

Large Generators of Infectious Waste

PURPOSE

The purpose of this document is to provide an overview of Ohio's infectious waste regulations applicable to large generators of infectious waste.

APPLICABILITY

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 small generator when less than 50 pounds of infectious waste are generated per calendar month and a large generator when 50 pounds or more of infectious waste are generated per calendar month. The scope of the infectious waste regulations includes waste segregation, packaging, storage, shipping, and treatment of infectious wastes generated or disposed of in Ohio.

DEFINITIONS

"Generator" means any person who produces infectious waste. A "person" can be governmental bodies, or a business operated by a sole proprietor, partnership, or corporation.

"Infectious agent" means a type of microorganism, helminth, or virus that causes or significantly contributes to the cause of increased morbidity or mortality of human beings.

"Zoonotic agent" means a type of microorganism, helminth, or virus that causes disease in vertebrate animals and that is transmissible to human beings and causes or significantly contributes to the cause of increased morbidity or mortality of human beings.

"Infectious waste" includes the following categories:

- Cultures and stocks of infectious agents and associated biologicals
- Laboratory wastes that were, or were likely to have been in contact with infectious agents
- Pathological wastes, including human and animal tissues, organs, and body parts
- Waste materials from the rooms of humans, or the enclosures of animals, that have been isolated because of a diagnosed communicable disease
- Human and animal blood specimens and blood products, provided that the animals were or are likely to have been exposed to a zoonotic or infectious agent. "Blood products" does not include patient care waste such as bandages or disposable gowns that are lightly soiled with blood
- Contaminated carcasses, body parts, and bedding of animals that were diagnosed with or intentionally exposed to infectious agents from zoonotic or human diseases during research, production of biologicals, or testing of pharmaceuticals
- Sharp wastes (including, but not limited to, hypodermic needles, syringes, and scalpel blades) 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 in medical, research, or industrial laboratories.
- Waste materials generated in the diagnosis, treatment, or immunization of human beings or animals, research pertaining to the immunization of human

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beings or animals, or in the production or testing of biologicals, that the public health council identifies as infectious wastes.

- 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.

COMPLIANCE REQUIREMENTS

Registration Certificate

Initial Registration: A large generator must register within 30 days after the last day of the month in which 50 pounds or more of infectious waste were generated. To register, complete and send the "Infectious Waste Generator Registration Certificate Application" to the address indicated in the form. One certificate is required per generator, listing all the premises at which infectious wastes are generated. The certificate is valid for three years and requires a single \$300.00 dollar registration fee.

Renewing registration certificates: Ohio EPA will send a renewal notification and application form to the 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 registration certificates: If there is an addition, deletion, or change of premises to a generator's certificate, complete and send the "Amended Infectious Waste Generator Registration Certificate Application". No fees are required for amendments.

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".

Obtaining forms: Contact the Division of Solid and Infectious Waste Management (DSIWM) at (614) 644-2621, or by visiting this website: http://www.epa.state.oh.us/dsiwm/pages/iw_do_cs.html#s.

Segregate and Properly Package Infectious Wastes

Infectious Sharps: All infectious sharps must be placed into containers specifically designed and manufactured for the management and/or disposal of sharps. The container must be labeled with the international biohazard symbol.

Unused & Non-infectious Sharps: Sharps such as hypodermic needles, syringes, hard plastic pipets, and scalpel blades that are non-infectious or are unused can be discarded in a cardboard box lined with a plastic bag. Used intravenous bags, bottles, and tubing that are not contaminated with blood or attached to a needle are not infectious wastes.

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 waste water treatment system.

Other infectious wastes: All other infectious wastes must be placed in red plastic bags manufactured for infectious waste disposal, or a bag labeled with an international biohazard symbol that is at least 5 inches in diameter and that must be:

- Impervious to moisture
- Constructed of a single thickness to prevent ripping, tearing, or bursting under normal handling conditions

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- Able to hold 25 pounds of water while being carried from its top, for 60 seconds without leakage
- Securely tied or sealed to prevent leakage or spillage of wastes during storage, handling, or transport.

Handling and storage requirements:

Packaged infectious wastes must be handled and stored in a manner that:

- Maintains the integrity of the packaging
- Maintains the infectious wastes in a non-putrescent state using refrigeration or freezing when necessary
- Protects 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. For information regarding hazardous waste, contact the Division of Hazardous Waste Management at (614) 644-2917 or visit this website <http://www.epa.state.oh.us/dhwm/>.

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 (<http://www.odh.state.oh.us/>) and the U.S. Nuclear Regulatory Commission (<http://www.nrc.gov/waste.html>) regulations.

