. The regulations require that Stericycle use a device certified by the Illinois Weights and Measures Act to weigh in pounds any load of PIMW received.¹ The regulations also require that Stericycle maintain a Daily PIMW Report at the transporter's principal place of business in Illinois or corporate headquarters.²
4. The regulations do not specify how the PIMW should be weighed (e.g., by individual container or collectively; "load" is not defined) or how the data should be recorded. Stericycle believes this ambiguity could result in inaccuracies and inconsistencies in the weight collection and recording system at the Facility.
5. Stericycle has met with Anna Van Orden, Environmental Protection Specialist, Division of Land, and Beverly Albarracin, Permit Writer, from the Illinois Environmental Protection Agency (the "Agency") to discuss the issues that are the subject of this Petition.

III. NATURE OF REGULATION OF GENERAL APPLICABILITY - § 104.406(b)

6. The primary purpose of the regulations for which the adjusted standard is sought is to ensure the accurate recording of PIMW transported in the State of Illinois for waste tracking and fee generation purposes. Granting the adjusted standard will not reduce the accuracy or consistency of Stericycle's PIMW weight measurement and recording data or procedures. Granting the adjusted standard will not reduce the ability of Stericycle or the State of Illinois to track PIMW or determine accurate PIMW fees.
7. The regulations for which the adjusted standard is sought are administrative in nature and do not provide substantive protection of human health or the environment.
8. Stericycle does not believe the rules or regulations were promulgated in whole or in part, to comply with the requirements of the Clean Water Act, the Safe Drinking Water Act, the Comprehensive Environmental Response Compensation and Liability Act, or the State programs implementing the Resource Conservation and Recovery Act, Underground Injection Control or the National Pollution Discharge Elimination System.

¹ Ill. Admin. Code tit. 35 § 1422.111(b)(1) (*see*, Exhibit A, attached); § 1450.105(a)-(b); § 1450.200(e) (*see*, Exhibit B, attached); and Condition 15 of Permit No. 1997-264-DE/OP, Supplemental Permit No. 2005-182-SP (*see*, Exhibit C, attached).

² Ill. Admin. Code tit. 35 § 1450.103.

IV. SPECIFIED LEVEL OF JUSTIFICATION - § 104.406(c)

9. The regulations of general applicability for which this adjusted standard is sought do not specify a level of justification for an adjusted standard.

V. FACILITY AND PROCESS DESCRIPTION - § 104.406(d)

10. The Facility is a 40-foot by 55-foot fenced area within 9.27 acres in the Southwest Quarter of the Southeast Quarter of Section 33, Township 39 North, Range 13 East, of the Third Principal Meridian, all in Cook County, Illinois. The Facility, in compliance with all applicable federal, state and local laws, rules and regulations, collects and transfers PIMW from individual customer locations such as medical facilities, hospitals, clinics, veterinary hospitals, outpatient surgery centers, dialysis centers and wound clinics across northern Illinois. The Petitioner employs approximately 23 people at the Facility.
11. The Facility is permitted by the Agency under Permit No. 1997-264-DE/OP and Supplemental Permit No. 2005-182-SP issued on September 21, 2005.
12. The Facility transfers approximately 33,500 pounds of PIMW daily in sealed containers in compliance with all federal, state and local laws, rules, regulations and permit requirements. The containers are not opened or compromised in any way during handling at the Facility, which consists entirely of moving the containers from one truck to another. Most of the PIMW received at the Facility is consolidated and shipped to Stericycle's facility in Sturtevant, Wisconsin ("Sturtevant"), within all applicable regulatory timelines. Sturtevant is approximately 75 miles from the Illinois Facility and approximately 20 miles across the Illinois state line.
13. PIMW that is not transferred to Sturtevant is transferred to Stericycle's facility in Clinton, Illinois, where it is weighed in the exact same manner as it is weighed in Sturtevant as described herein. The Clinton facility is located at RR 4, Box 243L, Clinton, Illinois 61727.
14. Stericycle currently weighs each truck load of PIMW received at the Facility on a truck scale owned by Waste Management and certified in Illinois. The Facility manually records the weight of each load. However, due to daily operational differences in truck weight such as amount of fuel on board, weight of the driver, etc., the weight measurement system at the Facility is inherently inaccurate. A daily weight log is manually kept at the Facility. This weight log is not used for billing customers or for determination of transporter fees to be paid to the State of Illinois.
15. Stericycle maintains and will continue to maintain records of the quantity and disposition of PIMW. This information is generated through Stericycle's waste manifesting and tracking systems and is available at Stericycle's corporate headquarters and the Stickney transfer station in electronic format.
16. Each Customer whose waste is transferred through Stickney is identified in Stericycle's state-of-the-art BioTrack system by route number and manifest. The BioTrack system contains nearly real time records of the PIMW picked up from each

generator, including the name of the generator, the time, the number of containers, the type of container, the driver and the route number. A manifest also accompanies the containers of PIMW from each generator. Attached as Exhibit A is a sample report that can be generated at any time at the Stickney facility. Data is downloaded on a daily basis from the drivers PDT (a device similar to a UPS driver's scanner). Once the system is updated, the information can be used to create a Daily report.

17. At the Stickney facility, a log is maintained that indicates by route number the PIMW that was collected and transferred to a designated trailer to be sent to one of Stericycle's PIMW processing and treatment facility. Using the log and the data in the BioTrack system, Stericycle tracks each container from the generator, to the transport vehicle, to the vehicle onto which the PIMW is transferred and stored, to the treatment and disposal facility. After transfer, the PIMW is scanned and weighed again when it is unloaded at the facility designed to treat it to eliminate its infectious potential. In this manner Stericycle can track the shipment and maintain a record of the weight from generator, to transfer station to treatment facility to final disposal.
18. Stericycle owns and operates an automatic scale system at Sturtevant that weighs each individual container of PIMW received. At Sturtevant, each container of PIMW is unloaded from the truck onto a conveyer belt. The customer label of each container is scanned for tracking purposes and the container is conveyed to a scale where it is automatically weighed. The Sturtevant scale is calibrated twice per year at a minimum, is certified by the State of Wisconsin Department of Agriculture,³ and has a certificate of conformance pursuant to National Institute of Standards and Technology Handbook 44. The Sturtevant scale system is maintained by Koehler Scale, Inc., 3475 Nemesis Avenue, Waukegan, Illinois 60087. Koehler Scale is certified by the State of Illinois Department of Agriculture, Bureau of Weights and Measures for registration of weighing devices.⁴
19. Sturtevant operates under Wisconsin Department of Natural Resources Permit No. 3550.⁵ As required by the Wisconsin permit, each container of PIMW is weighed on the State of Wisconsin-certified scale. Sturtevant's weight data collection system is more reliable and provides the best and most accurate PIMW weight information for PIMW transferred from Stickney to Sturtevant.
20. At Sturtevant, each container of PIMW is individually weighed and a simultaneous computer record of the weight of each container is made. This system accurately measures the actual weight of PIMW on scales that meet all national, Wisconsin and Illinois standards. The scale's computer data system automatically records the weight of each container, so it is less prone to human or mechanical error. Weight information from the Sturtevant system is used to bill customers and to determine transporter fees due and payable to the State of Illinois.

³ The most recent scale calibration report is attached hereto as Exhibit D.

⁴ See, State of Illinois certification attached hereto as Exhibit E.

⁵ See, Modification to Plan of Operation approved by State of Wisconsin Department of Natural Resources on October 24, 2000, attached hereto as Exhibit F.

21. PIMW is treated at Sturtevant by Electro-Thermal Destruction in compliance with all applicable federal, state and local laws rules and regulations, such that it does not pose a threat to human health or the environment. After treatment at Sturtevant, the waste is no longer considered to be PIMW. Stericycle maintains records sufficient to prove that all PIMW received at Sturtevant is treated and disposed in compliance with all applicable rules and regulations.
22. The Stickney Facility does not discharge into any waterway or onto any land. There are no air emissions from the Facility. The location of the nearest air monitoring station is not applicable. There are no permitted discharges, emissions or releases of PIMW at the Facility.
23. Stericycle has not received any prior variance or adjusted standard for the Stickney Facility. To the best of the Stericycle's knowledge no variance or adjusted standard was issued to any of Stericycle's predecessors.
24. Pollution at the Stickney Facility is controlled by the proper operation and handling of sealed containers of PIMW. Petitioner Stericycle invests heavily in the proper training of all employees who will handle PIMW, and safety is a paramount consideration. Under ordinary circumstances, there is no threat of pollution, discharge, emissions or release from operations at the Facility.

VI. REQUIREMENTS FOR COMPLIANCE - § 104.6(e)

25. The Facility is currently in compliance with the rules and regulations for which the adjusted standard is sought. The Facility achieves compliance by operating a truck scale owned by Waste Management at the Facility. The Facility has been deemed to be in compliance with Illinois rules by weighing each truck as it arrives at the Facility to determine the weight in pounds of each load of PIMW.
26. Stericycle uses weights measured and recorded at the Sturtevant facility for paying fees to the State of Illinois. Stericycle maintains duplicate weight recording systems. The weight of each load is recorded manually in a log at the Stickney Facility. The actual weight of the PIMW is recorded electronically in Stericycle's computer system at the Sturtevant facility. The weight information is transmitted daily to Stericycle's corporate headquarters in Illinois.
27. Because Stericycle uses the scales at Sturtevant to determine both amounts receivable from its customers and amounts payable to state regulatory authorities, Stericycle has balancing economic incentives to ensure the accuracy of the Sturtevant scales and the weights recorded there. Because the Sturtevant facility weighs each individual container of PIMW, it is more accurate than the truck scale system used at the Stickney Facility.

VII. DESCRIPTION OF ADJUSTED STANDARD - § 104.6(f)

28. Stericycle seeks an adjusted standard from the weight measurement and recording requirements generally applicable to transporters of PIMW. Stericycle requests an exemption from the requirement that each load of PIMW be weighed with a device for

which certification has been obtained under the Weights and Measures Act (Ill. Rev. Stat. 1991, ch. 147, pars. 101 *et seq.*) [225 Ill. Comp. Stat. 470].

29. Stericycle requests that the Board adopt the following language as an amendment to Condition 15 of Permit No. 1997-264-DE/OP, Supplemental Permit No. 2005-182-SP to effectuate the requested relief:
- a. Storage operations shall weigh in pounds the amount of PIMW received, unless 1) previously weighed by the transporter, or 2) the PIMW subsequently will be weighed at a facility designed to treat PIMW to eliminate its infectious potential.
 - b. The PIMW shall be weighed with a device for which a certificate of conformance has been obtained pursuant to National Institute of Standards and Technology Handbook 44. The PIMW may be weighed on a device outside the state of Illinois, provided the device conforms with the standards set forth in this section.
 - c. The Daily PIMW Report shall be maintained at the location where the PIMW is weighed and at the transporter's corporate headquarters in Illinois.
 - d. The Daily PIMW report shall be made contemporaneously with the receipt of each load at a facility designed to treat PIMW to eliminate its infectious potential. If the Daily PIMW report is generated at a facility outside the State of Illinois, the Daily PIMW report shall be transmitted electronically to the Stickney transfer station at the close of each business day.
 - e. The Daily PIMW report for the Stickney transfer station shall include all information required by Ill. Admin. Code tit. 35 § 1450.200(c).
 - f. It shall be a violation of the conditions of this Permit if a Daily PIMW report cannot be produced by Stericycle within 24 hours of a request for such information by the Illinois Environmental Protection Agency.
 - g. Stericycle shall first obtain an Adjusted Standard before changing the method for weighing and recording PIMW shipments."

VIII. IMPACT ON THE ENVIRONMENT - § 104.6(g)

30. There will be no environmental impact if the adjusted standard is granted.
31. Granting of the adjusted standard will not result in any emissions, discharges, or release of any constituent.
32. There will be no qualitative or quantitative impact on human health and the environment if the adjusted standard is granted.
33. If the adjusted standard is granted, Petitioner Stericycle will continue to operate its facilities in Illinois and Wisconsin in compliance with all applicable federal, state and

local laws, rules and regulations so as to minimize the chance for release or discharge of any PIMW.

IX. JUSTIFICATION FOR ADJUSTED STANDARD - § 104.6(h)

34. As stated in Section IV of this petition, the regulations of general applicability do not specify a level of justification for the adjusted standard. Section 28.1(c) of the Illinois Environmental Protection Act allows the Board to grant adjusted standards in the absence of a specified level of justification if the Board determines, based upon adequate proof by the petitioner that:
- a. factors relating to the petitioner are substantially different from the factors relied upon by the Board in adopting the general regulation applicable to that petitioner;
 - b. the existence of those factors justifies an adjusted standard;
 - c. the requested standard will not result in environmental or health effects substantially and significantly more adverse than the effects considered by the Board in adopting the rule of general applicability; and
 - d. the adjusted standard is consistent with any applicable federal law.
35. The regulations of general applicability were adopted some 13 years ago by the Board. The rulemaking documents that are now available do not specifically address the adoption of the rules requiring PIMW be weighed on a scale certified by the State of Illinois. However, based upon a common sense reading of the regulations, Stericycle believes the Board was primarily concerned with ensuring the accurate and consistent weighing of PIMW on an independently-certified weight measurement system and the accurate recording of such data. An accurate and consistent weight measurement and recording system is important for waste tracking and fee determination purposes.
36. In the only reference to the rules of general applicability found in the rulemaking documents, the Board quoted the Agency as promulgating § 1422.111(b) because:

“These requirements are necessary to meet the intent of the Act to reduce the potential environmental and public health risks associated with PIMW, since the permitted storage operation is not normally the generator of the waste. The owner or operator of the storage operation does not possess the same knowledge of the waste as the generator and does not maintain the same control over what is placed in the packages as the original generator. In addition, safeguards are necessary because PIMW is stored for varying lengths of time and under varying conditions.”⁶

⁶ Proposed Rule, First Notice, Opinion and Order of the Board at 34, see Exhibit G.

Section 1422.111(b) contains standards for PIMW storage operations required to have a permit. The rules in § 1422.111(b) prescribe general design and operating standards, most of which have nothing to do with weight measurement or recording.

37. The factors relating to Stericycle are substantially different from the factors relied upon by the Board in adopting the regulations of general applicability. As discussed above, in adopting the regulations of general applicability, the Board was concerned with ensuring the accurate and consistent weighing and recording of PIMW weight information. The requirement that the weight measurement device be certified under the Illinois Weights and Measures Act is to ensure that all weight measurement systems are accurate and can be certified by an independent third party – either a private scale certification company or state regulators. The rules did not contemplate a transporter being required to operate dual weight measurement systems simply because it was transporting PIMW a short distance across the state line. The rules of general applicability apply differently because:
- a. The regulations require Stericycle to operate and maintain duplicative measurement and recordkeeping systems. The duplicative systems are not necessary to accomplish the goals of the regulations to ensure the accurate and timely measurement of PIMW weight information. Stericycle's BioTrack system is able to track and record the PIMW from the generator to final disposal such that it maintains control of all necessary information about the PIMW at all times. Requiring PIMW be weighed at a facility where the material is simply moved from one truck to another does not generate any new or more accurate information. These duplicative systems require investment of time, effort, materials and manpower which place an unreasonable economic burden on Stericycle. Granting of the adjusted standard will allow Stericycle to reduce administrative costs without reducing the accuracy or completeness of the weight measurement and data recording system and without a detriment to human health or the environment;
 - b. The weight measurement system currently used at the Facility has inherent flaws, as described above. The Clinton and Sturtevant facilities' weight measurement system are much more accurate and less susceptible to human error. Because of this inherent inaccuracy, the weight measurement system at the Stickney Facility is not used for billing customers or determining transporter fees to be paid to the State of Illinois. The rules of general applicability apply differently because they require Stericycle to operate and maintain a system that is inherently inaccurate, is not essential for proper waste tracking and is useless for billing or state fee purposes.
 - c. The requirement that all PIMW be measured on a scale certified in accordance with the Illinois Weights and Measures Act does not protect human health or the environment, nor does it provide any additional assurance of accurate weight measurement or recordkeeping for the PIMW. The regulations were passed to ensure that PIMW was weighed on a scale that satisfied Illinois' standards for accuracy. The standard is the same in Wisconsin. The rules of general applicability apply differently because both Illinois and Wisconsin require scales

to conform with the National Institute of Standards and Technology (“NIST”) Handbook 44. The NIST Handbook 44 has been adopted by 40 states, including Illinois and Wisconsin. In those 40 states, the state regulations are automatically updated any time changes are made to Handbook 44 such that the rules remain consistent within all 40 states at all times;

- d. Sections 1450.105(a)-(b) were enacted to ensure the State of Illinois collected proper fees pursuant to the Illinois Medical Waste Transporter Fee System. The rules apply differently to Stericycle’s Illinois Facility because the company does not use weight data collected at the Facility for fee payment purposes. Stericycle uses the more accurate weight data from Sturtevant for both billing customers and making payments to the State of Illinois. Because of the dual use of the weight information, Stericycle has an economic and regulatory incentive to ensure the accurate and consistent collection of PIMW weight data.
 - e. The rules of general applicability require a Daily PIMW Report to be kept at the Facility. As stated above, the Facility’s scales are inherently inaccurate, and therefore the manually created Daily PIMW Report based on the use of the truck scale at the Facility is inaccurate and may be inconsistent with the actual weight of PIMW as recorded at Sturtevant. The Sturtevant facility is able to electronically transfer PIMW weight information to both Stickney and Stericycle’s corporate headquarters in Illinois where the records can be reviewed by Illinois regulators. The rules of general applicability apply differently because Stericycle maintains weight information at Sturtevant in a more accurate and consistent way than the manual log at Stickney. Additionally, Illinois regulators have access to and can view Stericycle’s PIMW weight information without traveling outside the state of Illinois.
 - f. Finally, in enacting the rules, the Board likely assumed that transfer stations would transfer PIMW to other facilities in Illinois or to facilities not owned or operated by the transporter or transfer station operator. Stericycle’s interstate operations allow it to operate an efficient network of collection, transportation and treatment facilities across state lines. Stericycle’s waste tracking system allows it to track each container from generation to disposition. This allows Stericycle to generate and maintain accurate and timely information regarding the quantity and disposition of each load of PIMW without weighing each container arriving at the Stickney transfer station. The requirement that PIMW be weighed twice by different scales applies differently to Stericycle than it would for wholly intrastate operations or to transporters, transfer stations and disposal facilities that operate independently.
38. The adjusted standard is justified because under rules of general applicability Stericycle is required to maintain a duplicative administrative system that provides no additional protection of human health or the environment; does not increase revenues to the State of Illinois; creates the possibility of inaccuracies and inconsistencies; and because Wisconsin-certified scales must conform to the same standards as Illinois-certified scales and are at least as accurate.

39. If the Board grants the adjusted standard there will be no adverse effect on human health or the environment, nor will revenue to the State of Illinois be reduced. The environmental and health effects of operations at the Facility will be exactly the same if the adjusted standard is granted. The environmental and health effects will not be substantially or significantly more adverse than the effects considered by the Board in adopting the rule of general applicability.
40. The adjusted standard is consistent with federal law.

X. CONSISTENCY WITH FEDERAL LAW - § 104.6(i)

41. The Board may grant the adjusted standard consistent with federal law including the Clean Air Act, the Clean Water Act, the Safe Drinking Water Act, the National Primary Drinking Water Regulations, the Underground Injection Control Program, the Resource Conservation and Recovery Act, and all federal regulations adopted pursuant thereto. The Facility does not have any air emissions or water discharges, and granting the adjusted standard will not impact air emissions, water discharges or public drinking water. The Facility is not subject to regulation under the Underground Injection Control Program or RCRA.

XI. WAIVER OF HEARING - § 104.6(j)

42. Stericycle has discussed this Proposed Adjusted Standard with the Illinois Environmental Protection Agency, which has indicated it intends to recommend the Adjusted Standard be granted barring unforeseen circumstances. Unless an objection is raised by the Agency or a hearing is requested by a member of the public or an interested party, Stericycle hereby waives hearing in this matter.

XII. SUPPORTING DOCUMENTS - § 104.6(k)

43. Supporting documents cited in this petition are attached hereto.

VII. CONCLUSION

Stericycle petitions the Illinois Pollution Control Board (the "Board") for a adjusted standard from Ill. Admin. Code tit. 35 § 1422.111(b)(1); § 1450.105(a)-(b); § 1450.200(e); and Condition 15 of Permit No. 1997-264-DE/OP, Supplemental Permit No. 2005-182-SP. Under the rules for which the adjusted standard is sought, Stericycle is required to maintain a duplicative administrative system that provides no additional protection of human health or the environment and does not increase revenues to the State of Illinois. This duplicative system creates the possibility of inaccuracies and inconsistencies while the Wisconsin-certified scales, which are used for billing and fee-payment purposes, conform to the same standards as required by the State of Illinois and are at least as accurate. Requiring strict compliance with the Illinois rules is an unreasonable and arbitrary burden for Stericycle.

Respectfully submitted,



Jessica E. DeMonte, Esq. (Ill. No. 6288817)
Squire, Sanders & Dempsey L.L.P.
Three First National Plaza
70 W. Madison, Suite 2015
Chicago, IL 60602
(312) 781-1123
jdemonte@ssd.com

EXHIBIT A

Section 1422.107 PIMW Permit Application Filing Requirements

- a) All permit applications must be filed with the Agency, on forms as prescribed by the Agency. Hand delivered applications must be delivered during the Agency's normal business hours to the offices of the Permit Section. The Agency shall provide a dated, signed receipt of filing only if the applicant requests. The date of filing must be that recorded by the Agency, unless proven otherwise by a dated, signed receipt.
- b) The permit application must be accompanied by all filing fees required pursuant to Section 5(f) of the Act.

SUBPART B: STORAGE OR TRANSFER OPERATIONS

Section 1422.110 Scope and Applicability

This Subpart applies to the owner or operator of a PIMW storage site or transfer station, collectively referred to as a "storage operation" in this Subpart.

Section 1422.111 Design and Operating Standards and Criteria

- a) ANY PERSON WHO STORES PIMW PRIOR TO TREATMENT OR DISPOSAL ON-SITE OR TRANSPORT OFF-SITE MUST COMPLY WITH ALL OF THE FOLLOWING STORAGE REQUIREMENTS:
 - 1) STORE THE PIMW IN A MANNER AND LOCATION THAT MAINTAINS THE INTEGRITY OF THE PACKAGING AND PROVIDES PROTECTION FROM WATER, RAIN, AND WIND.
 - 2) MAINTAIN THE PIMW IN A NONPUTRESCENT STATE, USING REFRIGERATION WHEN NECESSARY.
 - 3) LOCK THE OUTDOOR STORAGE AREAS CONTAINING PIMW TO PREVENT UNAUTHORIZED ACCESS.
 - 4) LIMIT ACCESS TO ON-SITE STORAGE AREAS TO AUTHORIZED EMPLOYEES.
 - 5) STORE THE PIMW IN A MANNER THAT AFFORDS PROTECTION FROM ANIMALS AND DOES NOT PROVIDE A BREEDING PLACE OR FOOD SOURCE FOR VECTORS. (Section 56.1(e)(2)(D)(i)-(v) of the Act)
 - 6) PIMW packages must not be compacted or subjected to stress that compromises the integrity of the container.

- 7) Multiple generators in the same building may store their PIMW packages in a common storage area.
- 8) Reusable PIMW containers or facility equipment (e.g., carts, squeegees or shovels) which are visually contaminated with PIMW must be cleaned in a designated area in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle.
- 9) Residues from cleaning a PIMW contaminated container, equipment or work surface are regulated under this Subtitle, except when directly discharged into a sanitary or combined sewer in accordance with 35 Ill. Adm. Code: Subtitle C.

BOARD NOTE: Interested persons should note that discharges to sewer systems can also be regulated by units of local government.

- 10) Copies of all PIMW manifests required by 35 Ill. Adm. Code 1420.105 of this Subtitle must be retained by and kept at the storage operation for three (3) years and must be made available at the storage operation during normal business hours for inspection and photocopying by the Agency. The retention period for PIMW manifests is extended automatically during the course of any unresolved enforcement action regarding the storage operation or as requested in writing by the Agency.
 - 11) Upon closure of a storage operation, the owner or operator shall clean the area, equipment and structures in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle.
- b) In addition to the requirements listed in subsection (a) of this Section, storage operations required to have a permit pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle must also comply with the following requirements that the Agency shall review during the permitting process:
- 1) Storage operations shall weigh in pounds the amount of PIMW received, unless previously weighed by the transporter. PIMW must be weighed with a device for which certification has been obtained under the Weights and Measures Act (Ill. Rev. Stat. 1991, ch. 147, pars. 101 et seq.) [225 ILCS 470].
 - 2) PIMW packages must be stored in designated areas so as not to contaminate other waste or materials.
 - 3) Cardboard packages must be stored in an enclosed area at an elevation above that of the floor.

