Environmental Protection Agency

Division of Materials and Waste Management
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# Large Generators of Infectious Waste

*This guidance document provides an overview of Ohio's infectious waste regulations applicable to large generators of infectious waste. The scope of the infectious waste regulations includes waste segregation, management, storage, and treatment of infectious wastes generated or disposed of in Ohio.*

## Who is a large generator of infectious waste?

Any business that generates infectious waste is considered an infectious waste generator and is subject to Ohio's infectious waste regulations. An infectious waste generator is classified as a large generator when 50 pounds or more of infectious waste are generated in a calendar month.

## Definitions

"Infectious agent" means a type of microorganism, pathogen, virus or prions that can cause or significantly contribute to disease in or death of human beings.

"Zoonotic agent" means a type of microorganism, pathogen, virus or prion that causes disease in vertebrate animals, is transmissible to human beings and can cause or significantly contribute to disease in or death of human beings.

"Infectious waste" means any wastes or combination of wastes that include cultures and stocks of infectious agents and associated biological, human blood and blood products, and substances that were or are likely to have been exposed to or contaminated with or are likely to transmit an infectious agent or zoonotic agent, including the following:

- laboratory wastes;
- pathological wastes;
- animal blood and blood products;
- animal carcasses and parts;
- waste materials from the rooms of humans, or the enclosures of animals, that have been isolated because of a diagnosed communicable disease;
- sharp wastes used in the treatment of human beings or animals, or sharp wastes that have or are likely to have come in contact with infectious agents;
- waste materials generated in the diagnosis, treatment, or immunization of human beings or animals, research pertaining to the immunization of human beings or animals, or in the production or testing of biologicals, that the public health council identifies as infectious wastes;
- "blood products" does not include patient care waste such as bandages or disposable gowns that are lightly soiled with blood; and
- any other waste materials the generator designates as infectious wastes.

Note: nearly all categories of infectious waste depend upon the presence or the possibility of the presence of infectious agents. The exceptions to this are blood, blood products, and cultures, which are always considered infectious waste.

## Applicable Rules

Ohio Administrative Code
3745-570-100, 3745-570-120

## More Information

For more information regarding this document, please contact the Infectious Waste Unit at 614.644.2621.

## Disclaimer

The procedures set out in this document are intended solely for guidance. The procedures in this document are not intended and cannot be relied upon to create rights, substantive or procedural, enforceable by any party against Ohio EPA. While this guidance document is not legally binding, all statutes and rules referenced herein are binding and enforceable.

Ohio EPA reserves the right to vary this guidance or to change it at any time without public notice and reserves the right to deviate from this guidance on a case-by-case basis.

## Compliance Requirements

Registration

# Large Generators of Infectious Waste

- Initial Registration: A large generator must register as an "Infectious Waste Generator" within 30 days after the last day of the month in which 50 pounds or more of infectious wastes were generated. To register, submit your application through Ohio EPA's eBusiness Center at ***ebiz.epa.ohio.gov***. Contact the Division of Materials and Waste Management (DMWM) at 614-644-2621 for assistance with the online registration process. One registration is required per generator, listing all the premises owned by that generator which generate 50 pounds or more of infectious waste in any calendar month. The registration is valid for three years and requires a $140.00 fee.
- Renewing registrations: Ohio EPA will send a renewal notification with link to the eBusiness Center to the electronic address, and contact person, on the current certificate approximately two months before the generator certificate expires. Generators are required to submit the renewal application at least 30 days before the current certificate expires.
- Amending registrations: If there is an addition, deletion, or change of premises to a generator's registration, log in to your eBusiness Center account, update the information as necessary and submit as an amendment (modification). No fees are required for amendments made within the duration of the registration cycle. Contact DMWM at 614.644. 2621 for assistance with the online registration amendment process.
- Reversion to small generator status: Once registered you must follow the large generator regulatory requirements for the duration of your registration cycle. If at the end of the cycle you meet the small generator status, please obtain and complete a "Reversion to Small Generator Form" by contacting DMWM at 614.644.2621, or visiting https://epa.ohio.gov/infectious-waste.