Infectious Waste Spills

Generators must maintain a spill containment and clean-up kit in the general area where infectious waste is handled. The kit must

contain the following items:

- Materials designed to absorb spilled liquids
- Red or biohazard labeled bag(s)
- An U.S. EPA Registered hospital disinfectant that is also tuberculocidal (follow manufactures directions), or materials necessary to prepare a minimum 10% sodium hypochlorite solution with a minimum contact time of 30 minutes
- Disposable gloves and personal protective equipment (PPE)
- A first aid kit (unless emergency medical care is available on the premises), boundary tape, and other appropriate safety equipment

Generators of infectious waste must develop and implement a spill containment and clean-up procedure as follows:

- Have the clean-up personnel utilize the appropriate PPE.
- Limit the access of the spill area to authorized personnel.
- Place any broken containers and spilled materials in the appropriate infectious waste containers.
- Use absorbent materials to collect any spilled liquids. The absorbent material shall be managed as infectious waste.
- After all materials have been picked up, clean the contaminated area.
- After cleaning, disinfect the spill area.
- Clean and disinfect any non-disposable items.
- Remove PPE and manage the disposable items as an infectious waste.
- Call for emergency help as needed from the fire department, the police department, the local health department, any existing local emergency management office, or the Ohio EPA.

A copy of the procedure must be posted or readily available on the location to all people likely to handle infectious wastes. The name, address, and telephone number of the manager

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and their back-up must also appear at the top of the spill containment procedure.

Infectious Waste Treatment

Generators who send their waste off-site for treatment at a licensed infectious waste treatment facility must follow these guidelines.

Packaging requirements: Bags of infectious wastes to be sent to an infectious waste treatment facility must be:

- Placed inside a second sealed bag of the same criteria; or
- Be placed inside of a fully enclosed, sturdy container

If containers are used they must be:

- Disposable (cardboard) or reusable
- Labeled with the international biohazard symbol on at least two opposite sides
- In good repair, clean on the outside, leak resistant, and able to withstand handling

If reusable, they must be disinfected between uses with a detergent and disinfectant. The disinfectant must be an US EPA registered tuberculocidal. A 10% vol/vol of household bleach may be used instead of the registered hospital disinfectant.

Use a Registered Infectious Waste Transporter: Untreated infectious wastes must be transported by a business registered with Ohio EPA to transport infectious waste. Generators of infectious waste that wish to transport untreated infectious waste from a satellite facility to a main facility for centralized pick-up must also use a registered vehicle. Ohio EPA rules exempt large generators from fee payment when they register as transporters of infectious waste to transport their own infectious waste from a satellite facility to a main facility.

Infectious wastes that have not been treated to render them noninfectious must be transported in shipments consisting only of untreated infectious wastes and may not be transported in

the same shipment with solid waste, hazardous waste, radioactive waste, or treated infectious waste.

Treatment shipping papers: A treatment shipping paper must accompany all shipments of untreated infectious waste that are being transported. Generators must retain the “yellow” copy and the matching white copy signed by the treatment facility, for a minimum of three years. Since the shipping papers list the amount of infectious waste sent each month, no other quantification records are necessary. Treatment shipping papers are also required for the transportation of untreated infectious wastes from a satellite facility to a main facility for centralized pick-up. If a different transporter picks up the waste at the centralized location, then that transporter would be listed as the second transporter.

Large Generators Who Treat Their Own Infectious Wastes

Large generators who treat their infectious wastes are considered infectious waste treatment facilities; however, they are NOT required to obtain a permit-to-install from Ohio EPA-DSIWM or an annual operating license from the local Board of Health. 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. These generators must list on their certificate the location of the treatment unit and identify the type of treatment (autoclave, incinerator, chemical, other) used. 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.

Packaging requirements: Infectious wastes that will be treated on the same premises where they are generated do not need to be double bagged or placed into a sturdy, rigid, tightly

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closed container. However, infectious wastes that will be transported from a satellite facility to another premise for treatment must be packaged in the same manner as if transported to an off-site treatment facility.

Storage requirements: 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 of 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.

Use of shipping papers: Shipments of infectious waste to an infectious waste treatment facility owned or operated by the generator are not required to be accompanied by shipping papers.

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 three 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.

- Maintain a spill containment and clean-up kit in the general area of the infectious waste treatment unit.
- Develop and implement a spill containment and clean-up procedure.

Treated Infectious Waste: Once infectious waste has been treated to render it noninfectious, it may be disposed as solid waste. It is not necessary to use a registered transporter when disposing of a load of treated infectious waste. A disposal shipping paper must accompany the load of treated infectious waste to the landfill. The disposal shipping 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 shipping papers are not required for chemically treated cultures and stocks of infectious waste treated on site; however, a daily log of operations is required.

APPLICABLE RULES

OAC	3745-27-01	3745-27-32	3745-27-35
	3745-27-30	3745-27-33	3745-27-36
	3745-27-31	3745-27-34	

CONTACT INFORMATION

Infectious Waste Unit (614) 644-2621
PO Box 1049
Columbus, OH 43216

DSIWM Supervisors:
Central District Office (614) 728-3778
Northeast District Office (330) 963-1200
Northwest District Office (419) 352-8461
Southeast District Office (740) 385-8501
Southwest District Office (937) 285-6357