- 4) PIMW must be stored on a surface that allows drainage and collection of liquids and that minimizes exposure to workers and the public.
- 5) Adequate aisle space, as specified in the permit, must be maintained between packages to allow inspection of at least one side of each package. Packages must be stacked so that labels are readable. A vehicle containing PIMW is exempt from the above aisle space requirement:
 - A) When loading or unloading a vehicle; or
 - B) When a fully-loaded vehicle is on a site. Either exemption, or both exemptions, must not exceed five (5) calendar days.
- 6) Material handling equipment must be designed so as to maintain the integrity of the package.
- 7) Signs identifying the storage operation must be prominently displayed at the points of access to the secured storage area. Signs must be marked in lettering that is readable at a minimum distance of five (5) feet. At a minimum, the signs must display the International Biohazard Symbol as shown in 35 Ill. Adm. Code 1421.Illustration A and the word "biohazard".
- 8) Personnel training must be provided to all staff prior to the handling of PIMW. Annual personnel training must include, at a minimum, a thorough explanation of the operating procedures to be taken during normal and emergency situations. The owner or operator shall keep records verifying training of personnel.
- 9) Storage operations must have a written contingency plan and the applicable sections must be implemented in the event of a discharge or personal injury. The contingency plan must describe the actions that personnel shall take in response to emergency situations such as, but not limited to, personal injury, discharges of PIMW, rupture of plastic bags and equipment failure. This contingency plan must, at a minimum, include a list of all emergency equipment at the storage operation, an up-to-date list of names, addresses and phone numbers (office and home) of all persons qualified to act as emergency coordinator, procedures for cleanup, protection of personnel, disposal of spill residue, repackaging of PIMW and alternate arrangements for PIMW storage and transfer. A copy of the contingency plan must be maintained at the storage operation. Emergency phone numbers

and a brief description of the emergency procedures must be posted at the storage operation.

- 10) The owner or operator shall keep a written operating record at the storage operation. At a minimum, the following information must be recorded and maintained in the operating record:
 - A) Quantities and disposition of PIMW stored or transferred;
 - B) Date and time the PIMW arrived at the permitted storage operation site;
 - C) Date and time the PIMW left the storage operation;
 - D) Waste stream permit number (authorization number), if applicable, issued by the Agency;
 - E) Generator name(s), location(s) and if applicable, the generator identification number(s) issued by the Agency for each PIMW load received at the storage operation;
 - F) Temperature(s) the PIMW load was maintained at the storage operation;
 - G) Destination of packages, which must include at a minimum the name of the receiving facility, the location of the receiving facility, the identification number of the receiving facility issued by the Agency (if applicable) and the disposition (i.e., storage, transfer, treatment or disposal); and
 - H) In a separate log, the date, time, nature and extent of all discharges and personal injuries and the date, time, nature and result of any response(s) taken.
- 11) The records required by subsections (b)(8) and (10) of this Section must be retained by and kept at the storage operation and must be made available at the storage operation during normal business hours for inspection and photocopying by the Agency. These records must be kept until closure of the storage operation. The retention period is extended automatically during the course of any unresolved enforcement action regarding the storage operation or as requested in writing by the Agency.
- 12) Unless otherwise authorized by the Agency in the permit, PIMW must not be stored for more than:

- A) Seventy-two (72) hours at the storage operation unless the surface temperature of the package is maintained at or below 45 degrees Fahrenheit, and
 - B) Thirty (30) days at the storage operation regardless of temperature.
- 13) At least sixty (60) days prior to closing a storage operation, the owner or operator shall notify the Agency of the planned closure. Within ninety (90) days after the date the final load of PIMW is received at the storage operation, the owner or operator shall certify to the Agency that final closure has been completed in accordance with the permit, the Act and all applicable regulations promulgated thereunder.

SUBPART C: TREATMENT FACILITIES

Section 1422.120 Scope and Applicability

This Subpart applies to the owner or operator of a facility in Illinois that is designed to treat PIMW to eliminate its infectious potential. This Subpart also applies to owners or operators of treatment facilities where the treated PIMW residual is disposed of in Illinois. For purposes of this Part, a facility or operation that is designed to treat PIMW to eliminate its infectious potential is referred to as a "treatment facility".

Section 1422.121 Treatment Facility Certification

No person shall cause or allow the disposal of any PIMW where the infectious potential has been eliminated by treatment unless the treatment facility certifies to the transporter, if other than the generator, and certifies to the landfill operator or receiving facility operator that the PIMW has been treated in accordance with this Part, and, if applicable, with all terms and conditions specified in its operating permit. Data to verify the efficacy of the treatment unit must be made available to the receiving facility upon request of the receiving facility. No person shall falsely certify that PIMW has been treated in accordance with this Part.

Section 1422.122 Design and Operating Standards

- a) Treatment of PIMW must be conducted in a manner that:
 - 1) **ELIMINATES THE INFECTIOUS POTENTIAL OF THE WASTE.** A treatment process eliminates the infectious potential of PIMW if the owner or operator of a treatment unit demonstrates that an Initial Efficacy Test and Periodic Verification Test have been completed successfully.

EXHIBIT B

- e) a person transporting PIMW to a hospital when the person is a member of the hospital's medical staff.

Section 1450.103 Retention of Records

Copies of all records required to be kept under this Part shall be retained by the transporter for three years and shall be made available at the transporter's principal place of business in Illinois or corporate headquarters during normal business hours for inspection and photocopying by the Agency.

Section 1450.104 Certification of Documents

- a) All records and reports retained by or submitted to the Agency as required by this Part shall be signed by a person responsible for preparing and reviewing such documents as part of his or her duties in the regular course of business.
- b) Any person signing a report submitted to the Agency as required by this Part shall make the following certification:
I certify under penalty of law that this report and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Section 1450.105 Certification of Weight

- a) Although PIMW may be measured in other units, the transporter is responsible for accurately weighing any load of PIMW in pounds.
- b) The PIMW shall be weighed with a device for which certification has been obtained under the Weights and Measures Act (Ill. Rev. Stat. 1991, ch. 147, pars. 101 et seq.) [225 ILCS 470].

Section 1450.106 Severability

If any Section, subsection, sentence or clause of this Part shall be adjudged unconstitutional, void, invalid or otherwise unlawful, such adjudication shall not affect the validity of this Part as a whole or any Section, subsection, sentence or clause thereof not adjudged unconstitutional, void, invalid or otherwise unlawful.

SUBPART B: PROCEDURES FOR MAINTAINING REPORTS

Section 1450.200 Daily PIMW Report

- a) The Daily PIMW Report shall be maintained at the transporter's principal place of business in Illinois or corporate headquarters.
- b) The Daily PIMW Report shall be either on a form provided by the Agency or on another form that records the same information.
- c) The Daily PIMW Report shall include, but not be limited to, the following information for each load of PIMW transported:
 - 1) the date received;
 - 2) the PIMW transport company name;
 - 3) the permitted medical waste hauler number;
 - 4) the PIMW manifest number;
 - 5) the generator name and location (city/state);
 - 6) the designated facility name and location (city/state);
 - 7) the gross weight in pounds of PIMW subject to the PIMW transporter fee;
 - 8) the gross weight in pounds of PIMW exempt from the PIMW transporter fee and the reason for the exemption;
 - 9) the tare weight in pounds;
 - 10) the net weight in pounds of PIMW subject to the PIMW transporter fee;
 - 11) the net weight in pounds of PIMW exempt from the PIMW transporter fee;
 - 12) the grand totals of gross and net weight of PIMW and the grand total of tare weight;
 - 13) the page subtotal, if applicable; and
 - 14) the authorized name, signature and date.
- d) Upon written or oral request of the Agency, the transporter will submit copies of the Daily PIMW Reports covered by the quarter to the Agency with the Quarterly PIMW Report.
- e) Entries on a Daily PIMW Report shall be made contemporaneously with the receipt of each load unless the transporter uses a different method of recording the required information which assures that required information can be entered on the Daily PIMW Report by the end of each business day, in which case the information must be entered in the Daily PIMW Report by the end of each business day. When an alternative method of contemporaneous recording is used, that record must be maintained in accordance with the records retention provisions of Section 1450.103 of this Part.

Section 1450.201 Monthly PIMW Report

- a) The Monthly PIMW Report shall be submitted to the Agency on a form provided by the Agency.

EXHIBIT C



ILLINOIS ENVIRONMENTAL PROTECTION AGENCY

1021 NORTH GRAND AVENUE EAST, P.O. BOX 19276, SPRINGFIELD, ILLINOIS 62794-9276 - (217) 782-3397
JAMES R. THOMPSON CENTER, 100 WEST RANDOLPH, SUITE 11-300, CHICAGO, IL 60601 - (312) 814-6020

ROD R. BLAGOJEVICH, GOVERNOR DOUGLAS P. SCOTT, DIRECTOR

217/524-3300

September 21, 2005

Certified Mail
7002 3150 0000 1254 0596
7002 3150 0000 1254 0602

OWNER:
Waste Management of Illinois, Inc.
Ms. Luci Altieri
720 E. Butterfield Road
Lombard, Illinois 60148

OPERATOR:
Stericycle, Inc.
Ms. Cassie Karas
28161 N. Keith Drive
Lake Forest, Illinois 60045

SITE LOCATION:
Stericycle, Inc.
3801 S. Laramie Street
Cicero, Illinois 60804

Re: 0313000001 -- Cook County
Waste Management Metro Trans
Permit No. 1997-264-DE/OP
Supplemental Permit No. 2005-182-SP
Log No. 2005-182
Permit File

Dear Ms. Altieri and Ms. Karas:

Supplemental permit is hereby granted to Waste Management of Illinois Inc. as owner and Stericycle, Inc. as operator to modify the operation of the solid waste management facility to store and transfer Potentially Infectious Medical Waste (PIMW), consisting of a 40-foot by 55-foot fenced area within 9.27 acres in the Southwest Quarter of the Southeast Quarter of Section 33, Township 39 North, Range 13 East, of the Third Principal Meridian, all in Cook County, Illinois in accordance with the application and plans prepared by Luciane Altieri, P.E. of Waste Management of Illinois, Inc. Final plans, specifications, application and supporting documents as submitted and approved shall constitute part of this permit and are identified in the records of the Illinois Environmental Protection Agency, Bureau of Land by the permit number(s) and log number(s) designated in the heading above.

The application approved by this permit consists of the following documents:

Table with 3 columns: DOCUMENT, DATED, DATE RECEIVED. Row 1: Original Application, May 18, 2005, May 24, 2005. Row 2: Log No. 2005-182

ROCKFORD - 4302 North Main Street, Rockford, IL 61103 - (815) 987-7760 • DES PLAINES - 9511 W. Harrison St., Des Plaines, IL 60016 - (847) 294-4000
ELGIN - 595 South State, Elgin, IL 60123 - (847) 608-3131 • PEORIA - 5415 N. University St., Peoria, IL 61614 - (309) 693-5463
BLOOMINGDALE - 7620 N. University St., Peoria, IL 61614 - (309) 693-5462 • CHAMPAIGN - 2125 South First Street, Champaign, IL 61820 - (217) 278-5800
SPRINGFIELD - 4500 S. Sixth Street Rd., Springfield, IL 62706 - (217) 786-6992 • COLLINSVILLE - 2009 Mall Street, Collinsville, IL 62234 - (618) 346-5120
MARION - 2309 W. Main St., Suite 116, Marion, IL 62959 - (618) 993-7200

Additional Information	June 14, 2005	June 29, 2005
Additional Information	August 17, 2005	August 17, 2005 via fax
Additional Information	September 14, 2005	September 14, 2005 via fax

Specifically, Supplemental Permit No. 2005-182-SP approves the following changes: 1) modification of Condition 12 to require records of storage temperature only when refrigeration is used; 2) modification of Condition 25(b) to clarify manifest procedures; 3) modification of Condition 27 to update citations; and 4) relocation of the transfer dock, in accordance with the Site Plan in the approved application Log No. 2005-182. The portion of the application requesting to modify Condition 15 was withdrawn.

The Agency has withdrawn the portion of your application Log No. 2005-182 that requested a modification of Condition 15 in accordance with Cassie Karas's letter dated September 14, 2005 and received by the Illinois Environmental Protection Agency on September 14, 2005. The complete application is being kept in our files.

The permit is issued subject to the standard conditions attached hereto and incorporated herein by reference, and further subject to the following special conditions. In case of conflict between the application and plans submitted and these special conditions, the special conditions of this permit shall govern.

1. This permit allows for the operation of a solid waste management facility to store and transfer potentially infectious medical waste (PIMW) within the area identified on the map received by this Agency on September 18, 1997 titled 'Exhibit A: Facility Map: Bio-Medical Waste Handling Facility' as the 'Bio-Medical Waste Transfer Handling Facility'.
2. By such date as required by Federal regulations and the Illinois Environmental Protection Agency, Bureau of Water (IEPA-BOW), the operator shall obtain the required permits for stormwater management during construction of this facility, if applicable.
3. This facility may be subject to federal stormwater regulations of 40 CFR 122 for point source discharge upon completion of construction activities. You may contact the IEPA Bureau of Water, Permit Section at the address above.
4. The issuance of this permit does not relieve the Permittee of the responsibility of complying with the provisions of the State of Illinois Rules and Regulations, Title 35: Subtitle C, Water Pollution Control, Chapter 1.

5. This permit is issued with the expressed understanding that no process discharge to Waters of the State or to a sanitary sewer will occur from these facilities, except as authorized by a permit from the IEPA Bureau of Water (BOW).
6. The Permittee shall notify the Agency of any changes from the information submitted to the Agency in its application for a Development and Operating permit for this site. The Permittee shall notify the Agency of any changes in the names or addresses of both beneficial and legal titleholders to the herein-permitted site. Such notification shall be made in writing within fifteen (15) days of such change and shall include the name or names of any parties in interest and the address of their place of abode; or, if a corporation, the name and address of its registered agent. Any modification to the facility shall be the subject of an application for a supplemental permit for this facility.
7. Site surface drainage, during development, during operation, and after the site is closed, shall be such that no adverse effects are encountered by adjacent property owners.
8. The best available technology (mufflers, berms and other sound shielding devices) shall be employed to minimize equipment noise impacts on property adjacent to the site during both development and operation.
9. The Permittee may receive and transfer PIMW at the site 24 hours a day.
10. Fire safety equipment (fire extinguishers) shall be maintained in accordance with recommended practice.
11. A vector control specialist shall inspect the PIMW transfer station facility at least quarterly. If necessary, vector control measures shall be taken. The results of these inspections shall be maintained as part of the facility operating record and shall be made available to the Agency upon written or verbal request.
12. The Permittee shall maintain the following information in the PIMW facility operating record:
 - a. Quantities of PIMW stored and transferred.
 - b. Date and time the PIMW was placed into storage (i.e., arrived at the facility).
 - c. Date and time the PIMW left the storage operation.
 - d. Waste stream permit number, if applicable.

- e. Temperature at which the PIMW was maintained while refrigerated, in accordance with 35 Ill. Adm. Code 1422.111(a)(2).
 - f. The destination of the waste, including the name, address and Illinois ID number of the receiving facility.
 - g. In a separate log, date, time, nature, and extent of all discharges and personal injuries and the results of any response taken.
 - h. Records of annual personnel training.
 - i. Records of inspections.
13. PIMW shall be stored in designated areas so as not to contaminate other waste or materials. All cardboard packages shall be stored in an enclosed area at an elevation above that of the floor.
14. PIMW shall be stored and transferred on a surface that allows for decontamination, drainage and collection of liquids and that minimizes exposure of PIMW to workers and the public.
15. The Permittee shall weigh in pounds the amount of PIMW received, unless previously weighed by the transporter. PIMW must be weighed with a device for which certification has been obtained under the Weights and Measures Act (Ill. Rev. Stat. 1991, ch. 147, pars 101 et seq.)[225 ILCS 470].
16. The Permittee shall screen PIMW containers upon arrival at the facility for radioactive materials.
17. The Permittee shall use the following container management practices at this PIMW facility:
- a. Containers must be stored in a manner which prevents compaction or rupture of containers;
 - b. Containers shall not be stacked more than ten (10) feet high;
 - c. Containers may not be opened at this facility. Any situation which results in opening or rupture of a container or where a container is leaking shall require implementation of the contingency plan in the approved permit application.

18. PIMW shall remain at this site no longer than:
 - a. seventy-two (72) hours without refrigeration;
 - b. five (5) days without at least two (2) feet of aisle space between packages so that at least one (1) side of each package and its readable labels may be inspected;
 - c. a maximum of thirty (30) days with refrigeration and aisle space.
19. The Permittee shall prominently display signs at the entrance to the PIMW transfer and storage area. The signs must be marked in lettering that is readable at a distance of 5 feet. At a minimum, the sign must display the international biohazard symbol and the word "biohazard."
20. The Permittee shall conduct annual training to explain the daily operating procedures for the storage and transfer of PIMW and contingency plan. This training shall be given to all personnel that manage PIMW.
21. The owner/operator shall keep and make available for Agency inspection:
 - a. Records describing the amount of PIMW accepted for storage and transfer.
 - b. Records required by 35 Ill. Adm. Code 1422.111(b)(10) of the Act.
22. The Permittee shall maintain the surface of the PIMW management area so that it remains impervious.
23. The outdoor storage areas containing PIMW shall be secured against unauthorized access.
24. PIMW packages shall be stored and transferred in a manner and location which maintains the integrity of the packaging and provides protection from water, rain and wind.
25. The Permittee shall comply with the following manifesting requirements:
 - a. In order to implement the requirements of 35 Ill. Adm. Code 1420.104(d), the Permittee shall not accept any PIMW for storage/transfer at this facility which is not accompanied by a properly completed manifest. A properly completed manifest is one which:
 - i. complies with the Illinois EPA's current instructions for completing manifests;
 - ii. identifies the original waste generator or a permitted facility as the waste generator;
and

- iii. identifies the Permittee on the manifest as the designated facility.
 - b. In order to implement the requirements of 35 Ill. Adm. Code 1420.104(d), the Permittee shall not transport from this facility, any waste stored/transferred at this facility unless the waste is accompanied by a properly completed manifest which indicates the generator of the waste.
 - c. In accordance with 35 Ill. Adm. Code 1422.111(a)(10), the Permittee shall retain copies of all manifests for all wastes stored/transferred at this facility or transported from this facility.
26. All loading/unloading of PIMW shall be accomplished within the permitted paved PIMW area.
 27. Only waste which meets the definition of PIMW as defined in 35 Ill. Adm. Code 1420.102 or Regulated medical waste as defined in 29 CFR 1910.1030, or 49 CFR 173.134 may be accepted. This unit is not permitted to receive any RCRA Hazardous Waste, Radioactive Waste, or Asbestos Waste.
 28. The PIMW transfer facility shall be inspected daily to ensure compliance with Title XV of the Act.
 29. All rejected containers of PIMW shall be removed from the site within 24 hours of receipt in accordance with manifest requirements.
 30. All PIMW shall be subject to the fee structure in accordance with 35 Illinois Administrative Code 1450.
 31. Any modification to the PIMW facility beyond those approved by this permit shall be the subject of an application for supplemental permit for site modification submitted to this Agency.
 32. This permit is subject to review and modification by the Agency as deemed necessary to fulfill the intent and purpose of the Environmental Protection Act, and all applicable environmental rules and regulations.
 33. After the final volume of waste is transferred, closure must be conducted in accordance with 35 Ill. Adm. Code 1420.107 and the approved permit application. The operator shall notify the Agency of its plan to initiate closure and implement the closure plan within 30 days after receiving the final volume of waste.

34. The Permittee shall review the approved closure plan to insure it complies with the standard identified in 35 Ill. Adm. Code 1420.107 at least 180 days prior to initiating closure of the facility. If a closure plan modification is required, the operator shall not file any application to modify the closure plan less than 150 days prior to receipt of the final volume of waste.
35. Upon completion of closure activities, the operator will notify the Agency that the site has been closed in accordance with the approved closure plan utilizing the Agency's "Affidavit for Certification of Completion of Closure of Non-Hazardous Waste Facilities" included as Attachment 2 to this permit.
36. The contingency plan must be submitted to all emergency response units within 30 days of the date of issuance of this permit.

The original and two (2) copies of all certifications, logs or reports and three (3) copies of groundwater monitoring chemical analysis forms which are required to be submitted to the Agency by the permittee should be mailed to the following address:

Illinois Environmental Protection Agency
Planning and Reporting Section
Bureau of Land -- #33
1021 North Grand Avenue East
Post Office Box 19276
Springfield, Illinois 62794-9276

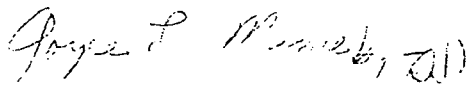
Within 35 days after the notification of the final permit decision, the applicant may petition for a hearing before the Illinois Pollution Control Board to contest the decision of the Agency, however, the 35-day period for petitioning for a hearing may be extended for a period of time not to exceed 90 days by written notice provided to the Board from the applicant and the Agency within the 35-day initial appeal period.

Work required by this permit, your application or the regulations may also be subject to other laws governing professional services, such as the Illinois Professional Land Surveyor Act of 1989, the Professional Engineering Practice Act of 1989, the Professional Geologist Licensing Act, and the Structural Engineering Licensing Act of 1989. This permit does not relieve anyone from compliance with these laws and the regulations adopted pursuant to these laws. All work that falls within the scope and definitions of these laws must be performed in compliance with

Page 8

them. The Illinois EPA may refer any discovered violation of these laws to the appropriate regulating authority.

Sincerely,


Joyce L. Munie, P.E.
Manager, Permit Section
Bureau of Land

JLM:BG^{JD}A:bjh\051031s.doc

Attachment: Standard Conditions

STANDARD CONDITIONS FOR CONSTRUCTION/DEVELOPMENT PERMITS
ISSUED BY THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY
BUREAU OF LAND

August 22, 2001

The Illinois Environmental Protection Act (Illinois Revised Statutes, Chapter 111-1/2, Section 1039) grants the Environmental Protection Agency authority to impose conditions on permits which it issues.

These standard conditions shall apply to all permits which the Agency issues for construction or development projects which require permits under the Bureau of Land. Special conditions may also be imposed in addition to these standard conditions.

1. Unless this permit has been extended or it has been voided by a newly issued permit, this permit will expire two years after date of issuance unless construction or development on this project has started on or prior to that date.
2. The construction or development of facilities covered by this permit shall be done in compliance with applicable provisions of Federal laws and regulations, the Illinois Environmental Protection Act, and Rules and Regulations adopted by the Illinois Pollution Control Board.
3. There shall be no deviations from the approved plans and specifications unless a written request for modification of the project, along with plans and specifications as required, shall have been submitted to the Agency and a supplemental written permit issued.
4. The permittee shall allow any agent duly authorized by the Agency upon the presentation of credentials:
 - a. to enter at reasonable times the permittee's premises where actual or potential effluent, emissions or noise sources are located or where any activity is to be conducted pursuant to this permit.
 - b. to have access to and copy at reasonable times any records required to be kept under the terms and conditions of this permit.
 - c. to inspect at reasonable times, including during any hours of operation of equipment constructed or operated under this permit, such equipment or monitoring methodology or equipment required to be kept, used, operated, calibrated and maintained under this permit.
 - d. to obtain and remove at reasonable times samples of any discharge or emission of pollutants.

- e. to enter at reasonable times and utilize any photographic, recording, testing, monitoring or other equipment for the purpose of preserving, testing, monitoring, or recording any activity, discharge, or emission authorized by this permit.
5. The issuance of this permit:
- a. shall not be considered as in any manner affecting the title of the premises upon which the permitted facilities are to be located;
 - b. does not release the permittee from any liability for damage to person or property caused by or resulting from the construction, maintenance, or operation of the proposed facilities;
 - c. does not release the permittee from compliance with other applicable statutes and regulations of the United States, of the State of Illinois, or with applicable local laws, ordinances and regulations;
 - d. does not take into consideration or attest to the structural stability of any units or parts of the project;
 - e. in no manner implies or suggests that the Agency (or its officers, agents or employees) assumes any liability, directly or indirectly, for any loss due to damage, installation, maintenance, or operation of the proposed equipment or facility.
6. Unless a joint construction/operation permit has been issued, a permit for operating shall be obtained from the Agency before the facility or equipment covered by this permit is placed into operation.
7. These standard conditions shall prevail unless modified by special conditions.
8. The Agency may file a complaint with the Board for modification, suspension or revocation of a permit:
- a. upon discovery that the permit application contained misrepresentations, misinformation or false statements or that all relevant facts were not disclosed; or
 - b. upon finding that any standard or special conditions have been violated; or
 - c. upon any violation of the Environmental Protection Act or any Rule or Regulation effective thereunder as a result of the construction or development authorized by this permit.

EXHIBIT D



State of Wisconsin
Jim Doyle, Governor

Department of Agriculture, Trade and Consumer Protection

Rod Nilsestuen, Secretary
Wisconsin Weights and Measures Laboratory

Test Date: July 6, 2005
Report Date: July 6, 2005

State Test No.: W05-214
Set Serial No.: Individual

Calibration Report

Koehler Scale, Inc.
3475 Nemesis Ave.
Waukegan, IL 60087
Contact: Mark Gruber
Phone: (847) 336-7883
PO Number: None

Item(s) Submitted: Cast Test Weights
Manufacturer: Assorted
Specification: NIST Handbook 105-1
Balance ID#: 08 & 10
Condition: Fair to Good
Temperature: 25.°C
Relative Humidity: 49. %
Pressure: 740.mmHg

Nominal Value	lb	Serial No.	Correction (mg)		Handbook 105-1 Class		Unc. (mg) (k=2)
			As Found	As Left	As Found	As Left	
500	lb		-2900.	-2900.	F	F	4314.
500	lb		-2200.	-2200.	F	F	4314.
500	lb		32000.	7800.	*	F	4314.
500	lb		10200.	10200.	F	F	4314.
50	lb	J200	40.	1350.	F	F	307.5
50	lb	W742	-2580.	850.	*	F	307.5
50	lb	O7R8	150.	320.	F	F	307.5
50	lb	N30	-1910.	2000.	F	F	307.5
50	lb	N34	110.	1500.	F	F	307.5
50	lb	O7R6	130.	520.	F	F	307.5
50	lb	O7R5	-1380.	890.	F	F	307.5
50	lb	W735	-760.	210.	F	F	307.5
50	lb	N36	-650.	1660.	F	F	307.5
50	lb	O7R9	190.	570.	F	F	307.5
50	lb	J196	-1510.	1070.	F	F	307.5
50	lb	O7R7	-100.	1920.	F	F	307.5
50	lb	O7R2	-60.	610.	F	F	307.5
50	lb	O7R0	-280.	880.	F	F	307.5

* Weight(s) as found exceed NIST Handbook 105 Class F tolerance.

