



ILLINOIS ENVIRONMENTAL PROTECTION AGENCY

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RENEE CIPRIANO, DIRECTOR



POTENTIALLY INFECTIOUS MEDICAL WASTE

-- A Summary of Regulatory Requirements --

GENERAL Requirements

Potentially Infectious Medical Waste (PIMW)

Title XV of the Illinois Environmental Protection Act (Act) establishes statutory requirements to ensure that *Potentially Infectious Medical Waste (PIMW)* will be handled in a safe and responsible manner. On June 17, 1993, the Illinois Pollution Control Board (Board), in accordance with Title VII of the Act, adopted regulations prescribing the standards and criteria for the handling of PIMW. These regulations became effective June 21, 1993. The requirements found in the Act and the Board's regulations are intended to reduce the occupational and environmental health risks that occur during the storage, treatment, transport, transfer, and disposal of PIMW.

The information presented in this fact sheet does not eliminate any person's responsibility to fulfill any legal obligation under the Act or regulations promulgated thereunder.

The purpose of this fact sheet is to provide some of the PIMW requirements, found in both the Act and the Board's regulations. For the complete requirements, please see Title XV of the Act and 35 Illinois Administrative Code (Ill. Adm. Code): Subtitle M.



For additional information on PIMW regulations in Illinois, contact the PIMW Coordinator at the Illinois Environmental Protection Agency; Bureau of Land #33; 1021 North Grand Avenue East; P.O. Box 19276; Springfield, Illinois 62794-9276; 217/524-3289, or look at our website www.iepa.state.il.us.

What is Potentially Infectious Medical Waste (PIMW)?

Potentially Infectious Medical Waste (PIMW) is waste generated in connection with:

- (1) The diagnosis, treatment (i.e., provision of medical services), or immunization of human beings or animals;
- (2) Research pertaining to the provision of medical services; or
- (3) The production or testing of biologicals.

Types of PIMW wastes are:

- (1) Cultures and stocks;
- (2) Human pathological wastes;
- (3) Human blood and blood products;
- (4) Used sharps;
- (5) Animal waste;
- (6) Isolation waste;
- (7) Unused sharps.

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PIMW does NOT include:

- (1) Medical waste generated as general household waste;
- (2) PIMW (except for sharps) which has been treated properly to eliminate its infectious nature; and
- (3) Sharps which have been treated to eliminate their infectious nature *and* which have been rendered unrecognizable by treatment.

Where does PIMW come from?

PIMW can be generated from activities conducted by hospitals, nursing homes, veterinary clinics, dental offices, clinical laboratories, pharmaceutical laboratories, university and research facilities, etc.

How should PIMW be segregated?

PIMW must be segregated into three categories:

- (1) Sharps,
- (2) Oversized PIMW, and
- (3) All other PIMW.

PIMW mixed with other waste is regulated under this Subtitle as PIMW and under any other applicable regulations.

How should PIMW be packaged?

All PIMW which is to be shipped OFF-SITE, except for oversized PIMW, must be placed in containers that are: (1) rigid, (2) leak-resistant, (3) impervious to moisture, (4) of sufficient strength to prevent tearing or bursting under normal conditions of use and handling, and (5) sealed to prevent leakage during transport.

In addition to the requirements listed above, *sharps* (e.g., needles, pipettes, scalpels, glass) must be packaged in containers that are also *puncture-resistant*.

Oversized PIMW must be covered or packaged so that contact with transport workers and the public is minimized. Sharps may not be packaged with oversized PIMW.

How should PIMW be labeled?

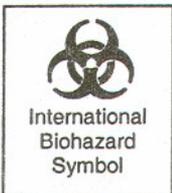
For persons who package PIMW for OFF-SITE transportation or who accept PIMW packages from off-site:

The *generator* must mark on two opposite sides of the *exterior* of the PIMW package (on one side of oversized PIMW), in lettering that is readable at a minimum distance of five feet:

- (1) the word 'BIOHAZARD',
- (2) the word 'Sharps' if the package contains sharps, and
- (3) the International Biohazard Symbol.

In addition, the generator must securely attach a water-resistant label or tag to each package and write in indelible ink:

- (1) Generator's name,
- (2) Generator's address,
- (3) Generator's phone number (24-hour number, if available).



