

GUIDANCE DOCUMENT FOR SMALL GENERATORS OF INFECTIOUS WASTE

The State of Ohio has specific regulations regarding the disposal of infectious waste. The detailed requirements can be found in Chapter 3734. of the Ohio Revised Code and Chapters 3745-27 and 3745-37 of the Ohio Administrative Code. This guidance document is a summary of responsibilities for generators of infectious waste who produce less than 50 pounds of infectious waste each calendar month (small generators). These statements reflect current effective language as appears in both the Revised Code and the Administrative Code. Please take note of the date of the guidance document at the end of the text. Each generator is ultimately responsible for keeping up to date with changes in Ohio statute and Administrative Code regulations. Also included are the specific categories of infectious waste and the definition of an infectious agent.

Categories of Infectious Wastes

1. Cultures and stocks of infectious agents and associated biologicals. This includes specimen cultures, cultures and stocks of infectious agents, wastes from the production of biologicals, and discarded live and attenuated vaccines.
2. Laboratory wastes that were, or were likely to have been, in contact with infectious agents that may present a substantial threat to public health if improperly managed.
3. Pathological wastes, including human and animal tissues, organs, and body parts, and body fluids and excreta that are contaminated with or are likely to be contaminated with infectious agents, removed or obtained during surgery, autopsy, or for diagnostic evaluation, provided that, with regard to pathological waste from animals, the animals have or are likely to have been exposed to a zoonotic or infectious agent.
4. Waste materials, from the rooms of humans or the enclosures of animals that have been isolated because of diagnosed communicable disease, that are likely to transmit infectious agents. Such waste materials from the rooms of humans do not include any wastes from patients on blood and body fluid precautions (universal precaution system established by the Centers for Disease Control), unless specific wastes generated under the universal precautions system have been identified as infectious wastes by the Public Health Council in rules adopted in accordance with Chapter 119 of the Ohio Revised Code.
5. Human and animal blood specimens and blood products that are being disposed, provided that, with regard to blood specimens and blood products from animals, 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 or other body fluids unless the generator determines that they are soiled to the extent that they should be managed as infectious wastes.

6. Contaminated carcasses, body parts, and bedding of animals that were intentionally exposed to infectious agents from zoonotic or human diseases during research, production of biologicals, or testing of pharmaceuticals; and carcasses and bedding of animals otherwise infected by zoonotic or infectious agents that may present a substantial threat to public health if improperly managed.
7. Sharp wastes used in the treatment, diagnosis, or inoculation of human beings or animals. Sharp wastes that have or are likely to have come into contact with infectious agents in medical, research, or industrial laboratories. Sharp wastes include, but are not limited to, hypodermic needles, syringes, scalpel blades, and glass articles that have been broken. Such waste items are referred to as "sharps" or "infectious sharps".
8. Any other waste materials generated, in the diagnosis, treatment, or immunization of human beings or animals; in research pertaining to the immunization of human beings or animals; or in the production or testing of biologicals, which the public health council identifies as infectious wastes after determining that the wastes present a substantial threat to human health when improperly managed because they are or may be, contaminated with infectious agents.
9. Any other waste materials the generator designates as infectious wastes.

It should be noted that nearly all of the categories of infectious waste depend upon the presence of infectious agents or the possibility of the presence of infectious agents. The exceptions to this are **blood and blood products, cultures, and sharps**, which are independent of the presence of infectious agents.

Definitions

"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.

SMALL GENERATORS OF INFECTIOUS WASTE MUST FOLLOW THESE REGULATORY REQUIREMENTS:

Segregation and Quantification of Infectious Wastes

Sharps: All used sharps (category # 7) must be placed in rigid, puncture resistant containers (specifically designed and manufactured for the management and/or disposal of sharps) that have a "sharps" label on them and if not treated in accordance with Rule 3745-27-32 of Ohio Administrative Code shall be conspicuously labeled with the international biohazard symbol. The weight of all used sharps must be obtained and recorded for each month. This may be most easily done by recording the initial weight of a sharps container at the beginning of the month and then subtracting this value from the final weight at the end of the month.

OTHER INFECTIOUS WASTE: All other categories of infectious waste must be segregated from the rest of the waste stream for quantification. Each small generator must weigh all other categories of infectious wastes that he produces and record a total for each calendar month. This monthly total is the summation of infectious sharps, blood, and all other infectious wastes.

There are handling requirements for all in-use and stored containers of infectious waste. Also, there are regulations pertaining to the management of the infectious waste within the containers. There is no longer any weight or day prohibition.