The corrections listed are expressed in terms of "apparent mass versus density 8.0 g/cm³". Correction for the weights were determined using electronic balances and by direct comparison to Wisconsin State Standards. The accuracy of all balances and standards have been verified using standards traceable to NIST.

The Wisconsin state laboratory is a participant in the NIST Weights and Measures Measurement Assurance Program. The State Standards are traceable to NIST and the laboratory maintains measurement proficiency through training and interlaboratory comparisons.

WISCONSIN WEIGHTS AND MEASURES

Warren R. ...
STATE METROLOGIST

Agriculture generates \$51.5 billion for Wisconsin

PO Box 7883 • Madison, WI 53707-7883 • 608-267-3510 • Wisconsin.gov



State of Wisconsin
Jim Doyle, Governor

Department of Agriculture, Trade and Consumer Protection
Rod Nilsestuen, Secretary
Wisconsin Weights and Measures Laboratory

Test Date: July 6, 2005
Report Date: July 6, 2005

State Test No.: W05-214
Set Serial No.: Individual

Calibration Report

Koehler Scale, Inc.
3475 Nemesis Ave.
Waukegan, IL 60087
Contact: Mark Gruber
Phone: (847) 336-7883
PO Number: None

Item(s) Submitted: Cast Test Weights
Manufacturer: Assorted
Specification: NIST Handbook 105-1
Balance ID#: 08 & 10
Condition: Fair to Good
Temperature: 25.0°C
Relative Humidity: 49. %
Pressure: 740. mmHg

Nominal Value	Serial No.	Correction (mg)		Handbook 105-1 Class		Unc. (mg) (k=2)
		As Found	As Left	As Found	As Left	
50 lb	N37	-390.	-390.	F	P	307.5
50 lb	W738	-1140.	-1140.	F	F	307.5
50 lb	O7R1	-380.	-380.	F	F	307.5
50 lb	J202	-190.	-190.	F	F	307.5
50 lb	J198	-510.	-510.	F	F	307.5
50 lb	N31	-10.	-10.	F	F	307.5
50 lb	O7R4	-1810.	-1810.	F	F	307.5
50 lb	W739	-880.	-880.	F	F	307.5
50 lb	O7R5	-280.	-280.	F	F	307.5
50 lb	W733	-760.	-760.	F	F	307.5
50 lb	N33	-790.	-790.	F	F	307.5
50 lb	J197	-1510.	-1510.	F	F	307.5
50 lb	W740	-640.	-640.	F	F	307.5
50 lb	W741	280.	280.	F	F	307.5
50 lb	N39	1970.	1970.	F	F	307.5
50 lb	N35	-440.	-440.	F	F	307.5
50 lb	J195	-360.	-360.	F	F	307.5
50 lb	J201	-1320.	-1320.	F	F	307.5

The corrections listed are expressed in terms of "apparent mass versus density 8.0 g/cm³". Correction for the weights were determined using electronic balances and by direct comparison to Wisconsin State Standards. The accuracy of all balances and standards has been verified using standards traceable to NIST.

The Wisconsin state laboratory is a participant in the NIST Weights and Measures Measurement Assurance Program. The State Standards are traceable to NIST and the laboratory maintains measurement proficiency through training and interlaboratory comparisons.

WISCONSIN WEIGHTS AND MEASURES

STATE METROLOGIST

Agriculture generates \$51.5 billion for Wisconsin

PO Box 7883 • Madison, WI 53707-7883 • 608-267-3510 • Wisconsin.gov



State of Wisconsin
Jim Doyle, Governor

Department of Agriculture, Trade and Consumer Protection
Rod Nilsestuen, Secretary
Wisconsin Weights and Measures Laboratory

Test Date: July 6, 2005
Report Date: July 6, 2005

State Test No.: W05-214
Set Serial No.: Individual

Calibration Report

Koehler Scale, Inc.
3475 Nemesis Ave.
Waukegan, IL 60087
Contact: Mark Gruber
Phone: (847) 336-7883
PO Number: None

Item(s) Submitted: Cast Test Weights
Manufacturer: Assorted
Specification: NIST Handbook 105-1
Balance ID#: 08 & 10
Condition: Fair to Good
Temperature: 25.°C
Relative Humidity: 49. %
Pressure: 740.mmlHg

Nominal Value	lb	Serial No.	Correction (mg)		Handbook 105-1 Class		Unc. (mg) (k=2)
			As Found	As Left	As Found	As Left	
50	lb	W736	-130.	-130.	F	F	307.5
50	lb	N32	-1040.	-1040.	F	F	307.5
50	lb	J199	-1720.	-1720.	F	F	307.5
50	lb	W734	-300.	-300.	F	F	307.5
50	lb	J193	-1240.	-1240.	F	F	307.5
50	lb	J194	-1460.	-1460.	F	F	307.5
50	lb	W737	-550.	-550.	F	F	307.5
50	lb	N38	-830.	-830.	F	F	307.5
25	lb	25C	30.	30.	F	F	266.368
25	lb	25A	1590.	930.	*	F	266.368
25	lb	25B	500.	500.	F	F	266.368

* Weight(s) as found exceed NIST Handbook 105 Class F tolerance.

The corrections listed are expressed in terms of "apparent mass versus density 8.0 g/cm³". Correction for the weights were determined using electronic balances and by direct comparison to Wisconsin State Standards. The accuracy of all balances and standards has been verified using standards traceable to NIST.

The Wisconsin state laboratory is a participant in the NIST Weights and Measures Measurement Assurance Program. The State Standards are traceable to NIST and the laboratory maintains measurement proficiency through training and interlaboratory comparisons.

WISCONSIN WEIGHTS AND MEASURES

[Signature]
STATE METROLOGIST

Agriculture generates \$51.5 billion for Wisconsin

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EXHIBIT E

STATE OF ILLINOIS



DEPARTMENT OF AGRICULTURE

Registration Number: 0014
Expires: February 28, 2007

Bureau of Weights and Measures

Registered Service Company Certificate of Registration

This is to certify that the named company has met all requirements
for registration with this office for weighing devices.

Issued To:

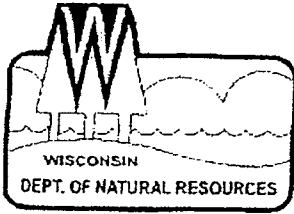
KOEHLER SCALE, INC
3475 NEMESIS
WAUKEGAN, IL 60087

Charles J. Forster
Director,
Department of Agriculture

LM10.015A

01/24/04 0011 0017

EXHIBIT F



State of Wisconsin | DEPARTMENT OF NATURAL RESOURCES

Tommy G. Thompson, Governor
George E. Meyer, Secretary
Gloria L. McCutcheon, Regional Director

Southeast Region Annex
4041 North Richards Street
PO Box 12436
Milwaukee, Wisconsin 53212-0436
Telephone 414-229-0800
FAX 414-229-0810

October 24, 2000

FID #: 252138260
Racine County
SW/ APPR

Mr. Joel P. Wilson
Vice President, Operations
Stericycle
28161 N. Keith Drive
Lake Forest, IL 60045

SUBJECT: Modification to the Plan of Operation Approval, Stericycle Inc., Yorkville, WI
Solid Waste (infectious waste) Processing Facility, License # 3550.

Dear Mr. Wilson:

I am pleased to inform you that your requested modifications to your Plan of Operation Approval have been reviewed and approved. The Department believes that the proposed modifications will not have an adverse effect on the performance of your processing facility provided the conditions in the enclosed conditional Plan Modification Approval are fulfilled. You should attach this conditional Plan Modification Approval directly to the Plan of Operation Approval issued on December 17, 1992.

The proposal includes a revised design of the processing equipment. The revised design consists of more automated, continuous processing of infectious waste. The process will still use the Electro-Thermal Destruction (ETD) method to disinfect the infectious waste. The change from a batch process to a continuous flow process results in changes to previous approval conditions. This approval contains a table (Attachment #1) that identifies the status of conditions issued for the facility. A condition of this approval also prohibits Stericycle from storing untreated infectious waste in the building when the facility is not in operation.

As a reminder, a construction documentation report is required in condition #25 of the December 17, 1992 Plan of Operation Approval. Operation of the facility may not commence until the construction documentation report is approved.

Please call Mark Stohl at (414) 884-2340, Ken Hein at (414) 229-0843 or Amalendu Bagchi at (608) 267-7576 if you have any questions regarding this approval.

Sincerely,

Frances M. Koonce
Frances Koonce, Waste Sub Team Supervisor
Waste Management Program
Southeast Region

cc: Mark Stohl - SER Sturtevant Service Center
Ken Hein - SER Annex
Amalendu Bagchi - Madison, WA/3
Jeanie Druckenmiller - Madison, DHFS

Quality Natural Resources Management
Through Excellent Customer Service



BEFORE THE
STATE OF WISCONSIN
DEPARTMENT OF NATURAL RESOURCES

CONDITIONAL PLAN OF OPERATION
APPROVAL MODIFICATION FOR THE
STERICYCLE, INC. SOLID WASTE (INFECTIOUS WASTE) PROCESSING FACILITY
(LICENSE # 3550)

FINDINGS OF FACT

The Department finds:

1. Stericycle owns and operates a solid waste (infectious waste) processing facility located in the SW 1/4, of the NE 1/4 of section 24, T3N, R21E, Town of Yorkville, Racine County, Wisconsin.
2. The Department issued a conditional Plan of Operation Approval for the facility on December 17, 1992.
3. The facility was severely damaged due to a fire on June 21, 2000.
4. Stericycle submitted a proposal dated July 25, 2000 requesting permission to rebuild the facility. The proposal included a revised design of the processing equipment. The revised design consisted of more automated, continuous processing of the infectious waste. The process will still use the Electro Thermal Destruction (ETD) method to disinfect the infectious waste.
5. The Department on August 10, 2000 received the \$3000.00 plan review fee.
6. The following additional documents were considered in connection with the modification:
 - a. A report dated August 22, 2000 containing additional information regarding process flow etc.
 - b. Plan of Operation Approval dated December 17, 1992
 - c. Plan Modification Approval dated October 18, 1993.
 - d. Site Construction Documentation approval dated November 17, 1993.
 - e. Plan Modification Approval dated December 12, 1994.
 - f. Plan Modification Approval dated February 5, 1996.
 - g. Plan Modification Approval dated August 14, 1996.
 - h. A letter from Stericycle to WDNR dated November 11, 1996 regarding process monitoring
 - i. Plan Modification Approval dated June 30, 1999.
 - j. Plan Modification Approval dated August 30, 1999.

- k. A letter from Linda Lee of Stericycle to Gene Mitchell of WDNR dated May 3, 1993 regarding air monitoring.
 - h. A letter from Linda Lee of Stericycle to Lakshmi Sridharan of WDNR dated July 22, 1993 regarding volatile organic compound testing.
8. The special condition set forth below are needed to assure that the processing facility is designed and operated in accordance with applicable portions of NR 500-536, Wis. Adm. Code. If the special conditions are complied with, the proposed modifications will not inhibit compliance with the standards set forth in the applicable portions of chs. NR 500-536, Wis. Adm. Code.

CONCLUSIONS OF LAW

1. The Department has authority under s. 289.30(8)(b) Stats., to modify a Plan of Operation Approval if the modification would not inhibit compliance with the applicable portions of chs. NR 500-536, Wis. Adm. Code.
2. The Department has authority to approve a plan of operation with special conditions if the conditions are needed to ensure compliance with the applicable portions of chs. NR 500-536, Wis. Adm. Code.
3. The conditions of approval set forth below are needed to ensure compliance with the applicable portions of chs. NR 500-536, Wis. Adm. Code.
4. In accordance with the foregoing, the Department has authority under s. 289.30 Stats., to issue the following conditional Plan of Operation Approval modification.

CONDITIONAL PLAN OF OPERATION APPROVAL MODIFICATION

The Department hereby approves the proposed modification to the December 17, 1992 Plan of Operation Approval and subsequent Plan Modification Approvals for the Stericycle solid waste (infectious waste) processing facility subject to the following conditions:

General

1. Condition 1 of the Plan of Operation Approval is hereby rescinded and replaced by the following:

"This approval allows for one Electro Thermal Deactivation (ETD) treatment unit, with an approved capacity of 25.7 million pounds per year".
2. Condition 3 of the Plan of Operation Approval is hereby rescinded and replaced by the following:

"All items of construction shall be completed as described in the plan of operation modification reports and drawings dated July 25, 2000 and August 22, 2000. Any significant design changes must first be approved by the Department in writing prior to implementing those changes".

3. Condition 1 of the October 18, 1993 Plan Modification Approval is hereby rescinded and replaced by the following:
"At least 50 test strips shall be tested during the shakedown period. At least a 6-log kill of Bacillus Subtilis spores shall be consistently demonstrated prior to ending the shakedown period. Because of the potential for false positives, at least 95% of the test strips must demonstrate a 6-log kill of Bacillus Subtilis spores."
4. Condition 1 of the February 5, 1996 Plan Modification Approval is hereby rescinded.

Operation

5. Condition 9 of the Plan of Operation Approval is hereby rescinded and replaced by the following:
"Operations at the facility shall follow the plan modification reports dated July 25, 2000 and August 22, 2000, conditions of this approval, applicable conditions of previous approvals and applicable portions of chs. NR 500 - 536, Wis. Adm. Code."
6. Condition 10 of the Plan of Operation Approval is hereby rescinded and replaced by the following:
"The disinfected waste shall be disposed of either at the Metro Recycling and Disposal Facility in Franklin, Wisconsin or at the Pheasant Run Landfill in Bristol, Wisconsin. Stericycle shall obtain approval from the Department prior to disposing the disinfected waste in any other landfill".
7. Condition 12 of the Plan of Operation Approval is hereby rescinded.
8. Condition 14 of the Plan of Operation Approval is hereby rescinded and replaced by the following:
"Stericycle shall follow the approved contingency plan regarding scheduled maintenance or breakdown of the facility".
9. Condition 2 of the October 18, 1993 Plan Modification Approval is hereby rescinded and replaced by the following:
"The processing temperature shall be 95^o C or more and the infectious waste shall be processed for a sufficient length of time to achieve a 6-log kill of Bacillus Subtilis spores".
10. The ETD unit shall be cleared of all treated infectious waste any time the continuous process is scheduled to be interrupted for 2 hours or more.
11. Untreated infectious waste containers shall not be placed on the loading conveyor belt any time the continuous process is scheduled to be interrupted for 2 hours or more.

Monitoring

12. Condition 3 of the October 18, 1993 Plan Modification Approval is hereby rescinded.

13. Condition 20 of the Plan of Operation Approval is hereby rescinded and replaced by the following:
"Stericycle shall propose additional monitoring parameters which will demonstrate that the routine processing time is within the range established during the shakedown test. This information must be submitted at least 15 days before the shakedown tests are performed".
14. Condition 2 of the February 5, 1996 Plan Modification Approval is hereby rescinded and replaced by the following:
"A minimum of one test strip containing at least 6 log Bacillus Subtilis spores shall be tested once every 50 hours the ETD unit is in operation. The test strip shall be tested along with the regular processing of the infectious waste for the same temperature and retention time routinely used for disinfecting the infectious waste. Based on the test results obtained during the first year of operation the Department may revert to the microbiological testing frequency indicated in s. NR 526.12(4)(b) Wis. Adm. Code".
15. Condition 3 of the February 5, 1996 Plan Modification is hereby rescinded and replaced by the following:
"Microbiological testing required in condition 14 of this approval shall be summarized and reported to the Department on a monthly basis by the 10th day of the following month".
16. Condition 23 of the Plan of Operation Approval is hereby rescinded.
17. Condition 24 of the Plan of Operation Approval is hereby rescinded and replaced by the following:
"The exhaust air, after passing through the HEPA filter, shall be tested for pathogens using the method described in the May 3, 1993 letter from Linda Lee of Stericycle to Gene Mitchell of WDNR. The Department may approve an alternate-testing program. The test shall be done within 180 days from the date the ETD unit starts processing infectious waste. The Department shall be informed at least 20 working days prior to the tests so that a Department representative can witness the testing. Results of this test shall be reported to the Department within 60 days from the date of completion of the test".
18. Stericycle shall test VOC at the following two locations: a) within 5 feet of the washing unit; b) within 5 feet of the compactor housing. Method described in the July 22, 1993 letter from Linda Lee of Stericycle to Lakshmi Sridharan of WDNR shall be used for these tests. The Department may approve an alternate-testing program. The tests shall be conducted when the testing location is being actively used. The tests shall be done within 180 days from the date the ETD unit starts processing infectious waste. The Department shall be notified at least 20 working days prior to the VOC tests required in condition #18, so that a Department representative can witness the testing. Results of these tests shall be reported to the Department within 60 days from the date of completion of the tests.

The Department retains the jurisdiction either to require the submittal of additional information or to modify this approval at any time, if, in the Department's opinion, further modifications are necessary. Unless specifically noted, the conditions of this approval do not supersede or replace any previous conditions of approval for this facility.

NOTICE OF APPEAL RIGHTS

If you believe that you have a right to challenge this decision, you should know that Wisconsin statutes and administrative rules establish time periods within which requests to review Department decisions must be filed.

For judicial review of decision pursuant to sections 227.52 and 227.53, Stats., you have 30 days after the decision is mailed, or otherwise served by the Department, to file your petition with the appropriate circuit court and serve the petition on the Department. Such a petition for judicial review shall name the Department of Natural Resources as the respondent.

This notice is provided pursuant to section 227.48(2), Stats.

Dated: 10/24/00

DEPARTMENT OF NATURAL RESOURCES
For the Secretary,

Frances M. Koonce
Frances Koonce, Sub Team Supervisor
Southeast Region Waste Management Program

Amalendu Bagchi by MK
Amalendu Bagchi, Waste Management Engineer
Technical Support Section
Bureau of Waste Management

Kenneth Hein
Kenneth Hein, Waste Management Specialist
Southeast Region Waste Management Program

Mark Stohl by AS
Mark Stohl, Waste Management Engineer
Southeast Region Waste Management Program

**STERICYCLE OCTOBER 24, 2000 PLAN MODIFICATION APPROVAL
 ATTACHMENT #1
 CONDITIONS OF APPROVAL STATUS**

DATE	APPROVAL TYPE	Cond. #	DESCRIPTION	STATUS
12/17/92	Plan of Operation	1	Approved design capacity	Superseded by October 24, 2000 Approval Condition # 1
		2	Follow OSHA and other Federal and State safety standards	Active
		3	Follow plans submitted on July, 30 1992	Superseded by October 24, 2000 Approval Condition # 2
		4	Shakedown testing protocols	Superseded by October 18, 1993 Approval Condition # 1
		5	Emission testing	Superseded by February 5, 1996 Approval Condition # 1
		6	Pre-shakedown meeting	Active
		7	Construction Inspection schedule	Active
		8	Acceptable Waste types	Active
		9	Follow Plans and DNR Guidance	Superseded by October 24, 2000 Approval Condition # 5
		10	Kestrel Hawk Park - approved landfill for treated waste	Superseded by October 24, 2000 Approval Condition # 6
		11	Accept only properly packaged containers	Active
		12	Refrigerate waste not processed by end of day	Superseded by October 24, 2000 Approval Condition # 7
		13	Don't open containers prior to processing	Active
		14	Submit waste routing contingency plan	Superseded by October 24, 2000 Approval Condition # 8
		15	Replace filters @ > 700 Pa pressure	Active
		16	Trained operators perform processing	Active
		17	Maintain records on operator training	Active
		18	90C processing temperature	Superseded by October 18, 1993 Approval Condition # 2
		19	Weekly sampling of pre and post treated materials	Superseded by October 18, 1993 Approval Condition # 3
		20	Record temp. and retention time for each tub	Superseded by October 24, 2000 Approval Condition # 13
		21	Perform #19 testing for 1 year	Superseded by February 5, 1996 Approval Condition # 2
		22	Schedule for reporting initial kill efficiency data	Superseded by February 5, 1996 Approval Condition # 3
		23	Schedule for submitting emission data	Superseded by October 24, 2000 Approval Condition # 16
		24	Ambient air pathogen testing	Superseded by October 24, 2000 Approval Condition # 17
		25	Submit as-built	Active
		26	Annual Report contents	Active
10/18/93	Plan Modification	1	Revised shakedown testing Protocols	Superseded by October 24, 2000 Approval Condition # 3
		2	95C temp and 95% kill efficiency	Superseded by October 24, 2000 Approval Condition # 9
		3	Efficiency testing protocol	Superseded by October 24, 2000 Approval Condition # 12
11/17/93	Construction Documentation	1	Submit biological test results weekly	Superseded by February 5, 1996 Approval Condition # 3
		2	Notify SER 2 weeks prior to annual Fire Drill	Active

DATE	APPROVAL TYPE	Cond. #	DESCRIPTION	STATUS
11/17/93	Construction Documentation	3	Air monitoring protocols	Inactive
12/12/94	Plan Modification	1	Operate air scrubber as installed	Inactive
		2	Submit air scrubber & compactor as-built	Inactive
2/5/96	Plan Modification	1	Rescinding of December 17, 1992 Approval Air monitoring conditions # 5 and 24	Superseded by October 24, 2000 Approval Condition # 4
		2	Spore testing every 100 hours of operation	Superseded by October 24, 2000 Approval Condition # 14
		3	Summarize spore test results in annual report	Superseded by October 24, 2000 Approval condition # 15
		4	Notify SER within 2 days of spore test failure	Active
		4	Perform shakedown test if 2 consecutive spore test failures	Active
		5	Soak time reduced from 2 hours to 1 hour	Active
		6	Report ETD hours of operation in annual report	Active
8/14/96	Plan Modification	1	Store only non-hazardous pharmaceuticals	Active
		2	Clearly mark pharmaceutical storage area	Active
		3	Pharmaceutical storage less than 90 days	Active
		4	Pharmaceuticals < 5% of total waste received	Active
		5	Submit as-built of sharps storage area	Active
		6	Submit spill plan for sharps handling area	Active
11/19/96	Other	1	Record incubator temperature	Active
		2	Use stop watch to record RF oven operation	Inactive
		3	Note recock vessels on partlow chart	Inactive
		4	Weekly spore testing schedule	Active
		5	Additions to 1996 Annual report	Active
6/30/99	Plan Modification	1	Submit as-built drawings loading chute and process room access improvements	Inactive
8/50/99	Plan Modification	1	Notify steri-med unit installation & removal	Active

EXHIBIT G

ILLINOIS POLLUTION CONTROL BOARD
June 17, 1993

IN THE MATTER OF:)
)
POTENTIALLY INFECTIOUS MEDICAL)
WASTE (PIMW): TREATMENT, STORAGE,) R91-20
AND TRANSFER FACILITIES and) (Rulemaking)
TRANSPORTATION, PACKAGING, AND)
LABELING (35 Ill. Adm. Code)
1420, 1421, and 1422))

Adopted Rule.

Final Action.

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

This matter comes before the Board upon the mandates of the Illinois General Assembly that the Board (1) adopt rules regulating facilities for the treatment, storage, and transfer of potentially infectious medical waste (PIMW) and (2) adopt standards for the transportation, packaging, and labeling of PIMW¹. Today the Board adopts amendments to 35 Ill. Adm. Code Part 1420 and new Parts 1421 and 1422 to meet these legislative mandates.

The Board is charged under the Illinois Environmental Protection Act (Act) to "determine, define and implement the environmental control standards applicable in the State of Illinois"². The Board is thereby responsible for promulgating the State's substantive environmental regulations, such as represented by today's action. More generally, the Board's rulemaking authority is based on the system of checks and balances integral to Illinois environmental governance: the Board is charged with the rulemaking and principal adjudicatory functions and the Illinois Environmental Protection Agency (Agency) is charged with carrying out the principal administrative functions.

Today's regulations closely follow the recommendations of the Governor's Medical Waste Tracking Study Group (Study Group) as that group's consensus has been proposed to the Board by the Agency. Today's regulations also are identical to the regulations adopted for second notice, with the exception of a modification at subsection 1422.122(a)(1) and several format and nonsubstantive modifications made at the recommendation of the Joint Committee on Administrative Rules (JCAR).

¹ The mandates occur at Section 56.2 of the Illinois Environmental Protection Act (Act), 415 ILCS 5/1 et seq.

² Act at Section 5(b).

0143-0263

The Board wishes to acknowledge the special contributions made to this proceeding by staff scientist LouAnn Burnett in her roles as technical consultant and participant in regulatory meetings with the Study Group, and to Board attorney Michelle C. Dresdow in her roles as hearing officer, contact person, and advisor in drafting of the several opinions and orders. The Board also expresses its appreciation for the quality and magnitude of the contributions made by the members of the Study Group and other participants, and for the leadership provided by the Agency.