The *transporter* must also affix a label to each package in the same manner:

- (1) Transporter's name,
- (2) Transporter's permit number,
- (3) Transporter's address,
- (4) Transporter's phone number (24-hour number, if available), and
- (5) For each package, the date when PIMW initially left the generator's site, or a unique ID number giving that information.

When there is more than one transporter, **each transporter** must label each PIMW package in this manner. Tags must not obscure any previous information on the package.

Inner packages must be marked with the word 'BIOHAZARD', the word 'SHARPS' if they contain sharps, and the International Biohazard Symbol.

What are transporters required to do?

Haulers of PIMW are required to have:

- (1) A permit issued by the Illinois EPA to transport PIMW (which is different from a special waste hauling permit), if required;
- (2) A completed PIMW manifest for the waste, if a manifest is required;
- (3) Paid the 1.5 cents/pound PIMW transportation fee, if required; and
- (4) The PIMW packaged and labeled properly, prior to transporting it.

The following requirements and fees are applicable to the transportation of PIMW:

HAULING PERMITS

The Illinois EPA collects a \$1,000 fee annually for each PIMW hauling permit application and, in addition, collects a fee of \$250 for each PIMW hauling vehicle identified in the annual permit application and for each vehicle that is added to the permit during the annual period. The fees must be submitted along with the permit application to Illinois EPA.

MANIFESTS

It is the transporter's responsibility to carry a completed PIMW manifest. The manifest must be in a form prescribed and provided by the Illinois EPA. The Illinois EPA assesses a fee of \$2.00 for each PIMW manifest.

TRANSPORTATION FEE REQUIREMENTS

A 1.5 cents per pound fee must be collected from:

- (1) A person required to have a PIMW hauling permit; or
- (2) A person transporting PIMW generated solely by that person's activity to a site or facility not owned, controlled, or operated by the transporter; or
- (3) An owner/operator of a PIMW storage site or treatment facility where the fee has not been previously paid by a transporter.

A person is exempt from obtaining a hauling permit or carrying a manifest if:

- (1) The person is transporting PIMW generated solely by that person's activities, if the PIMW is transported within or between sites or facilities owned, controlled, or operated by that person; or
- (2) The person is transporting less than 50 pounds of PIMW at any one time noncommercially; or
- (3) The transporter is the U.S. Postal Service.

Transportation Standards

The following Transportation Standards apply to persons required to have a PIMW Hauling Permit. PIMW must be transported:

- (1) so that the effects of putrescence are minimized;
- (2) only in enclosed compartments of vehicles secured against public access (except for oversized PIMW);
- (3) with vehicles in good repair and cleaned of visible PIMW contamination after each use;
- (4) in a manner that prevents a breeding place or food source for vectors;
- (5) so that the integrity of the container is maintained; and
- (6) for less than or equal to 10 days.

The Transporter must:

- (1) display information in accordance with the PIMW hauling permit;
- (2) develop and keep an emergency response plan in the vehicle. This plan must identify the names and phone numbers of State and local authorities who must be contacted in the event of an emergency or discharge. In addition, each vehicle must carry all equipment necessary to provide a response.
- (3) not use a vehicle which transports PIMW for the hauling of non-waste materials, except for equipment and supplies intended for the use of waste management (i.e., plastic containers, corrugated boxes, plastic bags, etc.).

Who needs a permit for treatment, storage, or transfer of PIMW?

Treatment, storage, and transfer operations are defined in the Act: treatment facilities are those facilities designed and operated to treat PIMW to eliminate its infectious potential; a storage operation is the containment of waste, either on a temporary basis or for a period of years, in such a manner as not to constitute disposal; a transfer station is a site or facility that accepts waste for temporary storage or consolidation and further transfer to a waste disposal, treatment, or storage facility. Any facility which performs OFF-SITE treatment, storage, or transfer operations will require a permit 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.

Please refer to Sections 1422.105, 1422.106, and 1422.107 of Subtitle M for details concerning permit applications, including documentation required and certifications necessary. Permit applications may be obtained from the Illinois EPA.