EXEMPTIONS FOR QUANTIFICATION: No wastes consisting of dead animals or their parts need to be considered when determining the quantity of infectious wastes generated if the dead animals or parts meet either of the following:

- (i) Were not intentionally exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals;
- (ii) Either were produced by a veterinarian holding a license issued under Chapter 4741. of the Revised Code;

Or were treated or disposed of by a person holding a license issued under Chapter 953. of the Revised Code (Rendering Plants)

Furthermore, a facility that holds a license issued under 4717.17 (Embalmers and Funeral Directors) of the Revised Code, by statute, does not have to quantify the amount of blood, blood products, other body fluids, or embalming fluids that are discharged, on the site where they were generated, into a wastewater disposal system.

Disposal of Infectious Wastes

USED SHARPS - Place in a commercial sharps container meeting the minimum operational requirements of rigid, tightly closed, puncture resistant, and leak resistant container labeled with the warning "sharps". If not treated to render them noninfectious, they must also be labeled with the international biohazard symbol. Once contained this way, they can be transported and disposed of like solid waste (placed in dumpster, picked-up by solid waste haulers, taken to a landfill). Please note that even though state

regulations allow the disposal of untreated sharps into the solid waste stream, many solid waste haulers and landfill operators exclude this type of waste as a business decision.

Many small generators may elect to treat their sharps themselves or have them treated by someone else. By statute, a small generator may take sharps to a hospital for treatment provided the small generator has staff privileges at the hospital. It should be noted that the hospital has the right to determine whether or not it wishes to accept such waste. Of course a small generator may also elect to have his waste treated at a commercial (licensed) infectious waste treatment facility.

Newly effective (5/1/95) Ohio EPA regulations contain provisions for the treatment and disposal of sharps by a process called applied heat sharps encapsulation. Through the application of thermal heat, this process results in the needles and syringes being encased in a solid plastic mass. The approved method, operational requirements, and quality assurance requirements are as follows:

- 1) Each load of sharps processed must contain at least 70% plastic.
- 2) The load must be processed at a minimum temperature of 330°F for 30 minutes.
- 3) If the resulting mass has any sharps protruding from it, then it must still go in a sharps container.
- 4) The load must consist of nothing but sharps*.
- 5) The sharps in the load must be free of liquids, except for residual amounts.
- 6) The following records must be maintained for three years:
 - a) a quality assurance log (contents explained in #9 below).
 - b) a daily operating log which documents the date, time of day, and name of person operating the unit for each cycle.
- 7) Posted operating procedures for the unit.
- 8) No radioactive, hazardous, or cytotoxic materials can go into the unit. Additionally, no sharps containing volatile chemicals may be treated in the unit.
- 9) After every 50 treatment cycles, or semi-annually, whichever comes first, the operator must perform quality assurance testing as follows:
 - a) By wrapping a spore strip containing at least 10^4 *Bacillus subtilis* spores in aluminum foil and then placing it at the bottom of the heating chamber so that the folded seams will be to the outside of the resulting solid mass. If the technology used would also encase the wrapped spore strip, then the spore strip may be run through a treatment cycle without the addition of waste.

- b) Upon completion of the treatment cycle, the spore strip is to be removed from the foil wrapping and then aseptically removed from its envelope and incubated according to the manufacturer's instructions.
 - c) Record daily for seven days whether or not the organisms on the strip grew (turbidity of the culture medium).
 - d) If the spore strip is positive for growth during the seven day incubation period, make a note of this in the quality assurance log and discontinue use of the unit until the problem has been rectified and another successful validation test has been performed.
- 10) Once processed in this manner, the resulting solid mass may be placed into the solid waste stream without an international biohazard symbol or the "sharps" designation.
- * Small Generators who wish to treat their own sharps on-site so that they do not have to use the international biohazard symbol on their waste must follow these requirements. Therefore, when encapsulating sharps the load must consist of nothing but sharps. Since small generators are not required to treat the rest of their infectious waste, except cultures, they may not use the encapsulation unit on these other waste types. The applied heat encapsulation method cannot be used on cultures.

UNUSED SHARPS - Discarded unused hypodermic needles, syringes, and scalpel blades must also be placed in the same type of container (rigid, tightly closed, puncture resistant, and leak resistant container labeled with the warning "sharps") or a sharps container. If it contains **only** unused sharps it does not need to be labeled with the international biohazard symbol. Once contained this way, they can be transported and disposed of in the same manner as solid waste. By statute, a small generator may take unused sharps to a hospital with other used sharps provided the small generator has staff privileges at that hospital. Unused sharps are not required to be quantified and included in the monthly infectious waste generation log.