HISTORY

Prior to discussing the particulars of the instant regulations, it is instructive to place their development in historical perspective. Although concern about infectious materials is long standing, the impetus to today's particular action is more recent, with antecedents at both the federal and state level.

National Concern with Medical Wastes

Broad public and national concern about medical waste reached a heightened consciousness after medically-related material washed up on beaches on the east coast during the summer of 1987 and again on the east coast and on the Michigan shores of Lake Michigan in the summer of 1988. In addition to general health and aesthetic concerns, fear of AIDS contributed heavily to the public's anxiety regarding these wastes. (Exh. 7 at iii.)

Following the second season of wash-ups, Congress passed Public Law 100-582, the Medical Waste Tracking Act of 1988 (MWTa). The MWTa has a research and information component that has provided for an expanded understanding of the nature and hazards associated with medical wastes³.

In addition, the MWTa requires that the United States Environmental Protection Agency promulgate regulations to establish a demonstration tracking system for medical waste. Several states along the Atlantic Coast (Connecticut, New York, New Jersey) were required to participate in the demonstration program. Participation of states bordering the Great Lakes was made optional.

³ Among the important MWTa documents is "The Public Health Implications of Medical Waste: A Report to Congress", prepared by the Agency for Toxic Substances and Disease Registry (ATSDR) of the Public Health Service, U.S. Department of Health and Human Services. This document is Exhibit 7 in the instant record.

All of the Great Lakes States elected to opt out of the federal MWTA demonstration program. Governor James R. Thompson outlined several reasons for Illinois' choice not to participate (Exh. 5 at 8):

1. Illinois already had a system in place which tracked the potentially infectious waste from hospitals. It was estimated at that time that approximately 60 percent of the potentially infectious waste generated in Illinois came from hospitals.
2. The intent of the MWTA was to prevent beach closings, yet even USEPA concluded that the program would have a very limited effect on the beaches.
3. No funding would be available from USEPA to implement the program in Illinois.

Medical Waste Tracking Study Group

Governor Thompson recognized, however, that there was need for additional study and planning for Illinois' medical waste program. Accordingly, on December 28, 1989, he announced the formation of the Medical Waste Tracking Study Group. The Study Group consisted of elected officials⁴ and representatives of state agencies⁵, the health community⁶, academia⁷, waste handling groups⁸, agriculture⁹, and the City of Chicago¹⁰.

⁴ State Senators Judy Baar Topinka, Margaret Smith, and Virginia MacDonald, and State Representative Myron Kulas.

⁵ The Agency, the Board, and Illinois Department of Public Health. Board Member Joan Anderson participated initially.

⁶ Including the Illinois State Medical Society (Dr. Larry A. Von Behren), the veterinary community (Dr. Raymond O. Hill), Illinois Council on Long Term Care (Mr. Peter P. Peters), the Illinois Hospital Association (Ms. Ann Guild), public health departments (Mr. J. Maichle Bacon), the Association for Practitioners in Infectious Control (Ms. Carol Mason), and the Illinois Dental Society (Dr. Robert Colantino).

⁷ Dr. Van Allen Anderson, University of Illinois Urbana-Champaign, and John Klaire, University of Chicago Hospital.

⁸ Including Waste Management, Inc. (Ms. Janet S. Emmerman), Sexton Environmental Services (Mr. Larry Lawrence), National Environmental Services Corp. (Mr. Bill Smith), Browning-Ferris Industries (Mr. Francis J. O'Brien), and Compliance Resources,

The Study Group met on many occasions and reviewed a large number of scientific, technical and legal materials preparatory to issuing its findings. (Exh. 5 at cover letter.) The culmination of these activities was the submission to Governor Jim Edgar on June 10, 1991 of the Study Group's report entitled "The Regulation of Potentially Infectious Medical Waste in Illinois"¹¹. The report contains background information on the scope of the PIMW problem and recommendations for managing PIMW in Illinois. These recommendations are directed to modifications of law, as well as educational and voluntary actions. The recommendations with respect to the law formed the basis for subsequent legislative actions and for the regulations today adopted.

Members of the Study Group have continued to participate in PIMW legislative and regulatory developments, including presentation of much of the proposal, testimony, and general record upon which today's action is based.

Legislative Action

During the spring 1991 legislative session, the Illinois General Assembly in House Bill 2491 adopted a variety of amendments to the Illinois Environmental Protection Act (Act) in response to the Study Group's recommendations. These were signed into law on September 26, 1991 by Governor Edgar as Public Act 87-752, effective January 1, 1992.

One of the cornerstones of P.A. 87-752 is the definition for potentially infectious medical waste¹²; its greatest importance is that it specifically limits the types of waste to which PIMW regulations apply.

P.A. 87-752 also added to the Act new *Title XV: Potentially Infectious Medical Waste*. This title consists of seven sections, numbered Sections 56 through 56.6. Section 56 consists of the findings of the General Assembly on the matter of PIMW and the statement of purpose for Title XV. In its entirety Section 56 reads:

Inc. (Mr. Ed Juracek).

⁹ Mr. Richard P. Myers.

¹⁰ Ms. Nancy Marren.

¹¹ This report is found in the instant record as Exhibit 5.

¹² The definition was originally placed at Section 3.81 of the Act. Pursuant to P.A. 87-1097 it was renumbered to Section 3.84.

0143-0266

- a. The General Assembly finds:
 1. that potentially infectious medical waste, if not handled properly, may constitute an environmental or public health problem.
 2. that potentially infectious medical waste, if not handled properly, may present a health risk to handlers of the waste at the facility where the waste is generated, during transportation of the waste, and at the facility receiving the waste.
- b. It is the purpose of this Title to reduce the potential environmental and public health risks associated with potentially infectious medical waste by establishing statutory and regulatory requirements to ensure that such waste will be handled in a safe and responsible manner.

Section 56.1 is a lengthy¹³ section consisting of a list of prohibitions against PIMW activities. The principal prohibitions are against:

1. Disposal of any PIMW (Section 56.1(a));
2. The landfill disposal of sharps unless their infectious potential has been eliminated and they are properly packaged (Section 56.1(a));
3. The delivery of PIMW for transport, storage, treatment, or transfer except where the PIMW is properly packaged (Section 56.1(b));
4. The delivery of PIMW to a person or facility that does not have an Agency-issued permit for storage, treatment, or transfer of PIMW, where such permit is required (Section 56.1(c));
5. The delivery or transfer of PIMW unless the transporter has an Agency-issued permit, where such permit is required (Section 56.1(d));

¹³ A substantial portion of the length of Section 56.1 arises from the inclusion of various effective dates (all now past except for the incineration date found at Section 56.1(j)) plus interim regulations which are to be in effect until the adoption of the instant regulations.

6. The delivery or transfer of PIMW unless a PIMW manifest is completed for the waste, where such manifest is required (Section 56.1(d));
7. The acceptance of any PIMW for transport, storage, treatment, or transfer except where the PIMW is properly packaged (Section 56.1(e));
8. The conducting of any PIMW transportation operation without an Agency-issued permit (where such permit is required), in violation of any permit condition, or in violation of a Board regulation or order (Section 56.1(f));
9. The conducting of any PIMW treatment, storage, or transfer operation without an Agency-issued permit (where such permit is required), in violation of any permit condition, or in violation of a Board regulation or order (Section 56.1(g));
10. The transport of unmanifested PIMW, where a manifest is required (Section 56.1(h)); and
11. The incineration of PIMW after January 1, 1994 at an existing incinerator in violation of standards established under Section 129 of the Clean Air Act (Section 56.1(j)).

Section 56.2 consists principally of mandates to the Board, including the mandates under which the instant action is being undertaken¹⁴. The first of these mandates is found at Section 56.2(a), and requires that the Board adopt regulations "prescribing design and operating standards and criteria for all potentially infectious waste treatment, storage, and transfer facilities". The mandate also directs that the Board, "at a minimum" require that PIMW be treated at a facility that:

¹⁴ In addition to the mandates to which today's action is addressed, Section 56.2 also requires at subsection (d) that the Board repeal its previous infectious waste regulations and at subsection (e) that the Board adopt the list of Class 4 etiologic agents. These two actions have been completed. The first was undertaken as In the Matter of: Repeal of 35 Ill. Adm. Code 809.Subpart I: Hazardous (Infectious) Hospital Waste, R91-18, Final Order December 19, 1991. The second was undertaken as In the Matter of: Potentially Infectious Medical Wastes: Etiologic Agents, R91-19, Final Order January 23, 1992.

1. eliminates the infectious potential of the waste;
2. prevents compaction and rupture of containers during handling operations;
3. disposes of treatment residuals in accordance with this Act and regulations adopted thereunder;
4. provides for quality assurance programs;
5. provides for periodic testing using biological testing, where appropriate, that demonstrate proper treatment of the waste;
6. provides for assurances that clearly demonstrate that potentially infectious medical waste has been properly treated; and
7. is in compliance with all Federal and State laws and regulations pertaining to environmental protection.

The second mandate that today's action addresses occurs at Section 56.2(c). It specifies that the Board shall adopt regulations "prescribing standards and criteria for transporting, packaging, segregating, labeling, and marking potentially infectious medical waste".

Sections 56.3, 56.4, 56.5, and 56.6 of Title XV generally deal with the Agency's direct role in PIMW matters, including reporting, manifesting, permit issuance, and fee collection. Some of these matters bear peripherally on today's action.

In the spring 1992 legislative session, the General Assembly revisited P.A. 87-752 for the purpose of making certain corrective amendments. These were proposed as House Bill 3666 and signed into law as P.A. 87-1097 on September 15, 1992. Among pertinent provisions, P.A. 87-1097 clarified the definition of PIMW, clarified various exceptions to the prohibitions of Section 56.1, and specified July 1, 1993 as the required date of completion of the instant rulemaking.

Actions before the Board

In anticipation of the need to take action in the PIMW arena, the Board on August 9, 1991 reserved several rulemaking dockets within which it intended to conduct the various rulemakings. On August 23, 1991 the Board called a public hearing (inquiry hearing), which was held on September 18, 1991.

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The purpose of this hearing was to determine the proper scope of the regulations to be developed under the Section 56.2 mandates.

On August 26, 1991 the Board issued orders formally opening the dockets. Included were separate dockets for the rulemaking covering treatment, storage, and transfer facilities (R91-20) and for the rulemaking covering transportation, packaging, and labeling (R91-21).

At the inquiry hearing testimony was received from Mr. Henry Henderson from the City of Chicago, Dr. Van Allen Anderson of the University of Illinois at Urbana-Champaign and the Study Group; Ms. Ann Guild of the Illinois Hospital Association and the Study Group; Dr. Larry Von Behren of the Illinois State Medical Society and the Study Group; Mr. Joe Suchecki from Waste Management of Illinois, Inc.; Mr. Francis J. O'Brien from Browning Ferris Industries Medical Waste Systems and the Study Group; Ms. Jacquelyn Flora from Browning Ferris Industries Medical Waste Systems; and Mr. Larry Lawrence of Sexton Environmental Systems and the Study Group. Testimony and questioning included the implementation provisions of the legislation requiring segregation, packaging, marking and labeling, transporting, storing and treating of PIMW (Tr1.¹⁵ at 98-144).

Based upon the inquiry hearing and in recognition that matters of PIMW facilities and transportation, packaging, and labeling overlapped, the Board on February 27, 1992 ordered dockets R91-20 and R91-21 to be consolidated, docket R91-21 to be closed, and the materials in docket R91-21 to be incorporated into R91-20 for the purpose of all subsequent considerations.

On April 27, 1992 the Agency filed the draft proposal upon which the merit hearings have been held and upon which today's adopted rules are based; the Agency has also subsequently acted as proponent for the instant rulemakings. Accordingly, for purposes of the following discussions, the Board will identify the April 27 draft proposal in short form as the "Agency Proposal". It is to be acknowledged, however, that the Study Group and other interested persons contributed to the development of the Agency Proposal, and moreover that the Agency undertook extensive outreach and regulatory development meetings¹⁶ prior to

¹⁵ Citations to the pages of transcripts of the inquiry hearing are in the form "Tr1. at ____"; citations to the transcripts of the merit hearings, which are consecutively numbered, are in the form "Tr2. at ____".

¹⁶ Meetings were held on December 10 and 19, 1991, January 7, 23, and 24, 1992, and February 6, 7, and 24, 1992. Participants included members of the Study Group in addition to other interested persons. Ms. LouAnn Burnett and Mr. Philip Van Ness,

formalizing and filing its proposal. The Board extends its appreciation to the Agency and its personnel for the quality of its leadership role.

On April 27, 1992 the Agency also filed a recommendation (Exh. 37), pursuant to then Section 27 of the Act¹⁷, that an Economic Impact Study (EcIS) not be conducted; on May 11, 1992 the Illinois Department of Energy and Natural Resources joined in that recommendation (PC #7)¹⁸. On June 4, 1992 the Board issued an order finding that the EcIS need not be conducted. The Board noted:

The Agency states that representative members of the regulated community have participated in the development of the Agency's proposal, and that these representatives will attend the hearings and present information on the economic reasonableness of the rule. The Agency has also presented some economic information with its proposal (see Attachments 1-10), and will present additional information at hearing. The Department concurs in the Agency's comments, and further states that interested parties will have "ample opportunity to present testimony regarding technical feasibility and economic reasonableness during the Board's merit hearings." (P.C.#7 at 1). The Department further states that additional economic information will be available from the Agency at or before hearing.

Some of these representatives also participated on the Medical Waste Tracking Study Group (Study Group) formed by Governor Thompson. The Study Group was instrumental in drafting the legislation mandating the adoption of medical waste regulations.

Board staff, also participated in these meetings. Minutes of these meetings are included in this record as Exhibits 38-5, 38-13, 38-35, 38-64, 38-65, and 38-66.

¹⁷ PA 87-860, effective July 1, 1992, deleted those portions of the Act that required economic impact studies for this type of rulemaking. The Board's EcIS determination aside, the need for a formal EcIS study is accordingly now moot.

¹⁸ Public comments are cited to in this opinion in the form "PC #x at ___".

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The Board has held three merit hearings. These were held on June 16, 1992 in Bloomington, Illinois, and on July 14, 1992 and August 25, 1992 in Chicago, Illinois.

The June 16, 1992 hearing was devoted to presentation of the Agency Proposal and the taking of questions on the proposal. Providing testimony on behalf of the Agency were three members of the Permit Section of the Agency's Bureau of Land: Mr. Douglas Clay, Manager of the Disposal Alternatives Unit; Dr. Shirley Baer, Co-coordinator of the PIMW waste program, Disposal Alternatives Unit, and Mr. Theodore Dragovich, Permit Reviewer. Among persons posing questions to the Agency were ABB Sanitec, Inc., Sexton Environmental Systems (Sexton), Winfield Environmental Corporation, the National Solid Waste Management Association (NSWMA), Chemical Waste Management, Isolyser Company, and the Board.

The July 14, 1992 hearing focused on testimony directed to the merits of the Agency Proposal. Among those testifying were Dr. Cecil Lue-Hing of the Metropolitan Water Reclamation District of Greater Chicago; Dr. Van Allen Anderson of the University of Illinois, Urbana-Champaign and the Study Group; Dr. Edward Cohen of University of Illinois, Chicago, on behalf of Sexton; Mr. Travis Honeycutt of Isolyser Company; Mr. Robert Rechner of the Illinois State Dental Society and the Study Group; Ms. Ann Guild of the Illinois Hospital Association and the Study Group; Dr. Larry Von Behren of the Illinois State Medical Society and the Study Group. Drs. Anderson and Von Behren, Mr. Rechner, and Ms. Guild each spoke to the general support they and their organizations give to the Agency Proposal, with Dr. Anderson providing additional documentation in support of the position. The other presenters generally spoke to specific concerns.

The August 25, 1992 hearing continued the opportunity for testimony regarding the Agency Proposal and response testimony to that given at the July 14 hearing. Witnesses included Ms. Jean Furlan of the National Solid Waste Management Association; Mr. Corrie Frank of Rose Cartage; Mr. Harry Eiler of Recovery Corporation of Illinois; Ms. Carol Mason of the Association for Practitioners in Infection Control and the Study Group; Dr. John Keene from the Society for Hospital Epidemiology of America; Mr. Joseph Wilson of Ecomed; and Mr. Larry Eastep of the Agency and the Study Group. Dr. Cohen also testified again. Ms. Mason noted the support of her association for the Agency Proposal. The other presenters generally spoke to specific concerns.

Public Comments

Thirty-nine public comments have been filed with the Board, including nineteen filed subsequent to the start of merit hearings and fourteen filed in the post-first notice comment period. These are dominantly expansions upon or responses to

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matters addressed at hearing or raised in the first notice opinion. The Board has reviewed all public comments, with citations herein where pertinent.

The Board notes that it recently received comment from Medx Inc. and Custom Compactors Corporation. These comments were received on May 10, 1993 and May 13, 1993, respectively, three months after the February 11, 1993 close of the public comment period and well after the Board adopted today's rules for second notice (see below). The Board is not able to react to such late-filed comments; the Board is statutorily prohibited from altering any proposal subsequent to second notice, except at the recommendation of JCAR (see below).

First and Second Notices

Based on the record as then developed, the Board on December 3, 1992 adopted the first notice proposal¹⁹. The proposed rules were accompanied by a 39-page opinion, the major elements of which are repeated in the instant opinion. In its outlines and particulars, the first notice proposal closely tracked the Agency Proposal.

On March 25, 1993 the Board adopted the second notice proposal. The changes adopted for second notice were few and generally were of the nature of giving greater specificity to the regulations. The second notice proposal was accompanied by an opinion of 28 pages, the major elements of which are incorporated into today's opinion.

Among changes made at second notice was adoption of a recommendation of the National Solid Waste Management Association that the operational definition of "eliminates the infectious potential of the waste" found at Section 1422.122 (a)(1) be clarified (PC #36 at 3). The intent was to provide a definition that "more clearly reflects [the treatment] standards and more clearly articulates the specific standards that constitute elimination of infectious potential". (Second Notice Opinion at 17.) The NSWMA comment, plus a similar comment from Stericycle (PC #35), were filed prior to the end of the public comment period, and prior to the time the Agency filed its comment. The Agency, however, did not address this issue until after today's rules had gone to JCAR.

¹⁹ Publication of Part 1420 occurred at 16 Ill. Reg. 19625 (Dec. 18, 1992), Part 1421 at 16 Ill. Reg. 19615 (Dec. 18, 1992), and Part 1422 at 16 Ill. Reg. 20002 (December 28, 1992).

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Action Before JCAR

Immediately upon adoption of the second notice rules, the Board on March 26, 1993 forwarded them to JCAR pursuant to the Illinois Administrative Procedure Act (5 ILCS 100/1-1 et seq.); JCAR set the matter for consideration at its May 11, 1993 meeting.

On May 10, 1993 the Agency asked JCAR to object to adoption of these rules on the basis that the modification made to Section 1422.122(a)(1) -- see above -- at second notice resulted in an internal inconsistency between that subsection and some other portions of Part 1422²⁰. On May 11 JCAR voted the objection. Under the terms of an objection, the Board is required to address the objection.

This objection presented a number of concerns for the Board. The first was that the objection delayed the adoption of the entire set of rules pending resolution of the objection. Moreover, it is statutorily required that this rulemaking process be completed by July 1, 1993, further necessitating that action be expeditious.

A second whole area of concern for the Board is that the Board is statutorily and by its own rules and established practices bound to the principle of equitable and impartial hearing of the concerns of all interested parties on the public record. Accordingly, if any person, the Agency included, wishes the Board to modify the Board's rules, it has available to it clearly established public procedures by which petition may be made.

Given the circumstances of the objection, the Board at its first opportunity on May 20, 1993 ordered a special and short public comment period to address solely the matter of the appropriate language for subsection 1422.122(a)(1). To expedite the matter, the Board suggested language that it believed would address the JCAR concern. Further, the Board both invited comment on the new proposed language and invited acceptable alternatives; only the Agency responded.

On June 3, 1993 the Board voted adoption of the language today found at subsection 1422.122(a)(1) (see discussion below for specifics), and submitted that language to JCAR via a Board resolution as the Board's response to the JCAR objection.

²⁰ The Agency's letter to JCAR requesting that an objection be voted has not been served upon the Board; the Board nevertheless takes official notice of it as a public document. At no time, in fact, has the Agency addressed any of its perceived problems with subsection 1422.122(a)(1) on the record.

GENERAL CONSIDERATIONS

In addition to the history of PIMW matters, there are a number of general considerations necessary to put today's regulations into perspective.

Immediacy of the PIMW Problem

While it is generally conceded that PIMW presents a real problem, it is also generally conceded that the problem should be addressed by a reasoned consideration of existing rules and regulations and awareness of the professional practices employed in those fields where PIMW is generated and handled. It was in recognition of this situation that Illinois opted out of the MWTA program (see above). It was also in recognition of this situation that the broad interests represented in the Study Group were brought together to recommend a concerted PIMW program.

It is also worth noting that the ATSDR's report to Congress (Exh. 7), made in accordance with the MWTA (see above), observed that the general public's health is not likely to be adversely affected by medical waste generated in the traditional health care setting and that OSHA's "Occupational Exposure to Bloodborne Pathogens" rule should decrease workplace medical waste-related injuries and infections nationwide. (Exh. 7 at E.9.) ATSDR also concluded that medical waste can be effectively treated by chemical, physical, or biological means and that research indicates that medical waste does not contain any greater quantity or different types of microbiological agents than does residential waste. Medical waste is approximately 0.3% of the solid wastestream in the U.S. (Exh. 7 at E.11.)

Design of Rules

Today's rules are designed as a multi-pronged attack on the chain of events leading to infection and disease. For infection to occur, each of these events must take place:

- 1) A person must come in contact with medical waste;
- 2) An injury must occur following this contact, thereby creating an appropriate portal of entry, or a portal of entry must already exist; and
- 3) A sufficient number of viable infectious agents must enter a susceptible individual via this portal of entry, then cause infection.

Infection does not always result in disease. (Exhs. 7 at E.5, 38-26, and 39-30 at 3.)

Appropriate segregation of PIMW from other wastes allows a generator to apply more extensive safety measures to a smaller waste stream. Proper packaging should nearly eliminate the possibility of contact (Tr2. at 84) or the creation of a portal of entry (i.e., packaging sharps in a puncture-proof container). Storage and transportation requirements also help limit the exposure of handlers or the general public to potentially infectious agents. Treatment reduces the number of potentially infectious agents, thereby reducing the possibility of infection if contact and injury does occur. Any of these preventive methods applied individually should reduce the possibility of infection, but used in concert and properly, the entire PIMW management system should reduce the possibility of infection almost completely. (Tr2. at 113.)

Today's rules are also designed to complement the Occupational Safety and Health Administration rules issued December 6, 1991 that contain provisions requiring employers to protect their employees from bloodborne pathogens through training, engineering controls, work practices, personal protective equipment, recordkeeping, and Hepatitis Type-B virus vaccinations (Exhibit 37-6; Tr2. at 72, 84).

Definition of Potentially Infectious Medical Waste (PIMW)

The definition of potentially infectious medical waste, or PIMW, is set by statute at Section 3.84 of the Act. In its entirety, that definition is as follows:

- a. "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:
 1. 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.

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2. 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.
 3. 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.
 4. 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.
 5. 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.
 6. 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. "Highly communicable diseases" means those diseases identified by the board in rules adopted under subsection (e) of section 56.2 Of the act.
 7. 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.
- b. Potentially infectious medical waste does not include:
1. waste generated as general household waste;
 2. waste (except for sharps) for which the infectious potential has been eliminated by treatment; or

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3. sharps that meet both of the following conditions:
 - A. the infectious potential has been eliminated from the sharps by treatment; and
 - B. the sharps are rendered unrecognizable by treatment.

Early in the history of this proceeding there was concern raised by various persons about the appropriateness of this definition. A portion of that concern was addressed by the corrective amendments undertaken in P.A. 1097; these amendments limited the types of waste that are PIMW²¹.

The remaining questions regarding the PIMW definition are largely concerned with interpretation and implementation of certain phrases used within the definition, as, for example, the meaning of "rendered unrecognizable" found in the last subsection of the definition. These will be discussed in context in the following part-by-part analyses.

The Treatment Standard

The fundamental provision around which the instant regulations are built is the provision of treatment to render waste non-PIMW. Because a waste that is PIMW may not be disposed of in Illinois, and because treatment is the process by which a waste ceases to be PIMW²², the ultimate disposition of PIMW depends upon its being treated.

Suitably, treatment standards and criteria form the largest single portion, Subpart B of Part 1422, of today's regulations. Moreover, treatment has been the single greatest focus of participant interest, both at hearing and in public comments. Much of that interest has focused on the question of what constitutes successful treatment.

²¹ The principal changes were to eliminate the phrase "... but not limited to ..." prior to the lists of materials included in the definitions of human pathological wastes, human blood and blood products, and isolation waste, and to rephrase the definition of animal waste.

²² A partial exception occurs for sharps. These must be both treated and "rendered unrecognizable" in order to leave the PIMW wastestream. "Recognizable" sharps, which remain PIMW, may be disposed of provided that they are both treated and packaged, pursuant to Section 1422.126. See discussion of the term "recognizable" in the part-by-part discussion, below.