### Segregate and Properly Manage Infectious Wastes

- Infectious Sharps: All infectious sharps must be placed in a container labeled with the biohazard symbol and designed to contain sharps.
- Untreated liquid or semi-liquid infectious waste: Infectious wastes consisting of blood, blood products, body fluids, and excreta may be disposed of into a sanitary sewer if the disposal is allowed for the wastewater treatment system.
- Other infectious wastes: All other categories of infectious waste must be segregated at the point of generation from the rest of the waste stream. At a minimum, infectious wastes shall be placed in separate containers, from other wastes until rendered non-infectious.
    - Maintain the integrity of the container
    - Maintain infectious wastes in a non-putrescent state using refrigeration or freezing when necessary
    - Protect infectious waste from becoming a food source or breeding ground to animals or insects
    - Outside storage areas must be locked to prevent unauthorized access.
    - Entrance to unlocked storage areas must be marked with a sign that states "warning: infectious waste" and/or displays the international biohazard symbol or lock the storage area.
- Infectious waste that is also a hazardous waste: Any infectious waste or infectious waste mixture that meets the definition of a hazardous waste shall be managed as a hazardous waste. Some vaccines contain thimerosal, a mercury containing preservative, and must be disposed of as a hazardous waste.
- Infectious waste that is also a radioactive waste: Any infectious waste that is also radioactive shall be managed in accordance with applicable Ohio Department of Health and the U.S. Nuclear Regulatory Commission.

## Infectious Waste Treatment

### Large Generators That Treat Their Own Infectious Wastes

Large generators that treat their infectious wastes are considered infectious waste treatment facilities; however, they are NOT required to obtain a permit-to-install from Ohio EPA-DMWM or an annual operating license from the local Board of Health. Generators that treat their own infectious waste must identify on their registration the location of the treatment unit and specify the type of treatment (autoclave, incinerator, chemical, other) used. If the generator uses an incinerator, a permit-to-install and a permit-to-operate is required from Ohio EPA's Division of Air Pollution Control. In addition:

- Hospitals that are infectious waste treatment facilities may accept infectious wastes from small generators that have staff privileges, generated by individuals from their own care, and by emergency medical squads, without losing the permitting and licensing exemption.
- Infectious wastes that are transported from a satellite facility to a centralized location to be treated, are subject to the U.S. Department of Transportation hazardous materials regulations contained in 49 C.F.R. 171 to 49 C.F.R. 180.
- Storage requirements for Treatment Facilities: Additional storage requirements apply to generators who treat their own infectious waste since they are also considered infectious waste treatment facilities. Infectious waste can be stored for 14 days once the waste has been transferred to the treatment area. If a generator does not want to treat all

their waste on-site, Ohio EPA recommends that the generator have two storage areas, one for infectious waste that will be sent to an off-site treatment facility and one for infectious waste that will be treated on-site.

- Infectious Waste Treatment Facility Requirements: Infectious waste treatment facilities shall be inspected at least four times per year and must follow these general requirements:
    - Retain all records for five years.
    - Develop and maintain in the area of the treatment unit, a facility management plan (FMP) (excluding generators who utilize chemical treatment of cultures).
    - Provide training on the contents of the FMP for each employee who will operate the infectious waste treatment unit. A written certification statement attesting that the employee received the specified training shall be signed and dated by each employee and owner/operator of the facility.
    - Use a daily log of operation to record charging of the infectious waste treatment unit.
    - Provide the operating procedures for the treatment unit in the immediate area of the unit.
- Treated Infectious Waste: Once infectious waste has been treated to render it noninfectious, it may be disposed as solid waste. A disposal paper must accompany the load of treated infectious waste to the landfill. The disposal paper is a three-part form with one copy retained by the waste generator, one copy retained by the landfill, and one copy returned to the generator by the landfill. Disposal papers are not required for chemically treated cultures and stocks of infectious waste treated on site; however, a daily log of operations is required.