Storage or transfer operations

Any person who stores PIMW prior to treatment or disposal on-site, or transport off-site, either permitted or unpermitted, must comply with the following:

- (1) Maintain the integrity of the packaging and provide protection from water, rain, and wind;
- (2) Maintain 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 (i.e., insects and rodents);

- (6) Must not compact the PIMW packages or subject them to stress which compromises the integrity of the container;
- (7) Multiple generators in the same building may store their PIMW in a common storage area;
- (8) Reusable PIMW containers or equipment which are visibly contaminated with PIMW must be cleaned in a designated area;
- (9) Copies of all PIMW manifests must be kept at the storage operation for at least 3 years and must be made available to the Illinois EPA upon request.

In addition to the above requirements, *facilities which are required to have a storage/transfer permit* must comply with the following:

- (1) PIMW must be weighed in pounds on a certified scale, unless previously weighed by the transporter;
- (2) PIMW must be stored in designated areas, so as not to contaminate other materials;
- (3) Cardboard packages must be elevated above the floor in an enclosed area;
- (4) PIMW must be stored on a surface that allows drainage and that minimizes exposure to workers and the public;
- (5) Adequate aisle space must be maintained between packages to allow inspection of at least one side of each package; labels must be readable.
A vehicle containing PIMW is exempt from this requirement:
 - (A) when loading or unloading, or
 - (B) when the vehicle is fully loaded.
 Either or both of these exemptions must not exceed five days.
- (6) Signs must be posted at the points of access to the secured storage area. These signs must display the International Biohazard Symbol and the word 'BIOHAZARD' in lettering readable at five feet.
- (7) Annual personnel training must be provided to all staff prior to handling PIMW. Training must include a thorough explanation of operating procedures for daily and emergency situations. Records verifying personnel training must be kept.
- (8) Storage operations must have a written contingency plan which is to be implemented in the event of a discharge or personal injury. It must include a list of emergency equipment, names and phone numbers of persons qualified to act as emergency coordinator, and procedures for cleanup. A copy must be kept at the storage operation. Emergency phone numbers and a brief description of the emergency procedures must be posted at the operation.
- (9) A written operating record must be kept at the facility, including operating parameters, generator information, and quantities and disposition of PIMW.
- (10) These records (personnel training and written operating record) must be kept at the storage operation until closure. They must be made available to the Illinois EPA upon request.
- (11) Unless otherwise authorized by the Illinois EPA in the permit, PIMW must not be stored for more than:
 - (A) 72 hours unless the surface temperature of the package is maintained at or below 45 degrees Fahrenheit, and
 - (B) 30 days, regardless of the temperature.
- (12) At least 60 days before closure, the owner must notify the Illinois EPA. Within 90 days after the final load is received, the owner must certify to the Illinois EPA that closure has been completed in accordance with the permit and all applicable regulations.

Treatment Facilities

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 manufacturer/owner/operator demonstrates that an Initial Efficacy Test (IET) and Periodic Verification Test (PVT) have been completed successfully. Refer to Sections 1422.124 and 1422.125 of the Act or the Fact Sheet on Testing Requirements for details on these tests.
- (2) prevents compaction and rupture of containers during handling operations, except when this is an integral part of the treatment process;
- (3) disposes of treatment residuals in accordance with all applicable regulations;
- (4) provides for quality assurance programs that must include a written plan;
- (5) provides for periodic testing using biological testing;
- (6) provides for assurances that clearly demonstrate that PIMW has been properly treated; and
- (7) is in compliance with all Federal and State laws and regulations pertaining to environmental protection.

In addition:

- (1) Copies of manifests must be kept at the treatment facility for three (3) years and must be made available to the Illinois EPA upon request;
- (2) An annual report must be filed by March 31 by treatment facilities required to have a permit and by those facilities not required to have a permit which treat more than 50 pounds of PIMW per month. This report must specify the quantities and disposition of PIMW treated during the previous calendar year. Forms are available from the Illinois EPA.
- (3) Upon closure, the area, equipment, and structures of the facility must be cleaned in accordance with the regulations.