Today's regulations follow the Agency Proposal in requiring two demonstrations of treatment efficacy. The first is the Initial Efficacy Test²³, in which it is required that the manufacturer assure that six types of "test" microorganisms²⁴ that are surrogates for pathogens be reduced to very low concentrations (a 6-log reduction²⁵) by the treatment process.

The second demonstration is made by operators of individual treatment units. They are required to verify that the manufacturer-demonstrated efficacy continues by conducting Periodic Verification Tests²⁶. These are accomplished by showing that concentrations of bacterial spores (typically the most resistant forms of microorganisms) are reduced to a number that correlates with the 6-log reduction of the organisms used in the manufacturer's efficacy test.

This program represents the consensus view of members of the Study Group, and the program which today is adopted in its major provisions. Nevertheless, several issues regarding treatment standards constituted major areas of debate during the course of this proceeding.

Among such issues have been the stringency of the efficacy standard, whether the standard is properly a "log-kill" or "log-reduction" standard, and which organisms should be used or allowed in efficacy determinations. Greater detail regarding these issues has been presented in the first notice opinion at pages 15-18 and 34-40 and the second notice opinion at pages 16-26.

ORGANIZATIONAL CONSIDERATIONS

The Board has established the following organizational scheme to accommodate the PIMW and related regulations.

²³ See Section 1422.124.

²⁴ *Staphylococcus aureus* (representative of gram-positive bacteria), *Pseudomonas aeruginosa* (representative of gram-negative bacteria), *Candida albicans* (representative of vegetative fungi--yeast), *Trichophyton mentagrophytes* (representative vegetative fungi--mold), MS-2 bacteriophage (hepatitis virus surrogate, and *Mycobacterium smegmatis* (tuberculosis bacteria surrogate).

²⁵ At various places in the record this term is also given as "6log". The hyphenated form is used here and in the text of the regulations.

²⁶ See Section 1422.125.

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Subtitle M, which is to consist of the 1400-1499 series of 35 Ill. Adm. Code, is reserved for regulations that control specific biological materials; currently, the only Board regulations within Subtitle M are the instant PIMW regulations.

As is the general scheme with 35 Ill. Adm. Code regulations, parts numbered 1400 to 1449 (Chapter I) are reserved for regulations promulgated by the Board, and parts numbered 1450 to 1499 (Chapters II and III) are reserved for regulations promulgated by the Agency or the Department of Energy and Natural Resources.

Today's specific regulations are collected into subchapter b, the PIMW subchapter. This subchapter, in turn, is subdivided into three parts to efficiently house general provisions (Section 1420), and the regulations today adopted in response to the separate Section 56.2(a) and 56.2(c) mandates of the Act (Sections 1421 and 1422)

PART-BY-PART ANALYSIS - Part 1420

In this portion of our opinion, the Board presents an explanatory analysis of today's regulations, beginning with Part 1420. Emphasis is on issues that have required Board resolution²⁷.

Part 1420 is the only one of the three parts in today's regulatory package that is not entirely new. Part 1420 originated in the Board's first PIMW proceeding, R91-19, that dealt with etiologic agents²⁸. It is expanded to house general provisions pertaining to PIMW.

Scope and Applicability (Section 1420.101)

The Scope and Applicability statement for the PIMW regulations was adopted in R91-19. At first notice the Board proposed, and today adopts, the deletion of both subsection (b) and the Board Note as no longer reflective of the overall content of either Part 1420 or the PIMW subchapter.

It is to be noted that, through the operation of Section 1420.101, the instant regulations are applicable to activities occurring in whole or in part within the State of Illinois. Thus, that part of any PIMW wastestream activity (e.g.,

²⁷ The interested person is directed to the testimony of Dr. Baer, Tr2. at 52-153, and Mr. Dragovich, Tr2. at 154-191, for a more extensive explanation of particular provisions.

²⁸ See footnote #14.

transporting) that takes places in Illinois is subject to these regulations, even if some portion of the PIMW wastestream activity (e.g., disposal) does not.

Definitions (Section 1420.102)

General definitions that apply to the three PIMW parts are found in Section 1420.102. Most of these definitions are standard, and need not be specifically discussed here. However, there are several around which question has been raised.

"PIMW". The full statutory definition of PIMW has been presented and discussed above. It is also presented within the body of the rule at Section 1420.102²⁹. As noted above, there have been some concerns raised regarding this definition that have now been addressed by the General Assembly. The Board has no authority to modify the statutory definition.

In response to a question raised by Chemical Waste Management (CWM) regarding whether discarded unused test kits should be considered PIMW (Tr2. at 282-305; PC #22), the Board in its first notice opinion proposed that any waste containing blood components was PIMW:

As a general rule, a waste is not a PIMW if it has no infectious potential and is otherwise not explicitly identified in the statutory definition of PIMW . . . It follows that an unused medical test kit, where the test kit is not in whole or part a culture or stock, an unused sharp, contains blood components, or somehow otherwise covered under the statutory PIMW definition, is not PIMW. (First notice opinion at p. 22, emphasis added.)

During the post-first notice comment period, two commenters observed that a discarded unused test kit that contains blood components should not be considered to be PIMW. The Agency observed that PIMW is by statutory definition waste generated in connection with: (1) the diagnosis, treatment or immunization of human beings or animals; or (2) research pertaining to the provision of medical services; or (3) provision or testing of biologicals. (PC #39 at 2.) The Agency further observed that unused test kits that contain blood components should not be regulated as PIMW since they are not generated in connection with any of these situations. (Id.) Dr. Anderson also observed that blood components in test kits have been sterilized, and as such have no infectious potential. (PC #37 at 1.) In its second

²⁹ It is to be noted that, in accord with standard construction, statutory language in the regulations is denoted by capitalization.

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notice opinion, page 3, the Board noted that these points with regard to unused test kits are well taken, and accordingly receded from its first notice proposed position on this matter.

"Site". The term "site" appears in many places within the today's regulations, including within other definitions ("storage site" and "transfer station"), within provisions defining the circumstances under which permits and manifests are required³⁰ and within various provisions defining on- and off-site circumstances³¹. There is thus a special importance to having the definition be clear and precise.

The following definition was offered in the Agency Proposal:

"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 THIS ACT OR REGULATIONS THEREUNDER. (Section 3.43 of the Act). In the case of a hospital or an educational institution, the Agency shall determine what constitutes a site based on location, ownership, operation, charter or license.

The first, capitalized part of this definition is identical to the definition of "site" found in the Act. It has not been at issue.

However, the second, lower case part of the definition has been of concern. The purpose of the language is to allow for flexibility in determining the geographic bounds of a site, particularly in the circumstance where an organization (epitomized by hospitals and universities) may consist of geographically separated buildings and structures. The intent is that such organizations need not necessarily acquire separate permits for each structure or manifest all loads transferred between buildings. The Agency's resolution of this matter was to allow a case-by-case determination under its supervision.

The problem with this resolution is that it constitutes a delegation of authority of questionable validity. Accordingly, the Board at first notice declined to propose the lower case language of the Agency Proposal. Instead, at the lead of several participants, the Board observed that the term "campus" has sufficient ordinary meaning as to itself be explicit, and

³⁰ Sections 1420.105(c)(1) and (e)(1).

³¹ Sections 1421.120, 1421.130, 1421.131(a)(2)(E), 1421.131(e)(2)(E), 1422.111(a), 1422.111(a)(4), and 1422.111(b)(5)(B).

therefore proposed to address the matter by replacing the lower case language with:

For the purpose of this Subtitle, each campus of an educational institution is considered to be a single site.

This resolution did not explicitly address the issue of hospitals. However, based on additional comments received in the post-first notice comment period, the Board at second notice concluded that it would be both unnecessary and unwise to attempt more explicit consideration of hospitals within the definition of "site". This conclusion is based, among other matters, on the special mention made of hospitals, and the permits required by them, both in the statute and within the main body of the instant regulations. (See second notice opinion at p. 4-7.) The Board today affirms its analysis as presented at second notice.

Unrecognizable. Pursuant to the definition of PIMW at Section 3.84 of the Act all sharps are considered to be PIMW unless they meet both of the conditions:

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

The sharps are rendered unrecognizable by treatment.

This definition has raised the question of how the phrase "rendered unrecognizable" is to be interpreted³². The issue is significant in that it factors into a determination of when a sharp no longer is a PIMW, and hence is no longer subject to PIMW treatment and disposal limitations³³.

In the original Agency Proposal it is recommended that the term "unrecognizable" be included within the general definitions, as follows:

"Unrecognizable" means physical alteration (i.e., melted, charred, corroded, or ground) so that the sharp may no longer be used for its intended purpose.

As the Board concluded at first notice, an effect of this recommendation is to incorporate into the definition the concept of usability. The Board also concluded that this incorporation

³² The meaning of infectious potential being "eliminated" has also been raised in this proceeding. A discussion of this matter is found in the "General Considerations" portion of this opinion, above.

³³ See discussion of Section 1420.104, below.

is consistent with the PIMW threat posed by sharps and the circumstance under which that threat is allayed. The Board accordingly adopted the concept³⁴. (See first notice opinion at p. 25.) The Board today affirms these conclusions.

Also at first notice the Board discussed the encapsulation and solidification process of Isolyser Company, Inc., as a method for the treatment of sharps³⁵. (First notice opinion at p. 25.) For second notice Isolyser asked that "encapsulating/solidifying" be specified in the definition of "unrecognizable" as an example of physical alteration. (PC #30 at ¶1.) This the Board declined to do because it believes that the record does not support a blanket endorsement of all processes that involve encapsulation or solidification. (Second notice opinion at p. 7.) The Board today affirms these analyses.

Incorporations by Reference (Section 1420.103)

Incorporations by reference for the full PIMW subchapter occur at Section 1420.103. All incorporations are placed in one section to simplify future amendments and updates, and for more ready reference.

Today's regulations contains two incorporations by reference. They are Standard Methods for the Examination of Water and Wastewater (18th Edition) and Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (EPA SW-846)³⁶.

Prohibitions (Section 1420.104)

Section 1420.104 sets out the PIMW prohibitions. Much of the section is statutory, as found at Section 56.1 of the Act.

Disposal of sharps. In a post-first notice public comment Stericycle, Inc., requested clarification of sharps disposal, as

³⁴ The actual language adopted was slightly modified for grammatical reasons. See first notice opinion at p.26.

³⁵ Under the Isolyser process sharps are treated and bound into a polymer matrix. During the binding process pressure forces the polymer into the barrels of syringes and needles, with the whole enclosed in an opaque container. Isolyser contends that this process renders the sharps no longer usable (Tr2. at 279; 663-94).

³⁶ The former is referenced in the Initial Efficacy Test procedures at Section 1422.124(e)(2) and 1422.Appendix A, and in the Periodic Efficacy Test procedures at Section 1422.125(b)(4). The latter is referenced in the Initial Efficacy Test procedures at 1422.Appendix A.

referenced at Section 1420.104(a). (PC #35 at 2.) Stericycle noted the absence of a requirement that sharps be rendered "unrecognizable" before disposal in a landfill. In addressing Stericycle's concern, the Board notes that there are two portions of the Illinois Environmental Protection Act and one section of the regulations that reflect on the disposal of sharps. The first is in the definition of PIMW³⁷ at Section 3.81(b) of the Act:

- (b) Potentially infectious medical waste does not include:

* * *

- (3) sharps that meet both of the following conditions:
 - (A) the infectious potential has been eliminated from the sharps by treatment; and
 - (B) the sharps are rendered unrecognizable by treatment.

This definition thereby establishes that sharps that have had their infectious potential eliminated and have been treated and are rendered unrecognizable no longer meet the definition of PIMW.

It is further established at Section 56.1(a) of the Act that:

No person shall:

- (a) cause or allow the disposal of any potentially infectious medical waste. Sharps may be disposed in any landfill permitted by the Agency under Section 21 of this 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:
 - (A) Board regulations; or

³⁷ The same definition is repeated at Section 1420.102 of the instant regulations.

- (B) subsection (b)(2), until Board regulations relating to the packaging of potentially infectious medical waste are adopted and effective.

(emphasis added.)

The reference to sharps in this section is contained in an exception to the prohibition of disposal of PIMW in landfills. Pursuant to Section 3.81(b)(3), sharps that are unrecognizable and treated are not PIMW at the time of disposal. Thus, Section 56.1 applies only to those sharps that remain PIMW after treatment (i.e., sharps that have not been rendered unrecognizable).

Read together, these two sections of the Act therefore establish that there are two pathways by which sharps may ultimately be disposed. The first is to package, treat, and render the sharps unrecognizable. After this processing, the sharps are not considered to be PIMW and may be disposed of in a manner the same as that of any solid waste. However, if the sharps are packaged and treated appropriately, but are not rendered unrecognizable, those sharps may still be landfilled under the exception provided in Section 56.1 of the Act.

This dual disposal pathway is reflected in the recommendation of the Study Group, the Agency Proposal, and the instant regulations at Section 1422.126:

Section 1422.126 Sharps

Sharps may be disposed in a landfill only if they have been treated to eliminate the infectious potential and:

- a) Have been rendered unrecognizable and therefore are no longer PIMW; or
- b) Have been:
 - 1) Packaged, marked, and labeled in accordance with Part 1430, Subparts C and D;
 - 2) Delivered by a transporter with a PIMW hauling permit as required by Section 1420.104 of this Subtitle, unless specifically exempted.
 - 3) Accompanied by a PIMW manifest as required by Section 1420.104 of this Subtitle, unless specifically exempted.

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(emphasis added)

The "or" in subsection 1422.126(a) indicates that either route is an acceptable handling of sharps.

Disposal into sewers. Among the changes made to Section 1420.104 during the course of this proceeding has been the addition at subsection (1) of an explicit prohibition against the discharge of PIMW into sewers.

This action arose from concerns of the Metropolitan Water Reclamation District of Greater Chicago (MWRDGC) and the Illinois Association of Wastewater Agencies that the practice of flushing ground/shredded inert medical solid wastes into sewers is an inappropriate use of the public sewerage system, and that the public sewerage system is neither designed to function as a landfill nor as a depository for inert solid wastes regardless of origin. (Tr2. at 468-493; Exh. 43 and 44; PC #6, 11, and 12.) MWRDGC also observed difficulties posed to the biological treatment system of a sewage treatment plant and sludges when such solid materials are received in the waste stream. (Tr2. at 478-80.)

Permit and Manifest Exceptions, Penalty Factor, and Cleaning and Disinfection (Sections 1420.105, 1420.106, and 1420.107)

The first two of these sections basically present language from the PIMW statute. The third contains at a single location language required in support of various other sections³⁸.

The three sections have remained basically unaltered from the Agency Proposal, although conforming and minor amendments have been made, as discussed in the first notice opinion at page 28-29 and in the second notice opinion at page 11-12.

Severability (Section 1420.120)

Section 1420.120 contains severability language as found generally in Board regulations.

PART-BY-PART ANALYSIS - Part 1421

Part 1421 is a new part intended to address the mandate of Section 56.2(c) of the Act regarding the prescription of "standards and criteria for transporting, packaging, segregating, labeling, and marking potentially infectious medical waste". The

³⁸ Within the definition of "reusable container" at Section 1420.102, as well as at Sections 1421.121(d), 1421.121(e), 1421.141(i), 1422.111(a)(8), 1422.111(a)(11), and 1422.122(b)(5).

part is divided into five subparts, each addressing one of the natural divisions of the topic. Part 1421 also has an Appendix A that contains the International Biohazard Symbol.

The entire part is adopted today with only minor, generally nonsubstantive modification from the Agency Proposal.

General Provisions (Subpart A)

This short subpart contains a single section specifying that the date for compliance with Part 1421 is the effective date of the part. That is, compliance is required immediately upon the regulation becoming effective; that, in turn, will be upon the acceptance by the Office of the Illinois Secretary of State of the filing by the Board of today's action.

Waste Segregation (Subpart B)

Subpart B consists of two sections that apply to all PIMW generators, transporters, storage sites, transfer stations, and treatment facilities (Section 1421.110).

A principal requirement, found in Section 1421.111(a), is that generators segregate PIMW into sharps, oversized PIMW (a single waste item that is too large to be placed into a 33-gallon bag or container), and all other. These three categories are derived from similar categories used in Section 56.1 of the Act, including the interim PIMW regulations found there.

Subsections 1421.111(b) and (c) specify that properly packaged and labeled sharps and mixed waste must be handled as though the entire wastestream originated as PIMW. They do not, however, preclude the applicability of other regulations. For example, if a hazardous substance is also PIMW, both the hazardous waste and PIMW rules are intended to apply.

This latter provision has raised the question of whether rules that govern a waste as PIMW and rules that govern the same waste under another categorization (e.g., hazardous waste) could be incompatible. (Tr2. at 252-268.) The Board does not immediately see that this presents a problem. As the Agency indicates, a waste that is both PIMW and a hazardous waste may occur, but is likely to be rare. (Tr2. at 271-276.) Where overlap does occur, compliance with rules applicable to both PIMW and hazardous wastes is required.

Packaging (Subpart C)

Subpart C consists of standards and criteria for packaging that apply to any person who packages PIMW for off-site transportation. (Section 1421.120.)

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The standards and criteria, which are found in Section 1421.121, are designed to prevent discharge and protect handlers from contact with PIMW (Tr2. at 27). They include packaging requirements for all PIMW, with different standards for sharps and oversized PIMW. Also included are standards for reusable containers, standards for the management of the outside of containers that are contaminated by PIMW, and standards for residues from the cleaning of PIMW containers or discharges from packages.

It is broadly believed that packaging is a critical element in PIMW management, and that Subpart C correctly addresses that matter. Subpart C is fashioned on the premise that performance standards, rather than design standards, provide the most effective method of assuring good PIMW management (Tr1. at 100, 137; Exhs. 38-5, 38-13, 38-35, 38-64, 38-65, and 38-66).

Labeling and Marking (Subpart D)

This subpart applies to any person who packages PIMW for off-site transportation or who accepts packages from off-site. The specific standards for labeling and marking are found in Section 1421.131. Among these are requirements for marking the exterior of the outer package by the generator and transporter(s), and different standards for marking sharps containers and oversized PIMW.

Transportation (Subpart E)

This subpart applies to transporters required to have a PIMW hauling permit. It contains requirements regarding the conditions under which PIMW can be transported, including the condition of the vehicle, the management of the packages, the information that must be displayed on the vehicle, the emergency response plan that is required to be kept, and a 10 calendar-day limitation for the transportation of PIMW.

Dedicated vehicles. At hearing the issue was raised as to whether it was necessary to require "dedicated vehicles" for PIMW transportation³⁹. (Tr2. 776-814; Exh. 54.) In particular, it was asked whether "long-haul" vehicles (i.e., those vehicles that engage in interstate transport) should be allowed to backhaul "hardgoods" (paint, water seal stains, plastic, etc.) after the

³⁹ Subsection (i) reads: "Vehicles transporting PIMW cannot be used for the hauling of non-waste materials, with the exception of equipment and supplies intended for the use of waste management, new PIMW containers or PIMW containers that have been cleaned and disinfected in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle".

vehicle has been decontaminated in accordance with the procedures given in Section 1420.107. (Tr2. at 796, 805.)

At first notice the Board proposed to follow the recommendation of the Study Group and the Agency by requiring "dedicated vehicles". At second notice the Board again addressed the issue, and observed that post-first notice public comments uniformly contended that no exceptions to the prohibition against hauling non-PIMW loads should be allowed beyond those already specified within 1421.141(i). (See second notice opinion at p. 14.)

Manifests. The Environmental Protection Act sets out various requirements of PIMW handlers that are met through the use of manifests. Most specifics regarding the form and use of these manifests are either statutory or statutorily within the purview of the Agency⁴⁰. This notwithstanding, the Board at first notice raised the issue of whether, for the sake of clarity within the instant regulations, some additional presentation of the use of manifests is needed. (First notice opinion at p. 32.) None of the post-first notice public comments rose to this issue, and accordingly no further consideration of manifests within the bounds of today's rules has been entertained by the Board.

PART-BY-PART ANALYSIS - Part 1422

Part 1422 is addressed to the mandate of Section 56.2(a) of the Act regarding the prescription of "design and operating standards and criteria for all potentially infectious waste treatment, storage, and transfer facilities". Like Part 1421, Part 1422 is a new part.

Effective Date (Section 1422.101)

This section specifies that the date for compliance with Part 1422 is the effective date of the part. That is, compliance is required immediately upon the regulation becoming effective⁴¹.

⁴⁰ See, for example, the Act at Sections 56.1(d)(2), 56.1(h), and 56.4.

⁴¹ This provision notwithstanding, it should be noted that in certain circumstances the requirements for an existing unit are different than those for a unit that begins operation after the effective date. An example is the Initial Efficacy Test requirement for an autoclave, incinerator, or ethylene oxide unit at Section 1422.123(c).

Permit Applications (Sections 1422.105 through 1422.107)

At first notice the Board raised an issue concerning the need for greater specificity and clarification in the regulations regarding the procedures for, and contents of, applications for permits for treatment, storage, or transfer operations. (First notice opinion at p. 18-19.) The Agency in response submitted recommended provisions addressing application requirements. (PC #39 at 5-12.)

The Board accordingly at second notice added three new sections, Sections 1422.105, 1422.106, and 1422.107, that track the Agency's recommendation. The first section deals with content of the application, the second with application certifications, and the third with application filing requirements. In each case, the provisions closely track similar permit application provisions found in the Board's landfill regulations at 35 Ill. Adm. Code 812.

The addition of Sections 1422.105 through 1422.107 also required collateral amendments at Section 1420.105(a) and (d).

Storage/Transfer Operations (Subpart B)

Subpart B consists of two sections that apply to the owner or operator of any PIMW storage operation⁴². The subpart is adopted today without substantive modification from the Agency Proposal.

Design and operating requirements, which occur at Section 1422.111, constitute the principal standards and criteria of the subpart. Standards and criteria applicable to any person who stores PIMW prior to treatment or disposal on-site or transport off-site are contained in subsection (a); these apply whether or not a permit is required for the storage operation. Many of these standards are repeated from Section 56.1(e) of the Act, including requirements for maintaining the integrity of the packages, limiting access to the storage operation, maintaining the PIMW in a nonputrescent state, and protecting the PIMW from animals and vectors. Other requirements in this subsection include the management of reusable PIMW containers and residues, retention of manifest copies, and closure of the storage operation.

⁴² For the purpose of 1422.Subpart B a storage operation is defined at Section 1422.110 to collectively include a "storage site" or a "transfer station". The latter two terms are defined in the Act at Sections 3.47 and 3.83, respectively, and repeated in the instant regulations in the definitions at Section 1420.102.

Subsection 1422.111(b) contains additional standards for those storage operations that are required to have a permit. These generally are facilities that receive waste from off-site. (Tr2. at 30.) The standards include more detailed requirements regarding to operating records, aisle space, the manner of storage, signs, personnel training, contingency plan, storage time limitations, and notification of closure. As the Agency notes:

These requirements are necessary to meet the intent of the Act to reduce the potential environmental and public health risks associated with PIMW, since the permitted storage operation is not normally the generator of the waste. The owner or operator of the storage operation does not possess the same knowledge of the waste as the generator and does not maintain the same control over what is placed in the packages as the original generator. In addition, safeguards are necessary because PIMW is stored for varying lengths of time and under varying conditions. (Tr2. at 165-75.)

Treatment (Subpart C)

This subpart applies to all facilities that treat PIMW to eliminate its infectious potential.

PIMW may not be disposed of in Illinois unless it has been treated in accordance with the standards of this subpart; the standards apply whether the treatment occurred at a facility located in Illinois or elsewhere (Section 1422.120).

At Section 1422.121 it is required that there be certification of the treatment:

No person shall cause or allow the disposal of any PIMW where the infectious potential has been eliminated by treatment unless the treatment facility certifies to the transporter, if other than the generator, and certifies to the landfill operator or receiving facility operator that the PIMW has been treated in accordance with this Part, and, if applicable, with all terms and conditions specified in its operating permit. Data to verify the efficacy of the treatment unit shall be made available to the receiving facility. No person shall falsely certify that PIMW has been treated in accordance with this Part.

Design and operating requirements for PIMW treatment facilities occur in Section 1422.122. Subsections (a) and (b) apply to all treatment facilities, including those that do not require a permit. Requirements include proper management of residues, filing of an annual report, and the cleaning and

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disinfection of the facility upon closure. Mechanical treatment of PIMW is allowed only if it is an integral step in the treatment process; this is to minimize the dispersion of airborne particles (Tr2. at 33).

The (a)(1) portion of Section 1422.122 has undergone particular evolution during the course of this proceeding. 1422.122(a)(1) is intended to provide an operational definition of the statutory term "eliminates the infectious potential of the waste", which is critical to the whole concept of treatment of PIMW. Initially in the Agency proposal and in the first notice proposal the definition was attempted by directing the interested person to Sections 1422.124 and 1422.125. By the time of second notice, however, it was apparent that this device did not provide very much useful instruction and moreover was a source of confusion to at least some of the affected persons (see PC #35, #36, and Second Notice Opinion at p. 17). Accordingly, at second notice and at the recommendation of the National Solid Waste Management Association (PC #36 at 3), the Board modified the language in a manner that it thought to be consistent with the whole of Part 1422.

The Agency later objected to the amendment of its favored language and sought to have JCAR reinstate that language (see discussion above). Reinstatement was not acceptable either to other participants or the Board.