SPECIMEN CULTURES AND CULTURES OF VIABLE INFECTIOUS AGENTS - These items must be treated on the premises where they are generated or transported to a licensed infectious waste treatment facility by a registered transporter. This document contains the specific requirements that must be followed for either one of these two options available to small generators.

UNTREATED LIQUID INFECTIOUS WASTES - Untreated liquid or semi-liquid infectious wastes consisting of blood, blood products, body fluids, and excreta may be discharged into a sanitary sewer system if the discharge is consistent with the permit for the system. If you are connected to the sanitary sewer system, please contact the local sewer operator or the pretreatment unit of the Division of Water Pollution Control (DWPC) in the appropriate Ohio EPA District Office. If you are not connected to a sewer system, contact the permit unit of the DWPC in the appropriate Ohio EPA district office. A map of Ohio with Ohio EPA districts is attached to this document. It should be noted that even though these types of infectious wastes may be disposed of in this manner, one must still quantify these wastes if they meet the criteria of a category of infectious waste. However under Ohio statute, a facility that holds a license under section 4717.17 of the Revised Code does not have to quantify the amount of blood,

blood products, other body fluids, or embalming fluids that are discharged on the site where they were generated into a disposal system, as defined in section 6111.01 of the Revised Code, as infectious waste. Liquids or semi-solids may be physically weighed or the following conversion may be used:

$$\begin{aligned} 1 \text{ cc [or milliliter (ml)]} &= 1 \text{ gram (g)} \\ 454 \text{ g} &= 1 \text{ pound (lbs.)} \end{aligned}$$

Example: Disposing of 5cc's of blood.

$$5 \text{ cc's} = 5 \text{ g}$$

$$\begin{array}{r} 5 \text{ g} \\ \hline 454 \text{ g/lbs} \end{array} = 5 \text{ g} \times \frac{1 \text{ lbs}}{454 \text{ g}} = 0.011 \text{ lbs.}$$

Hence, 5cc = 0.011 lbs.

ALL OTHER INFECTIOUS WASTES - All other infectious wastes can be transported and disposed of like solid waste after the amount of waste has been weighed and recorded in the monthly infectious waste generation log.

Treatment of Specimen Cultures and Cultures of Viable Infectious Agents on the Site Where They Were Generated

Three different methods may be used to render cultures noninfectious on the site where they were generated. Once treated by any one of the three methods, the cultures may be disposed of, without a shipping paper, like solid waste.

CHEMICAL TREATMENT - Only cultures may be rendered noninfectious by chemical treatment. The approved chemical solution is a 15 % vol/vol hypochlorite (household bleach). Stronger solutions (for example, 25%) of household bleach may also be used. All cultures must be submerged for a minimum of 20 minutes. The treatment solution must be mixed immediately before use and discarded after use, and excess treatment solution must be decanted from the cultures before disposal. The treatment area must have the procedure for mixing the appropriate strength bleach solution posted.

AUTOCLAVING - Autoclaves must operate at a minimum temperature of 121 degrees centigrade (15 psi) for at least 60 minutes.

INCINERATION - All incineration must occur in a controlled air multi chamber incinerator which gives complete combustion of the waste to carbonized or mineralized ash (excluding glass, ceramic, and metallic items). Any ash that is not completely combusted must be re-incinerated. The primary chamber temperature must be at least 1200 degrees Fahrenheit and the secondary chamber must operate at a minimum temperature of 1600 degrees Fahrenheit with a one second retention time (Please be aware that the Division of Air Pollution Control, Ohio EPA, also regulates incinerators and that their rules may differ from infectious waste regulations). The charging system must have a mechanical process to prevent infectious wastes from being charged until these minimal conditions are achieved. The

secondary chamber must have automatic auxiliary burners that can independently maintain the temperature at 1600 degrees.

Handling Requirements for Specimen Cultures and Cultures of Viable Infectious Agents Shipped Off-Site to a Licensed Infectious Waste Treatment Facility for Treatment

PROPER PACKAGING -

Placed in plastic bags that are:

- ! Impervious to moisture.
- ! Red in color, or another color that is clearly labeled with an international biohazard symbol that is at least 5 inches in diameter.
- ! Thick enough to prevent bursting as determined by the 165 gram dropped dart impact resistance test.
- ! Able to hold 25 pounds of water while being carried suspended from their tops for 60 seconds without leakage.