In addition, those treatment facilities required to have a permit must comply with the following:

- (1) PIMW must be weighed in pounds on a certified scale, unless previously weighed by the transporter;
- (2) Signs must be posted at the points of access to the secured storage area. These signs must display the International Biohazard Symbol and the word 'BIOHAZARD' in lettering readable at five feet.
- (3) Annual personnel training must be provided to all staff prior to handling PIMW. Training must include a thorough explanation of operating procedures for daily and emergency situations. Records verifying personnel training must be kept.
- (4) Treatment facilities must have a written contingency plan which is to be implemented in the event of a discharge or personal injury. It must include a list of emergency equipment, names and phone numbers of persons qualified to act as emergency coordinator, and procedures for cleanup. A copy must be kept at the storage operation. Emergency phone numbers and a brief description of the emergency procedures must be posted at the operation.
- (5) A written operating record must be kept at the facility, including operating parameters, generator information, and quantities and disposition of PIMW.
- (6) These records (personnel training and written operating record) must be kept at the storage operation until closure. They must be made available to the Illinois EPA upon request.

- (7) At least 60 days before closure, the owner must notify the Illinois EPA. Within 90 days after the final load is received, the owner must certify to the Illinois EPA that closure has been completed in accordance with the permit and all applicable regulations.

For treatment facilities required to have a permit, the permit application must include the following information regarding the treatment unit:

- (1) an operating plan that includes a description of 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.

A treatment facility must certify to the transporter, if other than the generator, and certify to the landfill operator or receiving facility operator that the PIMW has been treated in accordance with 35 Ill. Adm. Code 1422 and, if applicable, with all terms and conditions specified in its operating permit. Data verifying the efficacy of the treatment unit must be made available to the receiving facility upon request of the receiving facility.

Treatment Unit Requirements

A treatment unit must be:

- (1) Designed and operated to eliminate the infectious potential of PIMW as demonstrated by the IET and PVTs;
- (2) Operated according to the manufacturer's instructions, if commercially available;
- (3) Operated day-to-day under the same conditions used to demonstrate the elimination of the infectious potential;
- (4) Operated with a feed rate not to exceed that used to demonstrate elimination of the infectious potential; and
- (5) Designed and operated to limit the emission of microorganisms into the air.

A treatment unit may be used by a treatment facility not required to have a permit if one of the following is met:

- (1) The treatment unit meets the above standards and all testing requirements, as defined in these regulations, are met. Proof that the requirements have been met must be kept on file and made available to the Agency upon request.
- (2) The treatment facility applies for a voluntary permit.
- (3) The treatment facility or manufacturer obtains an adjusted standard from the Illinois Pollution Control Board (IPCB).

Autoclaves, incinerators, and ethylene oxide units installed or operated prior to June 21, 1993 are not required to perform an IET. The first PVT must be performed by September 21, 1993 to demonstrate that the infectious potential has been eliminated.

What should I do with treatment and cleaning residues?

Treatment residuals must be disposed of in accordance with all applicable regulations.

Residues from cleaning and disinfecting anything contaminated with PIMW are regulated as PIMW, except when discharged directly into a sanitary or combined sewer in accordance with 35 Ill. Adm. Code: Subtitle C (Water Pollution). Please note: Local government or sanitary districts may have requirements that are more restrictive than these regulations. The generator of any residue is responsible for checking with the local sanitary district before disposing of any liquid PIMW into the sewer system. Solids are prohibited from disposal into any sewer system.

Residues which have been treated as PIMW in accordance with these regulations are no longer considered PIMW and may go to any municipal landfill, EXCEPT:

- (1) ash from incineration, which must be managed as a "special waste" (details of the management of special waste may be found in Section 3.45 of the Act or in the Illinois EPA Fact Sheet on Non-Special Waste Certification);
- (2) liquids ONLY may be discharged to the sewer system in accordance with a water pollution permit and local sanitary district regulations;
- (3) sharps must be treated to eliminate the infectious potential and be unrecognizable or packaged in accordance with these regulations before they can be landfilled.

**Untreated
medical waste
cannot be
disposed of
into any
landfill!**

Untreated PIMW is banned from all landfills in Illinois. Once PIMW has been properly treated to eliminate its infectious potential, it is no longer PIMW (except in the case of sharps) and may be disposed of into any landfill permitted by the Illinois EPA to accept municipal waste. For sharps, both the infectious nature must be eliminated and the sharps must either be rendered unrecognizable or packaged in accordance with the regulations prior to disposal. A treatment facility must certify to the transporter, if other than the generator, and to the landfill operator or receiving facility operator that the PIMW has been treated in accordance with 35 Ill. Adm. Code 1422 and, if applicable, with all terms and conditions specified in its operating permit. Data verifying the efficacy of the treatment unit must be made available to the receiving facility upon request of the receiving facility.