Today's final subsection (a)(1) language is language adopted by the Board on June 3, 1993 in its resolution responding to the JCAR objection (see discussion above). The language continues to provide an "upfront" operational definition of "eliminates the infectious potential", in addition to providing direction to the testing procedures of Sections 1422.124 and 1422.125.

Subsection (c) of Section 1422.122 contains additional requirements that apply to those treatment facilities for which a permit is required. These include personnel training, a written contingency plan, and a written operating record to be kept at the facility.

Section 1422.123 contains standards for treatment units. The emphasis is on performance standards rather than on authorization of particular techniques or technologies. Most fundamentally, the treatment unit must be designed and operated to eliminate the infectious potential of PIMW (subsection (a)(1)). It must also be operated in modes determined by manufacturer's specifications and under the same conditions that are used in the efficacy demonstrations (subsections (a)(2) to (a)(5)). The same level of treatment is required whether Agency permits are required or not.

Subsection (b) of 1422.123 allows treatment units to be used by treatment facilities not required to have permits if the unit meets certain requirements of the subsection or if the Board has granted an adjusted standard.

A principle underlying the Section 1422.123(b) provisions has been to allow for easy consideration of new technologies that do not fit the definition of chemical, thermal, or irradiation treatment. To achieve this end, participants and the Board have addressed these provisions in some detail, with resolution not achieved until second notice (see second notice opinion at pages 18-21).

The Initial Efficacy Test requirements are set out in Section 1422.124, with supporting materials present in Section 1422.Appendix A. The Initial Efficacy Test is a one-time demonstration made for each model of a particular treatment unit that demonstrates that the unit will achieve a 6-log reduction of all vegetative microorganisms. (Tr2. at 34.) If the Initial Efficacy Test is undertaken by the unit's manufacturer or some person other than the treatment facility, the treatment facility is responsible for obtaining and making available for inspection at any time documentation of the test.

Section 1422.125, supported by Section 1422.Appendix B, sets out the requirements of the Periodic Verification Tests. These are tests that are designed to be performed on an ongoing basis to ensure that treatment efficacy continues.

Section 1422.126 sets out those conditions, in addition to elimination of infectious potential, that are necessary before a sharp may be landfilled.

Section 1422.127 also allows the Agency to issue an experimental treatment permit for a period of up to two years, renewable once. Experimental permits are for processes or techniques that do not otherwise satisfy the standards of Subpart C. Residues from a treatment unit with an experimental permit may or may not be considered PIMW, depending on the experimental permit conditions.

ECONOMIC IMPACT

The Board is charged under the Act to take into account the technical feasibility and economic reasonableness of all regulatory proposals before it. (Act at Section 27(a).) Compliance can be achieved with existing technology, so the technical feasibility of reducing this type of pollution is not an issue in this proceeding. Therefore, by this discussion the Board examines the economic reasonableness of reducing this

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particular type of pollution by considering the information presented in the record on this topic.

In general, a small percentage of the testimony and comments address economic matters. A summary of that information is given below.

Affected Facilities and Costs

The record contains information on the facilities that generate medical waste as approximately: 2,500 health care facilities (including hospitals, long term care facilities, local health clinics), 24,000 physicians, 6,500 dentists⁴³, and 3,906 funeral directors. (Report to the Governor, Exh. 5 at 10, appendix 2). It is estimated that 103 Illinois colleges have programs that potentially generate medical waste. (Exh. 37 Att. 16). The Agency submitted a 63 page list of 1400 special waste haulers that may or may not opt to haul medical waste. A list of haulers who contacted the Agency requesting information on the requirements of commercial transportation of PIMW prior to submittal of the proposal was also included in the record (See, Exh. 37 Atts. 11 and 12). The Agency also states that there are currently seven off-site transfer/storage/treatment facilities permitted for PIMW by the Bureau of Land. There are 191 hospital incinerators and 148 sites and 88 ethylene oxide units at 56 sites currently permitted by the Bureau of Air. (See, Exh. 37 Atts. 14 and 15). All these facilities and businesses are estimated to be affected to some degree by these rules.

The Report to the Governor discusses costs of PIMW disposal as follows:

The Study Group recognized the problem of escalating health care costs and the increasing difficulty of access to health care. It is the intent of the Study Group that the effect of waste handling on health care costs be limited as much as possible.

The cost to dispose of PIMW in Illinois depends on several factors and obviously will vary within the state. However, based on the waste management companies polled, a common pricing arrangement is to charge larger generators, such as hospitals, on a per pound basis and the smaller ones per pickup or per carton. A common conversion in comparing the weight and volume of PIMW is 4.5 to 5.0 pounds/cubic foot.

* * *

⁴³ Robert A. Rechner, Illinois Dental Association, estimates that 7,000 dentists practice in Illinois. (Exh. 41).

A May 1989 American Hospital Association estimate placed the range of costs for PIMW disposal for a 200 bed hospital to be between \$63,000 and \$173,000 per year. Other factors could increase costs such as the recent Clean Air Act amendments, regulatory changes, etc.

(Exh. 5).

Throughout the hearing, members of the Study Group urged the Board to be sensitive to costs. (Exh 45 at 7; Tr1. at 109).

In addition, the NSWMA submitted a document it entitled an Economic Impact Analysis. NSWMA states that its intent and that of the Medical Waste Tracking Study Group has been to minimize cost impact the health care community in developing these regulations. NSWMA states that the PIMW regulations will have little appreciable economic impact on currently regulated hospital generators. Although the PIMW regulations will expand the scope of generators regulated beyond the hospitals currently regulated, NSWMA states that these generators "should be able to reduce the collection fee and treatment cost burden by employing one of the several on-site treatment options, or by transporting the limited quantity of PIMW they generate to a hospital with which they are affiliated for treatment. NSWMA estimates that 40 to 50% of these newly regulated small quantity generators will be able to utilize on-site or off-site hospital treatment." (Exh. 37 Att. 10).

NSWMA gives other estimates of economic impact as follows (Id.):

The economic impact for the estimated remaining 17,500 generators, who select commercial management of PIMW, should be negligible for two reasons. First, PIMW is defined by the new regulations in a way that permits generators to be more selective in the types of waste requiring PIMW management. Overall, this should reduce the volume of PIMW. Second, increased competition has reduced the cost for commercial PIMW management, and this trend should continue.

Finally, NSWMA estimates that efficient waste segregation, increased competition, and increased employee safety and awareness should all serve to reduce costs. (Exh. 37 Att. 10).

Robert A. Rechner of the Illinois Dental Society estimated that the costs of purchasing sharps containers and outer packages, and the pick-up fee increases costs to dentists approximately \$25.00 per month. He also estimated that the periodic verification tests, assuming the tests were conducted monthly for one autoclave for 2 dentists in the state would

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result in costs of \$4,410,000 for all the dentists in the state. (Exh. 41).

Cost-Benefit Analysis

The benefit to the rule, put most simply, is the lessening of the public health risks of infection from medical waste. The information in the record indicates that the costs associated with today's regulations have been minimized to the extent possible.

In addition to the discussion above, it is worth noting that the costs of these rules would be additionally offset when compared with similar programs already in place at health care facilities. The Agency states that OSHA's Occupational Exposure to Bloodborne Pathogens Rule (29 CFR 1910.1030 (1991)) (Exh. 37 Att. 6) contains requirements for segregation, packaging, labeling, marking, transportation, storage, and treatment of regulated medical waste that meets or exceeds the requirements for these rules. (Exh. 37 at 3).

The Board has considered the information in the record pertaining to the economic reasonableness of these rules, including comments, testimony, and exhibits. Actual dollar figures of the costs associated with these rules has been difficult to ascertain from the record. However, the Board concludes that the record supports the finding that the instant rule will not be economically unreasonable.

ORDER

The Clerk of the Board is directed to submit the text of the following regulations to the Secretary of State for final notice pursuant to Section 6 of the Administrative Procedure Act.

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
<u>1420.103</u>	<u>Incorporations by Reference</u>
<u>1420.104</u>	<u>Prohibitions</u>
<u>1420.105</u>	<u>Permit and Manifest Requirements and Exceptions</u>
<u>1420.106</u>	<u>Penalty Factor</u>
<u>1420.107</u>	<u>Cleaning and Disinfection</u>
<u>1420.120</u>	<u>Severability</u>

AUTHORITY: Implementing and authorized by Sections 56.2(e) and 27 of the Environmental Protection Act (Ill. Rev. Stat. 198991, ch. 111 1/2, pars. 1056.2(e), ~~as added by P.A. 87-752 effective January 1, 1992, as amended by P.A. 87-1097, effective January 1, 1993, and 1027~~) [415 ILCS 5/56.2 and 27].

SOURCE: Adopted in R91-19, at 16 Ill. Reg. 2594, effective February 3, 1992; amended in R91-20, at _____ Ill. Reg. _____, effective _____.

NOTE: Capitalization denotes statutory language.

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 throughout 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~~

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~~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 (e) 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. 111, par. 1001 et seq., as amended by P.A. 87-752, effective January 1, 1992).~~

(Source: Amended at 17 Ill. Reg. _____, effective _____)

Section 1420.102 Definitions

All definitions set forth in this Section shall have the following meanings throughout this Subtitle, unless specifically provided otherwise. Words and terms not defined have the meanings set forth 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 (Ill. Rev. Stat. 1989~~91~~, ch. 111 1/2, par. 1001 et seq., as amended by P.A. 87-~~1097~~, effective January 1, 1993-752 and P.A. 87-650, both effective January 1, 1992) [415 ILCS 5/1 et seq.].

"Agency" means the Illinois Environmental Protection Agency.

"ATCC" means American Type Culture Collection.

"Board" means the Illinois Pollution Control Board.

"CFU" means colony forming unit.

"Chemical treatment" means the treatment of PIMW in a unit that uses disinfectants or chemicals as the primary means to eliminate the infectious potential of the waste. Examples of chemical treatment are 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:

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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 3.814(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."

"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. The sanitizer must be registered by the United States Environmental Protection Agency, 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 provides protection 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" (T) means the logarithm of the indicator microorganisms that must be killed and correlates, at a minimum, to a 6-log reduction of viable test microorganisms.

"HIGHLY COMMUNICABLE DISEASE" MEANS THOSE DISEASES IDENTIFIED AS CLASS 4 ETIOLOGIC AGENTS under this Part. (Section 3.814(a)(6) of the Act)

"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 the treatment of PIMW in a unit that uses ionizing radiation as the primary means to eliminate the infectious potential of the waste. Examples of irradiation treatment are gamma (cobalt 60) and electron beam.

~~"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)~~

"Log" means logarithm to the base ten (10).

"Log kill" (L) 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 thirty-three (33) gallon bag or container.

"Package" means a receptacle that contains PIMW.

"PFU" means plaque forming unit.

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"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 3.26 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:

~~ANIMAL WASTE;~~

~~CULTURES AND STOCKS;~~

~~HUMAN BLOOD AND BLOOD PRODUCTS;~~

~~HUMAN PATHOLOGICAL WASTES;~~

~~ISOLATION WASTE; AND~~

~~UNUSED SHARPS;~~

~~USED SHARPS;~~

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.

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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. "HIGHLY COMMUNICABLE DISEASES" MEANS THOSE DISEASES IDENTIFIED BY THE BOARD IN RULES ADOPTED UNDER SUBSECTION (e) OF SECTION 56.2 OF THE ACT. (See Section 1420.102 of this Part)

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 ~~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

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THE SHARPS ARE RENDERED UNRECOGNIZABLE
BY TREATMENT. (Section 3.814 of the
Act)

"Putrescence" means the partial decomposition of organic matter by microorganisms so as to cause malodors, gases or other offensive conditions, or that is capable of providing food for vectors.

"Registered professional engineer" means a person registered under the Illinois Professional Engineering Practice Act (Ill. Rev. Stat. 1991, ch. 111, par. 5201 et seq.) [225 ILCS 325/1 et seq.].

"Reusable container" means a receptacle that meets the requirements of 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 so as to easily permit cleaning and disinfection in accordance with Section 1420.107 of this Subtitle. A reusable container is not a single-use container or is not made of cardboard.

"Sanitizer" means an antimicrobial agent that is intended for application to inanimate objects or surfaces for the purpose of reducing the microbial count to safe levels. The sanitizer must be registered by the United States Environmental Protection Agency, as identified on its label.

"Sharps" mean unused sharps and used sharps as stated in the definition of potentially infectious medical waste in this Section 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(s) that meets the same specifications as the original part.

"Single-use container" means a container intended by the manufacturer for one use only, such as 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 3.43 of the Act) For the purpose of this Subtitle, each campus of an educational institution is considered to be a single site.

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"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 3.46 of the Act)

"STORAGE SITE" means A SITE AT WHICH WASTE IS STORED. "STORAGE SITE" INCLUDES TRANSFER STATIONS. (Section 3.47 of the Act)

"Test microorganisms" means those microorganisms listed in Section 1422. Appendix A, Table A, as classified by ATCC.

"Thermal treatment" means the treatment of PIMW in a unit that uses elevated temperatures as the primary means to eliminate the infectious potential of the waste. 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 (1) A RAIL CARRIER TO A MOTOR VEHICLE OR WATER CARRIER; (2) A WATER CARRIER TO A RAIL CARRIER OR MOTOR VEHICLE; (3) A MOTOR VEHICLE TO A RAIL CARRIER, WATER CARRIER OR MOTOR VEHICLE; (4) A RAIL CARRIER TO A RAIL CARRIER, IF THE WASTE IS REMOVED FROM A RAIL CAR; OR (5) A WATER CARRIER TO A WATER CARRIER, IF THE WASTE IS REMOVED FROM A VESSEL. (Section 3.83 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 3.49 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 17 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) (18th Edition, 1992).

Test Methods for Evaluating Solid Waste. Physical/Chemical Methods, EPA Publication SW-846 (Third Edition, 1986 as amended by Update I (November, 1990)). SW-846 and Update I are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, (202) 783-3238.

(Source: Added at 17 Ill. Reg. _____, effective _____)

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 Part 1421, Subpart C of this Subtitle.
- b) CAUSE OR ALLOW THE DELIVERY OF ANY PIMW FOR TRANSPORT, STORAGE, TREATMENT OR TRANSFER EXCEPT IN ACCORDANCE WITH Part 1421, Subpart C of this Subtitle.
- c) BEGINNING JULY 1, 1992, CAUSE OR ALLOW THE DELIVERY OF ANY PIMW TO A PERSON OR FACILITY FOR STORAGE.

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TREATMENT, OR TRANSFER THAT DOES NOT HAVE A PERMIT ISSUED BY THE AGENCY TO RECEIVE PIMW pursuant to Section 39 of the Act, UNLESS NO PERMIT IS REQUIRED pursuant to subsection 1420.105(c) of this Part.

- d) BEGINNING JULY 1, 1992, 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 pursuant to subsection 1420.105(b) of this Part. Permit applications must be submitted on forms provided by the Agency.
 - 2) A PIMW MANIFEST IS COMPLETED FOR THE WASTE unless no manifest is required pursuant to subsection 1420.105(e) of this Part.
- e) CAUSE OR ALLOW THE ACCEPTANCE OF ANY PIMW FOR PURPOSES OF TRANSPORT, STORAGE, TREATMENT, OR TRANSFER EXCEPT IN ACCORDANCE WITH Part 1421, Subpart C of this Subtitle and Part 1422, Subpart B of this Subtitle.
- f) BEGINNING JULY 1, 1992, CONDUCT ANY PIMW TRANSPORTATION OPERATION:
- 1) WITHOUT A PERMIT ISSUED BY THE AGENCY TO TRANSPORT PIMW, unless no permit is required pursuant to subsection 1420.105(b) of this Part.
 - 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) BEGINNING JULY 1, 1992, 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 pursuant with Section 39 of the Act, unless no permit is required pursuant to subsection 1420.105(c) of this Part. Permit applications must be submitted on forms provided by the Agency.
 - 2) IN VIOLATION OF ANY CONDITION OF ANY PERMIT ISSUED BY THE AGENCY UNDER the ACT.

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- 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 pursuant to subsection 1420.105(e) of this Part.
- 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) BEGINNING JANUARY 1, 1994, CONDUCT A PIMW TREATMENT OPERATION AT AN INCINERATOR IN EXISTENCE ON THE EFFECTIVE DATE OF THIS TITLE 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 accordance with 35 Ill. Adm. Code: Subtitle C. No person shall cause or allow the discharge of inert or solid PIMW, or inert or solid materials resulting from the treatment of PIMW, into any sanitary sewerage system, combined sewerage system, or storm sewerage system directly or indirectly tributary to waters of the State. Such prohibition applies to, but is not limited 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.

BOARD NOTE: Interested persons should note that discharges to sewer systems can also be regulated by units of local government.

(Source: Added at 17 Ill. Reg. _____, effective _____)

Section 1420.105 Permit and Manifest Requirements and Exceptions

- a) The permit and permit appeal provisions of Sections 39 and 40 of the Act and Board regulations adopted thereunder apply to this Subtitle.

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- b) A person who conducts a PIMW transportation operation is required to obtain a PIMW hauling permit from the Agency, except:
- 1) A PERSON TRANSPORTING PIMW GENERATED SOLELY BY THAT PERSON'S ACTIVITIES; OR
 - 2) NONCOMMERCIAL TRANSPORTATION OF LESS THAN 50 POUNDS OF POTENTIALLY INFECTIOUS MEDICAL WASTE AT ANY ONE TIME; OR
 - 3) THE U.S. POSTAL SERVICE. (Section 56.1(f) of the Act)
- c) A person who conducts a PIMW treatment, storage, or transfer operation is required to 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; OR
 - 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) of the Act) If the transportation of PIMW is interrupted so as not to constitute storage, no permit is required under Section 56.1(g) of the Act. For example, transportation of PIMW interrupted by vehicle repairs or inclement weather does not constitute storage.
- d) A person applying for a permit for a PIMW treatment, storage, or transfer operation shall file an application with the Agency in accordance with the requirements and procedures of 35 Ill Adm. Code 1422.105 through 1422.107.
- e) Any person who transports PIMW is required to 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; OR
 - 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: Added at 17 Ill. Reg. _____, effective _____)

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) 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 POTENTIALLY INFECTIOUS MEDICAL WASTE. (Section 56.1(k) of the Act)

(Source: Added at 17 Ill. Reg. _____, effective _____)

Section 1420.107 Cleaning and Disinfection

a) Cleaning and disinfection comprises:

- 1) Washing with a solution of detergent used in accordance 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 Centigrade (180 degrees Fahrenheit) for a minimum of fifteen (15) seconds;
 - B) Rinsing with, or immersion in, a chemical disinfectant registered by the United States Environmental Protection Agency, as identified on its label and used in accordance with the manufacturer's instructions;
 - C) Rinsing with, or immersion in, a hypochlorite solution at a concentration of 50 ppm. 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

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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) of this Section.

b) A detergent-sanitizer used in conjunction with agitation to remove visible contamination may be substituted for the methods in subsection (a) of this Section, if used in accordance with the manufacturer's instructions.

(Source: Added at 17 Ill. Reg. _____, effective _____)

Section 1420.120 Severability

If any Section, subsection, sentence or clause of this Subtitle is adjudged unconstitutional, invalid or otherwise not effective for any reason, such adjudication does not affect the validity of this Subtitle as a whole or of any Section, subsection, sentence or clause thereof not adjudged unconstitutional, invalid or otherwise not effective for any reason.

(Source: Added at 17 Ill. Reg. _____, effective _____)

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

PART 1421
ACTIVITY STANDARDS

SUBPART A: GENERAL PROVISIONS

Section
1421.101 Compliance Dates

SUBPART B: SEGREGATION

Section
1421.110 Scope and Applicability
1421.111 Standards and Criteria

SUBPART C: PACKAGING

Section
1421.120 Scope and Applicability
1421.121 Standards and Criteria

SUBPART D: LABELING AND MARKING

Section
1421.130 Scope and Applicability
1421.131 Standards and Criteria

SUBPART E: TRANSPORTATION

Section
1421.140 Scope and Applicability
1421.141 Standards and Criteria

ILLUSTRATION A International Biohazard Symbol

AUTHORITY: Implementing and authorized by Sections 56.2 and 27 of the Environmental Protection Act (Ill. Rev. Stat. 1991, ch. 111 1/2, pars. 1056.2 and 1027) [415 ILCS 5/56.2 and 27].

SOURCE: Adopted in R91-20, at _____ Ill. Reg. _____, effective _____.

NOTE: Capitalization denotes statutory language.

SUBPART A: GENERAL PROVISIONS

Section 1421.101 Compliance Dates

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Persons subject to this Part shall comply with its standards and criteria by _____, 1993 (effective date).

SUBPART B: SEGREGATION

Section 1421.110 Scope and Applicability

This Subpart applies to persons who generate or transport PIMW, and to owners or operators of PIMW storage sites, transfer stations and treatment facilities.

Section 1421.111 Standards and Criteria

- a) Generators shall segregate PIMW as follows:
 - 1) Sharps,
 - 2) Oversized PIMW, and
 - 3) All other.
- b) PIMW mixed with other waste is regulated under this Subtitle as PIMW and the mixture is not exempt from any other applicable regulations.
- c) This Section does not prohibit the placing of previously segregated and properly packaged (in accordance with Subpart C of this Part) sharps with other waste, provided the mixture is managed in accordance with subsection (b) of this Section.

SUBPART C: PACKAGING

Section 1421.120 Scope and Applicability

This Subpart applies to persons who package PIMW for off-site transportation.

Section 1421.121 Standards and Criteria

- a) PIMW, except for oversized PIMW, must be placed in a container, or a combination of containers. Such container must be:
 - 1) RIGID;
 - 2) LEAK-RESISTANT;
 - 3) IMPERVIOUS TO MOISTURE;

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- 4) OF A STRENGTH SUFFICIENT TO PREVENT TEARING OR BURSTING UNDER NORMAL CONDITIONS OF USE AND HANDLING; AND
 - 5) SEALED TO PREVENT LEAKAGE DURING TRANSPORT.
(Section 56.1(b)(2)(A))
- b) Sharps unless treated and rendered unrecognizable pursuant to 35 Ill. Adm. Code 1422.126, must be packaged in a container, or a combination of containers, that is puncture-resistant and meets the requirements of subsection (a) of this Section.
 - c) Oversized PIMW must be covered or packaged in a manner that minimizes contact with transport workers and the public. Sharps must not be packaged with oversized PIMW in the same container.
 - d) If the outside of a container is contaminated by PIMW, a person shall place the container inside another container, or clean and disinfect the container in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle. In either case, the container or combination of containers must meet applicable requirements of subsections (a) or (b) of this Section.
 - e) Once a reusable container has been cleaned and disinfected in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle, it can be used for only waste. If a reusable container is not or cannot be cleaned and disinfected in accordance with Section 1420.107 of this Subtitle, it must be regulated as PIMW pursuant to this Subtitle.
 - f) Residues from cleaning a PIMW container, or discharges from PIMW packages, are regulated under this Subtitle, except when discharged directly into a sanitary or combined sewer in accordance with 35 Ill. Adm. Code: Subtitle C.

BOARD NOTE: Interested persons should note that discharges to sewer systems can also be regulated by units of local government.

SUBPART D: LABELING AND MARKING

Section 1421.130 Scope and Applicability

This Subpart applies to persons who package PIMW for off-site transportation or who accept packages of PIMW from off-site.

Section 1421.131 Standards and Criteria

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- a) The exterior of the outer package must be marked as follows prior to shipment:
 - 1) The generator shall:
 - A) Mark on two opposite sides of the outer package in lettering that is readable at a minimum distance of five (5) feet:
 - i) The International Biohazard Symbol as shown in Illustration A of this Part and the word "Biohazard"; and
 - ii) The word "sharps", if the package contains sharps.
 - B) Mark with indelible ink in lettering that is legible on a water-resistant label or tag securely attached to or marked on the outer package:
 - i) The generator's name,
 - ii) The generator's address, and
 - iii) The generator's phone number (a 24-hour phone number, if available).
 - 2) The transporter shall mark with indelible ink in lettering that is legible on a water-resistant label or tag securely attached to or marked on the outer package:
 - A) The transporter's name,
 - B) The transporter's permit number,
 - C) The transporter's address,
 - D) The transporter's phone number (a 24-hour phone number, if available), and
 - E) For each PIMW package, the shipment date when PIMW initially left the generator's site; or for each shipment, a unique identification number which directly corresponds to the initial date of shipment.
- b) Except for subsection (c) of this Section, inner packages must be marked as described in subsection (a)(1)(A)(i) of this Section.

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- c) If a sharps container is packaged within an outer container, the inner sharps container must be marked with indelible ink in lettering that is legible as follows:
 - 1) The International Biohazard Symbol as shown in Illustration A of this Part and the word "biohazard"; and
 - 2) The word "sharps".
- d) Containers which are not the inner or outer containers are exempt from the labeling requirements in subsection (a) of this Section. Packages may be placed in a transparent container provided that all required markings are legible through the transparent container. A non-rigid transparent container cannot be used as an outer container.
- e) For oversized PIMW, the following requirements must be met prior to shipment:
 - 1) The generator shall:
 - A) Mark on one side of the outer package in lettering that is readable at a minimum distance of five (5) feet the International Biohazard Symbol as shown in Illustration A of this Part and the word "biohazard".
 - B) Mark with indelible ink in lettering that is legible on a water-resistant label or tag securely attached to or marked on the outer package:
 - i) The generator's name,
 - ii) The generator's address, and
 - iii) The generator's phone number (a 24-hour phone number, if available).
 - 2) The transporter shall mark with indelible ink in lettering that is legible on a water-resistant label or tag securely attached to or marked on the outer package:
 - A) The transporter's name,
 - B) The transporter's permit number,
 - C) The transporter's address,

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- D) The transporter's phone number (a 24-hour phone number, if available), and
- E) For each PIMW package, the shipment date when PIMW initially left the generator's site; or for each shipment, a unique identification number which directly corresponds to the initial date of shipment.
- f) When PIMW is transported by more than one transporter, each transporter shall mark with indelible ink in lettering that is legible on a water-resistant label or tag securely attached to or marked on the outer package the information listed in subsection (a)(2) of this Section. The label, tag or mark must not obscure any previous information on the package.