Before leaving the generator's premises:

- ! Placed inside of a second sealed plastic bag like the first one; or
- ! Placed inside of a fully enclosed, rigid, sturdy container. If containers are used they must have the international biohazard symbol on two opposite sides, be leak resistant, have tight fitting covers, and be strong enough to withstand handling. Containers may be either disposable (cardboard) or reusable. Reusable containers must be cleaned with a detergent and fully disinfected after use with a disinfectant that is registered with the US EPA as a hospital disinfectant that is also tuberculocidal, or with a 10% volume/volume solution of hypochlorite (household bleach).

USE OF A REGISTERED TRANSPORTER - Untreated cultures that are being transported off the site where they were generated must be transported by an infectious waste transporter registered with the Ohio EPA.

SHIPPING PAPERS - Untreated cultures that are shipped off-site must be accompanied by a completed treatment shipping paper, unless they are being transported to another facility for treatment that is also owned or operated by the same generator who produced the infectious waste. The shipping paper can be prepared by either the generator, the transporter, or the infectious waste treatment facility treating the cultures. A master copy of such a form can be obtained by contacting the Ohio EPA's Infectious Waste Unit at (614) 644-2621.

Handling Requirements for Specimen Cultures and Cultures of Viable Infectious Agents and Generators Who Opt* to Have Their Infectious Waste Treated at a Licensed Infectious Waste Treatment Facility

- ! Maintain the integrity of the packaging.
- ! Kept in a nonputrescent state. Nonputrescent means that the infectious waste is not allowed to undergo biological degradation which is commonly characterized by the formation of malodorous products.
- ! Outside storage areas are locked.
- ! Storage access points are locked, or labeled with a sign that states "warning infectious waste" and/or displays the international biohazard symbol.
- ! Wastes protected from animals and are not a food source or breeding place for insects or rodents.

* It should be noted that in accordance with Ohio statute small generators of infectious wastes may transport and dispose of their untreated infectious wastes (except for specimen cultures and cultures of viable infectious agents) in the same manner as solid waste. Furthermore, by statute, sharps, may be transported by a small generator to a hospital for proper treatment, provided the small generator has staff privileges at that hospital.

Handling Requirements for Mixed Waste Types

HAZARDOUS WASTE AND INFECTIOUS WASTE - Any infectious waste or infectious waste mixture that meets the definition of a hazardous waste as specified in rule 3745-51-03 of the Ohio Administrative Code shall be managed as a hazardous waste in accordance with Chapters 3745-50 to 3745-69 of the Administrative Code.

RADIOACTIVE WASTE AND INFECTIOUS WASTE - Any infectious waste that is also radioactive shall be managed in accordance with applicable Ohio Department of Health and US Nuclear Regulatory Commission regulations.

Requirements for Small Generators of Infectious Waste Who Produce More than Fifty Pounds of Infectious Waste in Any One Month

Should a small generator produce 50 pounds or more infectious waste in any one month they must then submit an application for registration as a generator of infectious waste to the Director of the Ohio EPA within 30 days after the last day of the month in which 50 pounds or more of infectious waste was produced. Small generators who generate infectious wastes at more than one location must maintain monthly totals of infectious waste generated for each premises. Should one of the premises generate 50 pounds or more infectious waste in any one month then the generator is obligated to register all the premises that generate infectious waste with the Ohio EPA and follow all the guidelines applicable to large generators of infectious wastes at each premises. Application forms may be obtained by contacting the Ohio EPA's Infectious Waste Unit at (614) 644-2621. Along with a registration certificate, the registered generator will also receive a guidance document for generators of 50 or more

of infectious waste in any one month (large generators). The registration certificate is valid for three years, during which time the registered generator must follow all the rules applicable to large generators of infectious waste.

For further information regarding the Ohio EPA Division of Solid and Infectious Waste Management's regulations on small generators, please contact any of the following:

- 1) A registered sanitarian in your local health department. Currently 95 of the 150 local health districts have an approved program with the Ohio EPA and perform compliance monitoring and enforcement of the Ohio EPA's regulations. The phone number for your local health department can be obtained from your local phone directory.
- 2) An inspector in the Ohio EPA District Office - Division of Solid and Infectious Waste Management. Phone numbers and addresses for the District Offices are listed on the attachment to this guidance document.
- 3) An infectious waste specialist in the Ohio EPA central office who can be reached by telephone at (614) 644-2621 or write to: Ohio EPA - DSIWM; Infectious Waste Specialist; P.O. Box 1049; Columbus, OH 43216-1049.

For more information or to obtain a copy of the current infectious waste regulations, please call the Ohio EPA, Division of Solid and Infectious Waste Management, Infectious Waste Unit at (614) 644-2621.