SUBPART E: TRANSPORTATION

Section 1421.140 Scope and Applicability

This Subpart applies to persons who transport PIMW and are required to have a PIMW hauling permit in accordance with 35 Ill. Adm. Code 1420.105 of this Subtitle.

Section 1421.141 Standards and Criteria

- a) PIMW must be transported under conditions to minimize the effects of putrescence.
- b) Packages of PIMW must be transported only in enclosed compartments of vehicles that are secured against public access when unattended. This requirement does not apply to oversized PIMW, which must be handled in a manner that minimizes contact with transport workers and the public.
- c) Vehicles and associated storage compartments, doors, piping and valving must be:
 - 1) Cleaned of visible PIMW contamination after each use; and
 - 2) In good repair when transporting PIMW.
- d) PIMW must be transported in a manner that prevents a breeding place or food source for vectors.
- e) During transport, a PIMW package must not be compacted or subjected to stress that compromises the integrity of the container.

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- f) Residues from the cleaning of vehicles contaminated by PIMW are regulated under this Subtitle, except when discharged directly into a sanitary or combined sewer in accordance with 35 Ill. Adm. Code Subtitle C.

BOARD NOTE: Interested persons should note that discharges to sewer systems can also be regulated by units of local government.

- g) Vehicles transporting PIMW must display information in accordance with the PIMW hauling permit.
- h) The transporter shall develop and keep an emergency response plan in the vehicle. This plan must identify the names and telephone numbers of State and local authorities who must be contacted in the event of an emergency or discharge. In the event of an emergency or discharge of PIMW, the transporter shall take immediate action in accordance with the emergency response plan to protect the health and safety of the public and the environment. In addition, each vehicle transporting PIMW must carry all equipment necessary to provide a response.
- i) Vehicles transporting PIMW must not be used for the hauling of non-waste materials, with the exception of equipment and supplies intended for the use of waste management, including scales, bar coding equipment, printers, stampers, manifests, logs, dollies, load locks, conveyers, material handling equipment, plastic containers, corrugated boxes, plastic bags, tape, sharps containers, drums, labels, signs, stickers, spill kits, new PIMW containers or PIMW containers that have been cleaned and disinfected in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle.
- j) PIMW must not be in transport for more than ten (10) calendar days.
- k) This Subpart does not apply to the United States Postal Service.
- l) COMMENCING MARCH 31, 1993, AND ANNUALLY THEREAFTER, EACH TRANSPORTER OF PIMW REQUIRED TO HAVE A PERMIT UNDER SUBSECTION (f) OF SECTION 56.1 OF THE ACT SHALL FILE A REPORT WITH THE AGENCY SPECIFYING THE QUANTITIES AND DISPOSITION OF PIMW TRANSPORTED DURING THE PREVIOUS CALENDAR YEAR. SUCH REPORTS SHALL BE ON FORMS PRESCRIBED AND PROVIDED BY THE AGENCY. (Section 56.3 of the Act)

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Section 1421.Illustration A



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

PART 1422
DESIGN AND OPERATION OF FACILITIES

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- 1422.105 PIMW Permit Application Contents
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Section

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- 1422.APPENDIX A Initial Efficacy Test Procedures
 - TABLE A Test Microorganisms
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 - TABLE C Challenge Loads
- 1422.APPENDIX B Correlating Periodic Verification Test Procedures

AUTHORITY: Implementing and authorized by Sections 56.2 and 27 of the Environmental Protection Act (Ill. Rev. Stat. 1991, ch. 111 1/2, pars. 1056.2 and 1027) [415 ILCS 5/56.2 and 27].

SOURCE: Adopted in R91-20, at _____ Ill. Reg. _____, effective _____.

NOTE: Capitalization denotes statutory language.

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SUBPART A: GENERAL PROVISIONS

Section 1422.101 Compliance Date

Persons subject to this Part shall comply with its requirements by _____, 1993 (effective date).

Section 1422.105 PIMW Permit Application Contents

An application for a permit for a PIMW treatment, storage or transfer operation must contain the information specified in this Section. If the applicant believes that the documentation or information required pursuant to any subsection of this Section is not applicable for reasons such as irrelevancy, the application must include the reasons in support of such belief.

- a) Legal description of the site at which the facility is to be located.
- b) Maps and floor plans showing the location of the facility, the facility boundary and the location of all units included in the facility.
- c) Process flow diagrams or schematic drawings showing the flow of waste through the facility. The diagrams or drawings must show, but not be limited to, the locations of residuals, recycled streams, sample points, equipment and process monitoring devices. Equipment must be labeled on the process flow diagram to correspond to an equipment number.
- d) Written description of the facility or facility operations with supporting documentation describing the procedures and plans that will be used at the facility to comply with the requirements of Parts 1420 through 1422 of this Subtitle and any other applicable Parts of 35 Ill. Adm. Code: Chapter 1. Such description must include, but not be limited to, the following information:
 - 1) The type of waste management units and the types and volumes of waste;
 - 2) The overall process to be used for treating or storing PIMW and the anticipated performance of the process;
 - 3) In detail, the major activities at the facility, such as transfer, storing, screening, weighing, processing and treatment (including the number of units) of PIMW;

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- 4) The operations for initial facility startup, daily startup and scheduled and unscheduled shutdowns;
 - 5) The days and hours of operation;
 - 6) The operating parameters for the treatment units;
 - 7) The safety and monitoring equipment for the treatment units;
 - 8) A cleaning and disinfection plan describing the daily cleanup procedures, including the methods to disinfect emptied reusable PIMW containers, transport vehicles, and facility surfaces and equipment contaminated with PIMW;
 - 9) The methods to control: emissions of odors and aerosols generated, including all supporting design and engineering data; dust, noise, litter and vectors; and handling and storing;
 - 10) The methods to treat, transfer, or dispose of residual wastes generated from the operation of the facility;
 - 11) Adequacy of the utilities to operate the facility and to respond to emergency situations;
 - 12) Numbers and duties of employees directly responsible for the operation of the site or facility; and
 - 13) Location and type of security devices to prevent unauthorized access.
- e) A waste screening plan that describes procedures to be used to identify and prevent the acceptance of unauthorized wastes.
- f) Description of procedures to be used for inspection, contingency, recordkeeping and closure plans as required by this Part.
- g) For a facility at which the owner or operator is required to conduct either Initial Efficacy Tests or Periodic Verification Tests, a written description of procedures to be used for recordkeeping, classifying residuals and collecting data for the Document of Initial Efficacy Demonstration and Correlating Periodic Verification Demonstration.

An application for a permit for PIMW treatment, storage or transfer operation must contain the certifications specified in this Section.

- a) The permit application must contain a certificate of ownership of the permit area or a copy of the lease and its duration. The lease must clearly specify that the owner authorizes the construction of a PIMW waste management facility on the leased premises. The owner or operator shall certify that the Agency will be notified 30 days prior to any changes in ownership or conditions in the lease affecting the permit area.
- b) All permit applications must be signed by a duly authorized agent of the operator and the property owner, must be accompanied by an oath or affidavit attesting to the agent's authority to sign the application and must be notarized. The following persons are considered duly authorized agents of the operator and the property owner:
 - 1) For corporations, a principal executive officer of at least the level of vice president;
 - 2) For a sole proprietorship or partnership, a proprietor or general partner, respectively; and
 - 3) For a municipality, state, federal or other public agency, by the head of the agency or ranking elected official.
- c) All permit applications must contain the name, address, and telephone number of the duly authorized agent of the operator and the property owner to whom all inquiries and correspondence must be addressed.
- d) All designs presented in the application must be prepared by, or under the supervision of, a professional engineer. The professional engineer shall affix the name of the engineer, date of preparation, registration number, a statement attesting to the accuracy of the information and design and a professional seal to all designs.
- e) The applicant must state whether the facility is a new regional pollution control facility, as defined in Section 3.32 of the Act, which is subject to the site location suitability approval requirements of Sections 39(c) and 39.2 of the Act. If such approval by a unit of local government is required, the application must identify the unit of local government with jurisdiction. The application must contain any

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approval issued by that unit of local government. If no approval has been granted, the application must describe the status of the approval request.

Section 1422.107 PIMW Permit Application Filing Requirements

- a) All permit applications must be filed with the Agency on forms as prescribed by the Agency. Hand delivered applications must be delivered during the Agency's normal business hours to the offices of the Permit Section. The Agency shall provide a dated, signed receipt of filing only if the applicant requests. The date of filing must be that recorded by the Agency, unless proven otherwise by a dated, signed receipt.
- b) The permit application must be accompanied by all filing fees required pursuant to Section 5(f) of the Act.

SUBPART B: STORAGE OR TRANSFER OPERATIONS

Section 1422.110 Scope and Applicability

This Subpart applies to the owner or operator of a PIMW storage site or transfer station, collectively referred to as a "storage operation" in this Subpart.

Section 1422.111 Design and Operating Standards and Criteria

- a) ANY PERSON WHO STORES PIMW PRIOR TO TREATMENT OR DISPOSAL ON-SITE OR TRANSPORT OFF-SITE MUST COMPLY WITH ALL OF THE FOLLOWING STORAGE REQUIREMENTS:
 - 1) STORE THE PIMW IN A MANNER AND LOCATION THAT MAINTAINS THE INTEGRITY OF THE PACKAGING AND PROVIDES PROTECTION FROM WATER, RAIN, AND WIND.
 - 2) MAINTAIN THE PIMW IN A NONPUTRESCENT STATE, USING REFRIGERATION WHEN NECESSARY.
 - 3) LOCK THE OUTDOOR STORAGE AREAS CONTAINING PIMW TO PREVENT UNAUTHORIZED ACCESS.
 - 4) LIMIT ACCESS TO ON-SITE STORAGE AREAS TO AUTHORIZED EMPLOYEES.
 - 5) STORE THE PIMW IN A MANNER THAT AFFORDS PROTECTION FROM ANIMALS AND DOES NOT PROVIDE A BREEDING PLACE OR FOOD SOURCE FOR vectors. (Section 56.1(e)(2)(D)(i)-(v) of the Act)

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- 6) PIMW packages must not be compacted or subjected to stress that compromises the integrity of the container.
- 7) Multiple generators in the same building may store their PIMW packages in a common storage area.
- 8) Reusable PIMW containers or facility equipment (e.g., carts, squeegees or shovels) which are visually contaminated with PIMW must be cleaned in a designated area in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle.
- 9) Residues from cleaning a PIMW contaminated container, equipment or work surface are regulated under this Subtitle, except when directly discharged into a sanitary or combined sewer in accordance with 35 Ill. Adm. Code: Subtitle C.

BOARD NOTE: Interested persons should note that discharges to sewer systems can also be regulated by units of local government.

- 10) Copies of all PIMW manifests required by 35 Ill. Adm. Code 1420.105 of this Subtitle must be retained by and kept at the storage operation for three (3) years and must be made available at the storage operation during normal business hours for inspection and photocopying by the Agency. The retention period for PIMW manifests is extended automatically during the course of any unresolved enforcement action regarding the storage operation or as requested in writing by the Agency.
 - 11) Upon closure of a storage operation, the owner or operator shall clean the area, equipment and structures in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle.
- b) In addition to the requirements listed in subsection (a) of this Section, storage operations required to have a permit pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle must also comply with the following requirements that the Agency shall review during the permitting process:
- 1) Storage operations shall weigh in pounds the amount of PIMW received, unless previously weighed by the transporter. PIMW must be weighed with a device for which certification has been obtained under the Weights and Measures Act (Ill. Rev.

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Stat. 1991, ch. 147, pars. 101 et seq.) [225 ILCS 470].

- 2) PIMW packages must be stored in designated areas so as not to contaminate other waste or materials.
- 3) Cardboard packages must be stored in an enclosed area at an elevation above that of the floor.
- 4) PIMW must be stored on a surface that allows drainage and collection of liquids and that minimizes exposure to workers and the public.
- 5) Adequate aisle space, as specified in the permit, must be maintained between packages to allow inspection of at least one (1) side of each package. Packages must be stacked so that labels are readable. A vehicle containing PIMW is exempt from the above aisle space requirement:
 - A) When loading or unloading a vehicle; or
 - B) When a fully-loaded vehicle is on a site.Either exemption, or both exemptions, must not exceed five (5) calendar days.
- 6) Material handling equipment must be designed so as to maintain the integrity of the package.
- 7) Signs identifying the storage operation must be prominently displayed at the points of access to the secured storage area. Signs must be marked in lettering that is readable at a minimum distance of five (5) feet. At a minimum, the signs must display the International Biohazard Symbol as shown in 35 Ill. Adm. Code 1421. Illustration A and the word "biohazard".
- 8) Personnel training must be provided to all staff prior to the handling of PIMW. Annual personnel training must include, at a minimum, a thorough explanation of the operating procedures to be taken during normal and emergency situations. The owner or operator shall keep records verifying training of personnel.
- 9) Storage operations must have a written contingency plan and the applicable sections must be implemented in the event of a discharge or personal injury. The contingency plan must describe the actions that personnel shall take in

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response to emergency situations such as, but not limited to, personal injury, discharges of PIMW, rupture of plastic bags and equipment failure. This contingency plan must, at a minimum, include a list of all emergency equipment at the storage operation, an up-to-date list of names, addresses and phone numbers (office and home) of all persons qualified to act as emergency coordinator, procedures for cleanup, protection of personnel, disposal of spill residue, repackaging of PIMW and alternate arrangements for PIMW storage and transfer. A copy of the contingency plan must be maintained at the storage operation. Emergency phone numbers and a brief description of the emergency procedures must be posted at the storage operation.

- 10) The owner or operator shall keep a written operating record at the storage operation. At a minimum, the following information must be recorded and maintained in the operating record:
 - A) Quantities and disposition of PIMW stored or transferred;
 - B) Date and time the PIMW arrived at the permitted storage operation site;
 - C) Date and time the PIMW left the storage operation;
 - D) Waste stream permit number (authorization number), if applicable, issued by the Agency;
 - E) Generator name(s), location(s) and if applicable, the generator identification number(s) issued by the Agency for each PIMW load received at the storage operation;
 - F) Temperature(s) the PIMW load was maintained at the storage operation;
 - G) Destination of packages, which must include at a minimum the name of the receiving facility, the location of the receiving facility, the identification number of the receiving facility issued by the Agency (if applicable) and the disposition (i.e., storage, transfer, treatment or disposal); and

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- H) In a separate log, the date, time, nature and extent of all discharges and personal injuries and the date, time, nature and result of any response(s) taken.
- 11) The records required by subsections (b)(8) and (10) of this Section must be retained by and kept at the storage operation and must be made available at the storage operation during normal business hours for inspection and photocopying by the Agency. These records must be kept until closure of the storage operation. The retention period is extended automatically during the course of any unresolved enforcement action regarding the storage operation or as requested in writing by the Agency.
- 12) Unless otherwise authorized by the Agency in the permit, PIMW must not be stored for more than:
 - A) Seventy-two (72) hours at the storage operation unless the surface temperature of the package is maintained at or below 45 degrees Fahrenheit, and
 - B) Thirty (30) days at the storage operation regardless of temperature.
- 13) At least sixty (60) days prior to closing a storage operation, the owner or operator shall notify the Agency of the planned closure. Within ninety (90) days after the date the final load of PIMW is received at the storage operation, the owner or operator shall certify to the Agency that final closure has been completed in accordance with the permit, the Act and all applicable regulations promulgated thereunder.

SUBPART C: TREATMENT FACILITIES

Section 1422.120 Scope and Applicability

This Subpart applies to the owner or operator of a facility in Illinois that is designed to treat PIMW to eliminate its infectious potential. This Subpart also applies to owners or operators of treatment facilities where the treated PIMW residual is disposed of in Illinois. For purposes of this Part, a facility or operation that is designed to treat PIMW to eliminate its infectious potential is referred to as a "treatment facility".

Section 1422.121 Treatment Facility Certification

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No person shall cause or allow the disposal of any PIMW where the infectious potential has been eliminated by treatment unless the treatment facility certifies to the transporter, if other than the generator, and certifies to the landfill operator or receiving facility operator that the PIMW has been treated in accordance with this Part, and, if applicable, with all terms and conditions specified in its operating permit. Data to verify the efficacy of the treatment unit must be made available to the receiving facility upon request of the receiving facility. No person shall falsely certify that PIMW has been treated in accordance with this Part.

Section 1422.122 Design and Operating Standards

a) Treatment of PIMW must be conducted in a manner that:

- 1) ELIMINATES THE INFECTIOUS POTENTIAL OF THE WASTE. A treatment process eliminates the infectious potential of PIMW if the owner or operator of a treatment unit demonstrates that an Initial Efficacy Test and Periodic Verification Test have been completed successfully.
 - A) Successful completion of an Initial Efficacy Test must be demonstrated by a 6-log kill of test microorganisms. For a thermal unit that maintains the integrity of the container, a 6-log kill of indicator microorganism spores may be used as an alternative test. These demonstrations must be conducted in accordance with Section 1422.124.
 - B) Successful completion of a Periodic Verification Test must be demonstrated, in accordance with Section 1422.125, by:
 - i) a 6-log kill of test microorganisms or indicator microorganism spores as provided in subsection (a)(1)(A) above; or
 - ii) a minimum 3-log kill of indicator microorganism spores that has been correlated with a 6-log kill of test microorganisms; or
 - iii) an alternate method submitted to and approved in writing by the Agency.
- 2) PREVENTS THE COMPACTION AND RUPTURE OF CONTAINERS DURING HANDLING OPERATIONS, except when compaction

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or rupture is an integral part of the treatment process and the treatment process is conducted without discharge of PIMW to the environment;

- 3) DISPOSES OF TREATMENT RESIDUALS IN ACCORDANCE WITH THIS ACT AND REGULATIONS ADOPTED THEREUNDER;
 - 4) PROVIDES FOR QUALITY ASSURANCE PROGRAMS that must include, at a minimum, a written plan that:
 - A) Designates responsibility to personnel;
 - B) Describes operating parameters that must be monitored to insure effectiveness of the treatment process;
 - C) Identifies monitoring devices;
 - D) Insures monitoring devices are operating properly;
 - E) Establishes appropriate ranges for all operating parameters;
 - F) Identifies the person(s) who shall collect and organize data for inclusion in the operating record;
 - G) Identifies the person(s) who shall evaluate any discrepancies or problems;
 - H) Identifies the person(s) who shall propose actions to correct any problems identified; and
 - I) Identifies the person(s) who shall assess actions taken and document improvement;
 - 5) PROVIDES FOR PERIODIC TESTING USING BIOLOGICAL TESTING, WHERE APPROPRIATE, THAT DEMONSTRATE PROPER TREATMENT OF THE WASTE;
 - 6) PROVIDES FOR ASSURANCES THAT CLEARLY DEMONSTRATE THAT POTENTIALLY INFECTIOUS MEDICAL WASTE HAS BEEN PROPERLY TREATED; and
 - 7) IS IN COMPLIANCE WITH ALL FEDERAL AND STATE LAWS AND REGULATIONS PERTAINING TO ENVIRONMENTAL PROTECTION. (Section 56.2(a)(1)-(7) of the Act)
- b) In addition to the requirements in subsection (a) of this Section:

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- 1) Residues from cleaning a PIMW contaminated container, equipment or work surface are regulated under this Subtitle, except when directly discharged into a sanitary or combined sewer in accordance with 35 Ill. Adm. Code: Subtitle C.

BOARD NOTE: Interested persons should note that discharges to sewer systems can also be regulated by units of local government.

- 2) Ash resulting from the incineration of PIMW is an industrial process waste, as defined in Section 3.17 of the Act, and must be managed as a special waste in accordance with 35 Ill. Adm. Code 807 and 809.
 - 3) Copies of PIMW manifests required by 35 Ill. Adm. Code 1420.105 of this Subtitle must be retained by and kept at the treatment facility for three (3) years and must be made available at the treatment facility during normal business hours for inspection and photocopying by the Agency. The retention period for PIMW manifests is extended automatically during the course of any unresolved enforcement action regarding the treatment facility or as requested in writing by the Agency.
 - 4) COMMENCING MARCH 31, 1993, AND ANNUALLY THEREAFTER, EACH TREATMENT FACILITY FOR WHICH A PERMIT IS REQUIRED pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle and EACH FACILITY NOT REQUIRED TO HAVE A PERMIT pursuant to Section 1420.105 of this Subtitle THAT TREATS MORE THAN 50 POUNDS PER MONTH OF POTENTIALLY INFECTIOUS MEDICAL WASTE SHALL FILE A REPORT WITH THE AGENCY SPECIFYING THE QUANTITIES AND DISPOSITION OF POTENTIALLY INFECTIOUS MEDICAL WASTE TREATED DURING THE PREVIOUS CALENDAR YEAR. SUCH REPORTS SHALL BE ON FORMS PRESCRIBED AND PROVIDED BY THE AGENCY. (Section 56.3 of the Act)
 - 5) Upon closure of a treatment facility, the owner or operator shall clean the area, equipment and structures in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle.
- c) In addition to the requirements listed in subsections (a) and (b) of this Section, owners or operators of treatment facilities required to have a permit pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle shall also comply with the following requirements that the Agency shall review during the permitting process:

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- 1) Amounts of PIMW received must be weighed in pounds with a device for which certification has been obtained under the Weights and Measures Act (Ill. Rev. Stat. 1991, ch. 147, pars. 101 et seq.) [225 ILCS 470].
- 2) Signs identifying that the facility treats PIMW must be prominently displayed at the points of access to the treatment area. Signs must be marked in lettering that is readable at a minimum distance of five (5) feet. At a minimum, the signs must display the International Biohazard Symbol as shown in 35 Ill. Adm. Code 1421.Illustration A and the word "biohazard".
- 3) Personnel training must be provided to all staff prior to the handling of PIMW. Annual personnel training must include, at a minimum, a thorough explanation of the operating procedures to be taken during normal and emergency situations. The owner or operator shall keep records verifying training of personnel.
- 4) Treatment facilities must have a written contingency plan and the applicable sections must be implemented in the event of a discharge, equipment failure or personal injury. The contingency plan must describe the actions that personnel shall take in response to emergency situations such as, but not limited to, personal injury, discharges of PIMW and equipment failure. This contingency plan must, at a minimum, include a list of all emergency equipment at the treatment facility, an up-to-date list of names, addresses and phone numbers (office and home) of all persons qualified to act as emergency coordinator, procedures for cleanup, protection of personnel, disposal of spill residue and alternative arrangements for PIMW treatment. A copy of the contingency plan must be maintained at the treatment facility. Emergency phone numbers and a brief description of the emergency procedures must be posted at the treatment facility.
- 5) The owner or operator shall keep a written operating record at the treatment facility. At a minimum, the following information must be recorded and maintained in the operating record:
 - A) Quantities and disposition of PIMW treated;

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- B) Date and time the PIMW arrived at the permitted PIMW site;
 - C) Date and time the PIMW was treated;
 - D) The operating parameters of the treatment unit (e.g., temperature, pressure, residence time, chemical concentration, irradiation dose);
 - E) Date and time the PIMW left the treatment facility;
 - F) Generator name(s), location(s) and, if applicable, the generator identification number(s) issued by the Agency for each PIMW load received at the treatment facility;
 - G) The destination of the treated waste which must include, at a minimum, the name of the receiving facility, the location of the receiving facility, the identification number of the receiving facility issued by the Agency (if applicable) and the disposition; and
 - H) In a separate log, the date, time, nature and extent of all discharges and personal injuries and the date, time, nature and result of any response(s) taken.
- 6) The records required by subsections (c)(3) and (c)(5) of this Section must be retained by and kept at the treatment facility and must be made available at the treatment facility during normal business hours for inspection and photocopying by the Agency. These records must be kept until closure of the treatment facility. The retention period is extended automatically during the course of any unresolved enforcement action regarding the treatment facility or as requested in writing by the Agency.
- 7) At least sixty (60) days prior to closing a treatment facility, the owner or operator shall notify the Agency of the planned closure. Within ninety (90) days after the date the final load of PIMW is received at the treatment facility, the owner or operator shall certify to the Agency that final closure has been completed in accordance with the permit, the Act, and all applicable regulations promulgated thereunder.

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Section 1422.123 Treatment Units

a) A treatment unit must be:

- 1) Designed and operated to eliminate the infectious potential of PIMW as demonstrated by the Initial Efficacy Test and Periodic Verification Tests, pursuant to Sections 1422.124 and 1422.125 of this Part;
- 2) Operated according to the manufacturer's instructions, if it is a commercially available unit;
- 3) Operated under the same conditions that have been used to demonstrate that the infectious potential was eliminated in accordance with this Part;
- 4) Operated with a PIMW feed rate not to exceed that which was used to demonstrate that the infectious potential was eliminated; and
- 5) Designed and operated to limit the emission of microorganisms into the air.

b) A treatment unit may be used by the owner or operator of a treatment facility not required to have a permit pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle, if the requirements of subsection (b)(1) or (2) below are met.

- 1) The treatment unit meets the standards of subsections (a)(1)-(5) of this Section, and:
 - A) The treatment unit utilizes a thermal, chemical or irradiation treatment, as defined in 35 Ill. Adm. Code 1420.102 of this Subtitle; or
 - B) The owner or operator maintains a copy of the Initial Efficacy Test results for the treatment unit. In addition, the owner or operator shall conduct Periodic Verification Tests in accordance with the manufacturer's instructions and Section 1422.125. Test results shall be retained and made available for inspection in accordance with Section 1422.125(d) and (g); and
 - C) The owner or operator retains any notification from the manufacturer of the

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permitted commercially available treatment unit of a permit modification.

- 2) The Board has granted the owner's or operator's petition for an adjusted standard pursuant to 35 Ill. Adm. Code 106.Subpart G or a site-specific rulemaking pursuant to 35 Ill. Adm. Code 102. The petition must include a demonstration that the treatment unit meets the standards of subsection (a)(1)-(5) of this Section.
- c) For an autoclave, incinerator or ethylene oxide unit installed or operated prior to the effective date of these regulations, an Initial Efficacy Test is not required. The first Periodic Verification Test must be performed within three (3) months of the effective date of these regulations to demonstrate that the infectious potential has been eliminated.
- d) For treatment facilities required to have a permit pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle, the permit application must include, at a minimum, the following information regarding the treatment unit:
 - 1) An operating plan that includes a description of the treatment facility's operating procedures and parameters; and
 - 2) Test data and supporting documentation demonstrating that the infectious potential has been eliminated from either similar existing PIMW treatment units or pilot projects.
- e) The treated PIMW is managed in accordance with this Subtitle and 35 Ill. Adm. Code: Subtitle G.

Section 1422.124 Initial Efficacy Test

- a) The manufacturer, owner or operator of a treatment unit shall conduct an Initial Efficacy Test, pursuant to Appendix A of this Part, for each model prior to its operation. If significant mechanical changes are made to a treatment unit, the Initial Efficacy Test must be repeated. Treatment units are considered to be the same model if they:
 - 1) Are manufactured by the same company;
 - 2) Have the same capacity; and
 - 3) Have no significant mechanical changes.

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- b) The Initial Efficacy Test must be conducted by the use of Options 1, 2 or 3 of Appendix A of this Part, and the challenge loads as described in Table C of Appendix A of this Part. If any of the challenge loads fails the Initial Efficacy Test, the operating conditions must be revised and the Initial Efficacy Test must be repeated for all challenge loads. The Initial Efficacy Test must also meet the requirements of this Section.
- 1) Option 1 must be used for a treatment unit that does not maintain the integrity of the container of test microorganisms (e.g., grinding followed by chemical disinfection). This option is a two phase test.
 - A) The first phase is to determine the dilution of each test microorganism from the operation of the treatment unit for each challenge load. The log of the number of viable test microorganisms in the processed residue must be greater than or equal to six (6).
 - B) The second phase is to determine the effectiveness of the treatment unit. The log kill (L) for each test microorganism after treatment must be greater than or equal to six (6).
 - 2) Option 2 must be used for a treatment unit that maintains the integrity of the container of test microorganisms (e.g., autoclaving). The log kill (L) for each test microorganism after treatment must be greater than or equal to six (6).
 - 3) Option 3 can only be used for a thermal treatment unit that maintains the integrity of the container of indicator microorganism spores (e.g., autoclaving, incinerating). The log kill (L) of indicator microorganism spores after treatment must be greater than or equal to six (6).
- c) Composition of Challenge Loads
- 1) For treatment units designed to treat all types of PIMW, all three (3) types of challenge loads must be used in conducting the Initial Efficacy Test. The three (3) types of challenge loads represent PIMW with a high moisture content, low moisture content and high organic content. The quantity of each challenge load must equal 100% of the maximum capacity of the treatment unit. Each challenge load must include, at a minimum, 5% of each of the

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following categories: blood/broth cultures, fibers, metals, sharps, plastics, pathological waste, glass, non-woven fibers and bottles of liquids. Table C of Appendix A of this Part contains the moisture and organic content requirements that must be met in each type of challenge load.

- 2) For treatment units designed to treat only select categories of PIMW (e.g., a sharps treatment unit), a modification in the composition of the challenge load(s) may be used if approved by the Agency in writing.
- d) The Initial Efficacy Test must be conducted under the same operating conditions under which the treatment unit operates on a day-to-day basis. The feed rate for the treatment unit must remain constant throughout the Initial Efficacy Test. This feed rate must never be exceeded during the operation of the treatment unit.
- e) The Initial Efficacy Test must be performed so that:
 - 1) Each container of test microorganisms and/or indicator microorganism spores is placed in the load to simulate the worse case scenario (i.e., that part of the load that is the most difficult to treat). For example, the worst case scenario for an autoclave would be to place the container of test microorganisms and/or indicator microorganism spores within a sharps container that must in turn be deposited in a plastic biohazard bag that is then located centrally within each of the challenge loads.
 - 2) Test microorganisms and/or indicator microorganisms must be cultured and enumerated in accordance with instructions provided by the supplier of the microorganisms and Standard Methods for the Examination of Water and Wastewater, incorporated by reference at 35 Ill. Adm. Code 1420.103.
- f) A Document of Initial Efficacy Demonstration must be retained at the treatment facility, and made available at the treatment facility during normal business hours for inspection and photocopying by the Agency. The Document of Initial Efficacy Demonstration must include, at a minimum:
 - 1) A detailed description of the test procedures used, including all test data generated, with

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- descriptions of data handling, and a presentation and interpretation of final test results;
- 2) A detailed description and verification of the operating parameters (e.g., temperatures, pressures, retention times, chemical concentrations, irradiation doses and feed rates);
 - 3) A description of quality assurance/quality control procedures and practices for the culture, storage and preparation of test and/or indicator microorganisms (including, but not limited to, organism history, source, stock culture maintenance and enumeration procedures). The purity of the test microorganisms and/or indicator microorganism spores must be certified by a commercial or clinical laboratory;
 - 4) A description of microorganism preparation and packaging, challenge loadweight and composition, unit testing scheme (numbers of test rows) and sampling strategy (e.g., number and weight of solid and/or liquid samples);
 - 5) A description and demonstration of microorganism recovery including sample processing, incubation and effective neutralization, and absence of toxic compounds due to neutralization (as applicable);
 - 6) Appendices containing raw data and assumptions in tabular form;
 - 7) The name(s), date, signature(s) and title(s) of person(s) conducting the Initial Efficacy Test, and their qualifications; and
 - 8) A list of references used to evaluate the data and obtain the final conclusion.

Section 1422.125 Periodic Verification Test(s)

- a) The effectiveness of the treatment unit is verified by the Periodic Verification Test(s), which must be conducted in accordance with this Section. The manufacturer, owner or operator of a treatment unit must perform Periodic Verification Test(s) that satisfy at least one (1) of the following:
 - 1) Passing the Initial Efficacy Test by using Options 1, 2, or 3 of Appendix A of this Part (whichever is applicable). The three challenge loads

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described in Appendix A, Table C, do not need to be used. The test microorganisms or indicator microorganisms must be placed in a representative load in accordance with Section 1422.124(e)(1) of this Part. For example, an autoclave may use Option 3 (e.g., demonstrate at a minimum the destruction of one million (1,000,000) *Bacillus stearothermophilus* spores) to meet the Periodic Verification Tests(s) requirement. In the case of an incinerator, a stainless steel pipe with threaded ends and removable caps lined with a ceramic insulation may be used to contain a glass culture vial with *Bacillus subtilis* spore strips. The pipe with the spore strips may be placed in a load of PIMW for the Periodic Verification Test. After the treatment, the pipe with the spore strips may be recovered and the spores may be cultured to assess whether, at a minimum, one million spores have been destroyed to meet the Periodic Verification Test(s) requirement.

- 2) Correlating the log kill (L) of the test microorganisms in the Initial Efficacy Test to an equivalent log kill (T) of the indicator microorganism spores in accordance with Appendix B of this Part. The equivalent log kill (T) of the indicator microorganism spores must be used for all subsequent Periodic Verification Tests. The correlation must be done with the three (3) challenge loads identified in Table C of Appendix A of this Part. (See subsection (b) of this Section for further requirements); or
 - 3) Submitting and obtaining written approval by the Agency for a procedure that is equivalent to subsection (a)(2) of this Section. Examples of alternatives include, but are not limited to, use of another indicator microorganism or measurement of disinfectant concentrations in the treated residue. For incinerators only, an example of an alternative is visually inspecting the ash from each load of treated PIMW to insure that all PIMW within the load is completely combusted. The approval of an alternative by the Agency may require more frequent testing and/or monitoring of the treatment unit.
- b) For the Correlating Periodic Verification Test, which provides the correlation of log kill (L) of the test microorganisms with the equivalent log kill (T) of the indicator microorganisms, the following procedures apply:

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- 1) At a minimum, an initial population of one million (1,000,000) indicator microorganism spores per gram of waste solids in each challenge load must be used;
 - 2) The fraction of surviving indicator microorganisms that correlates to a log kill (L) of six (6) for each test microorganism must be used in future Periodic Verification Test(s). (For example, if a log kill (L) of four (4) for the indicator microorganism spores per gram of waste solids is achieved during this demonstration, then a population of ten thousand (10,000) of the indicator microorganism must be used in all future Periodic Verification Test(s)). For future Periodic Verification Tests, the three challenge loads described in Appendix A, Table C, do not need to be used. The test microorganisms or indicator microorganism spores must be placed in a representative load in accordance with Section 1422.124(e)(1) of this Part;
 - 3) An equivalent log kill (T) of three (3) for the indicator microorganism spores must be the minimum threshold death rate to insure that all test microorganisms are destroyed;
 - 4) Test microorganisms and/or indicator microorganisms must be cultured and enumerated in accordance with instructions provided by the supplier of the microorganisms and Standard Methods for the Examination of Water and Wastewater, incorporated by reference at 35 Ill. Adm. Code 1420.103.; and
 - 5) The Periodic Verification Test and the Initial Efficacy Test may be run concurrently to verify the correlation.
- c) If a load of PIMW fails a Periodic Verification Test(s), the Periodic Verification Test(s) must be repeated. The operator shall implement the quality assurance program (in Section 1422.122 (a)(4) of this Part) and contact the manufacturer, if applicable, to identify and correct the problem(s) until the unit can eliminate the infectious potential of the PIMW. If the operating parameters are altered, another Initial Efficacy Test must be performed to demonstrate the effectiveness of the unit and, if applicable, another Periodic Verification Test correlation, pursuant to subsection (a) of this Section, must also be repeated. Loads of PIMW that were first processed prior to

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receiving results showing a failure of the Periodic Verification Tests are considered treated. A second Periodic Verification Test must be run immediately after the first Periodic Verification Test indicates a failure. The second Periodic Verification Test is to determine whether or not the treatment unit is eliminating the infectious potential of the waste. After the second Periodic Verification Test shows a failure of the treatment unit, the processed waste is considered PIMW and must be managed in accordance with this Subtitle.

- d) Results of the Periodic Verification Test(s) must be received, verified and made available for inspection by the Agency within two weeks of when the test was conducted. When a Periodic Verification Test is used to confirm the failure of a treatment unit, the results of the Periodic Verification Test(s) must be received, verified and made available for inspection by the Agency within one week of when the test was conducted. Results of Periodic Verification Tests must be made available in accordance with the requirements of subsection (g), below.
- e) Periodic Verification Test(s) must be conducted monthly, or more frequently if required by the permit or recommended by the manufacturer.
- f) A Document of Correlating Periodic Verification Demonstration must be prepared by and retained at the treatment facility, and must be available at the treatment facility during normal business hours for inspection and photocopying by the Agency. The Document of Periodic Verification Demonstration must include, at a minimum:
 - 1) A detailed description of the test procedures used and documentation showing the correlation between the log kill (L) of the test microorganisms and the equivalent kill (T) of the indicator microorganism spores. An evaluation of the test results must include: All test data generated, with description of data handling, and a presentation and interpretation of final test results;
 - 2) A detailed description of the operating parameters (e.g., temperatures, pressures, retention times, chemical concentrations, irradiation dose and feed rates);

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- 3) A description of quality assurance/quality control procedures and practices for the culture, storage and preparation of test and/or indicator microorganisms (including, but not limited to, organism history, source, stock culture maintenance and enumeration procedures). The purity of the test microorganisms and/or indicator microorganism spores must be certified by a commercial or clinical laboratory;
 - 4) A description of microorganism preparation and packaging, challenge load weight and composition, unit testing scheme (numbers of test rows) and sampling strategy (e.g., number and weight of solid and/or liquid samples);
 - 5) A description and demonstration of microorganism recovery including sample processing, incubation and effective neutralization, and absence of toxic compounds due to neutralization;
 - 6) Appendices containing raw data and assumptions in tabular form;
 - 7) The name(s), date, signature(s) and title(s) of person(s) conducting the Initial Efficacy Test, and their qualifications; and
 - 8) A list of references used to evaluate the data and obtain the final conclusion.
- g) Records of Periodic Verification Test(s) must be prepared by and retained at the treatment facility, and made available at the treatment facility during normal business hours for inspection and photocopying by the Agency. These records must include, at a minimum:
- 1) The dates the Periodic Verification Test(s) were performed;
 - 2) Operating parameters (e.g., temperatures, pressures, retention times, chemical concentrations, irradiation dose and feed rates);
 - 3) Test protocols;
 - 4) Evaluation of test results; and
 - 5) The name(s), dates, signature(s) and title(s) of person(s) conducting the Periodic Verification Test(s).

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- h) Periodic Verification Test(s) must be conducted under the same operating conditions under which the treatment unit operates on a day-to-day basis. The feed rate for the treatment unit is the maximum feed rate at which the unit operates on a day-to-day basis. The feed rate must remain constant throughout the Periodic Verification Test(s). This feed rate must never be exceeded during the operation of the treatment unit.

Section 1422.126 Sharps

Sharps may be disposed of in a landfill only if they have been treated to eliminate the infectious potential and:

- a) Have been rendered unrecognizable and therefore are no longer PIMW; or
- b) Have been:
 - 1) Packaged, marked and labeled in accordance with Part 1421, Subparts C and D;
 - 2) Delivered by a transporter with a PIMW hauling permit as required by 35 Ill. Adm. Code 1420.105 of this Subtitle, unless specifically exempted; and
 - 3) Accompanied by a PIMW manifest as required by 35 Ill. Adm. Code 1420.105 of this Subtitle, unless specifically exempted.

Section 1422.127 Experimental Permits

- a) The Agency may issue Experimental Permits for processes or techniques that do not satisfy the standards set forth in this Subpart if the applicant can provide proof that the process or technique has a reasonable chance for success and that the environmental hazards are minimal. A description of the type of residuals anticipated and how they will be managed and disposed of must be included.
- b) A valid Experimental Permit constitutes a prima facie defense to any action brought against the permit holder for a violation of the Act or regulations promulgated thereunder, but only to the extent that such action is based upon the failure of the process or technique.
- c) All Experimental Permits have a duration not to exceed two (2) years. These permits can only be renewed once. Original experimental permits and renewals granted to any one person cannot exceed a total of four (4) years.

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- d) Application for renewal of an experimental permit must be submitted to the Agency at least ninety (90) days prior to the expiration of the existing permit. To the extent the information to be supplied for renewal is identical with that contained in the prior permit application, the applicant shall so note on the renewal application, and the Agency shall not require the resubmittal of data and information previously supplied to it.
- e) A report must be submitted at the end of the experimental permit period, or as required by the Agency, which includes, at a minimum, the following:
 - 1) A summary of operating data, including results of the Initial Efficacy Test(s) or Periodic Verification Test(s);
 - 2) A discussion of how the equipment performed;
 - 3) A discussion of how residuals were managed; and
 - 4) A demonstration that the infectious potential has been eliminated.

Section 1422.APPENDIX A INITIAL EFFICACY TEST PROCEDURES

All PIMW treatment units must demonstrate that the infectious potential has been eliminated by using an Initial Efficacy Test in accordance with this Appendix.

This Option 1 is for a treatment unit that compromises the integrity of the container of test microorganisms (e.g., grinding followed by chemical disinfection).

The purpose of this Phase 1 is to determine the dilution of each test microorganism from the treatment unit for each challenge load (Types A through C) identified in Table C of this Appendix.

- a) Prepare and sterilize by autoclaving, two (2) challenge loads of Type A as identified in Table C of this Appendix. Reserve one (1) challenge load for Phase 2.
- b) Each test microorganism must be processed in separate runs through the treatment unit. Prior to each run, the number of viable test microorganisms in each container must be determined in accordance with applicable manufacturer's recommendations, and Standard Methods for the Examination of Water and Wastewater, incorporated by reference at 35 Ill. Adm. Code 1420.103.

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- c) Processing of the PIMW must occur within thirty (30) minutes after introducing the container of test microorganisms into the treatment unit.
- d) The container of test microorganisms and challenge loads must be processed together without the physical and/or chemical agents designed to kill the test microorganisms. For example, in treatment units that use chemical disinfectant(s), an equal volume of liquid (e.g., sterile saline solution (0.9%, volume/volume), phosphate buffer solution, or tapwater) must be substituted in place of the chemical disinfectant(s).
- e) A minimum of five (5) representative grab samples must be taken from the processed residue of each challenge load in accordance with Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846), incorporated by reference at 35 Ill. Adm. Code 1420.103. The number of viable test microorganisms in each grab sample must be determined in accordance with applicable manufacturer's recommendations, and Standard Methods for the Examination of Water and Wastewater, incorporated by reference at 35 Ill. Adm. Code 1420.103.
- f) Calculate the effect of dilution for the treatment unit as follows:

$$SA = \text{Log NoA} - \text{Log N1A}; \text{ where } \text{Log N1A} \geq 6$$

where: SA is the log of the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) that were not recovered after processing challenge load Type A.

NoA is the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) introduced into the treatment unit for challenge load Type A.

N1A is the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) remaining in the processed residue for challenge load Type A.

If Log N1A is less than 6, then the number of viable test microorganisms introduced into the treatment unit must be increased and steps (a) through (f) in Phase 1 must be repeated until Log N1A is ≥ 6 . NoA is the inoculum size for challenge load Type A in Phase 2 below.

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- g) Repeat steps (a) through (f) in Phase 1 for challenge loads of PIMW for Types B and C identified in Table C of this Appendix to determine the effect of dilution (SB and SC, respectively).

The purpose of this Phase 2 is to determine the log kill of each test microorganism in each challenge load (Types A through C) identified in Table C of this Appendix.

- a) Using the inoculum size (NoA) determined in Phase 1 above, repeat Phase 1 steps (a) through (e) under the same operating parameters, except that the physical and/or chemical agents designed to kill the test microorganisms must be used.
- b) Calculate the effectiveness of the treatment unit by subtracting the log of viable cells after treatment from the log of viable cells introduced into the treatment unit as the inoculum, as follows:

$$LA = \text{Log NoA} - SA - \text{Log N2A} \geq 6$$

where: LA is the log kill of the test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) after treatment in the challenge load Type A.

NoA is the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) introduced into the treatment unit as the inoculum for challenge load Type A as determined in Phase 1 above.

SA is the log of the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) that were not recovered after processing the challenge load Type A in Phase 1 above.

N2A is the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) remaining in the treated residue for challenge load Type A.

- c) Repeat steps (a) through (b) in Phase 2 for challenge loads Types B and C identified in Table C of this Appendix to determine the effectiveness of the treatment unit (LB and LC, respectively).

This Option 2 is for a treatment unit that maintains the integrity of the container of test microorganisms (e.g., autoclaves).

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- a) One microbiological indicator assay containing one of the test microorganisms at numbers greater than one million (1,000,000) must be placed in a sealed container that remains intact during treatment. The inside diameter of the container must be no larger than required to contain the assay vial(s). The vial(s) must only contain the test microorganisms.
- b) The container of test microorganisms must be placed within a Type A challenge load as identified in Table C of this Appendix.
- c) Calculate the effectiveness of the treatment unit by subtracting the log of viable cells after treatment from the log of viable cells introduced into the treatment unit as the inoculum, as follows:

$$LA = \text{Log } N_0 - \text{Log } N_{2A} \geq 6$$

where: LA is the log kill of the test microorganisms (CFU and PFU) after treatment in challenge load Type A.

N_0 is the number of viable test microorganisms (CFU and PFU) introduced into the treatment unit as the inoculum.

N_{2A} is the number of viable test microorganisms (CFU and PFU) remaining after treatment in challenge load Type A.

- d) Repeat steps (a) through (c) in this option for challenge loads Types B and C identified in Table C of this Appendix to determine the effectiveness of the treatment unit (LB and LC, respectively).

This Option 3 is for a treatment unit that uses thermal treatment and maintains the integrity of the container of indicator microorganism spores (e.g., autoclaves and incinerators).

- a) One microbiological indicator assay containing at least one million (1,000,000) spores of one of the indicator microorganisms listed in Table B of this Appendix must be placed in a sealed container that remains intact during treatment. The inside diameter of the container must be no larger than required to contain the assay vial(s). The vial must contain only the indicator microorganism vial.
- b) The container of indicator microorganisms must be placed within a Type A challenge load as identified in Table C of this Appendix.

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- c) Calculate the effectiveness of the treatment unit by subtracting the log of viable cells after treatment from the log of viable cells introduced into the treatment unit as the inoculum, as follows:

$$LA = \text{Log } N_0 - \text{Log } N_{2A} \geq 6$$

where: LA is the log kill of the viable indicator microorganisms (CFU) after treatment in challenge load Type A.

N_0 is the number of viable indicator microorganisms (CFU) introduced into the treatment unit as the inoculum.

N_{2A} is the number of viable indicator microorganisms (CFU) remaining after treatment in challenge load Type A.

- d) Repeat steps (a) through (c) in this option for challenge loads Types B and C identified in Table C of this Appendix to determine the effectiveness of the treatment unit (LB and LC, respectively).

Section 1422.APPENDIX A: Initial Efficacy Test Procedures

Table A: Test Microorganisms

1. Staphylococcus aureus (ATCC 6538)
2. Pseudomonas aeruginosa (ATCC 15442)
3. Candida albicans (ATCC 18804)
4. Trichophyton mentagrophytes (ATCC 9533)
5. MS-2 Bacteriophage (ATCC 15597-B1)
6. Mycobacterium smegmatis (ATCC 14468)

Section 1422.APPENDIX A: Initial Efficacy Test Procedures

Table B: Indicator Microorganisms

1. Bacillus subtilis (ATCC 19659)
2. Bacillus stearothermophilus (ATCC 7953)
3. Bacillus pumilus (ATCC 27142)

Section 1422.APPENDIX A: Initial Efficacy Test Procedures

Table C: Challenge Loads

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This table identifies the three types of challenge loads of PIMW that must be used as part of the Initial Efficacy Test and Periodic Verification Test(s).

	COMPOSITION OF CHALLENGE LOADS % (w/w)		
	A	B	C
Moisture	≤5	≥50	-----
Organic	-----	-----	≥70

Section 1422.APPENDIX B: Correlating Periodic Verification Test Procedures

- a) A certified microbiological indicator assay containing the test microorganisms and indicator microorganism spores is introduced into each challenge load as identified in Table C of Appendix A.
- b) The test microorganisms and indicator microorganism spores must be placed in a sealed container that remains intact during treatment.
- c) The container must be placed in each challenge load to simulate the worst case scenario (i.e., that part of the load that is the most difficult to treat). For example, the worst case scenario for an autoclave would be to place the test microorganisms and indicator microorganism spores container within a sharps container that must in turn be deposited in a plastic biohazard bag that is then located centrally within the treatment unit.
- d) The effectiveness of the treatment unit is demonstrated by calculating the log kill (L) of the test microorganisms in accordance with Option 2 of Appendix A of this Part. The equivalent log kill (T) of the indicator microorganism spores is calculated by subtracting the log of viable cells after treatment from the log of viable cells introduced into the treatment unit as the inoculum as follows:

$$TA = \text{Log No} - \text{Log N2A} \geq 3$$

where: TA is the equivalent log kill of the viable indicator microorganisms (CFU) after treatment in challenge load Type A.

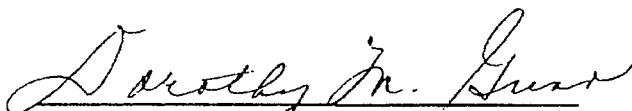
No is the number of viable indicator microorganism spores (CFU) introduced into the treatment unit as the inoculum (≥ 6)

N2A is the number of viable indicator microorganism (CFU) remaining after treatment in challenge load Type A.

- e) Repeat steps (a) through (d) for challenge loads Types B and C identified in Table C of Appendix A to determine the correlation between the log kill of the test microorganisms and the equivalent kill of the indicator microorganism spores (LB and LC, respectively).

IT IS SO ORDERED.

I, Dorothy M. Gunn, Clerk of the Illinois Pollution Control Board, hereby certify that the above opinion and order was adopted on the 17th day of June, 1993, by a vote of 7-0.


Dorothy M. Gunn, Clerk
Illinois Pollution Control Board

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