

**7842**

**G-000-104.245**

**RENEWAL OF REGISTRATION CERTIFICATE AS A GENERATOR OF  
INFECTIOUS WASTE, ID NO: 31-G-00711**

**09/12/96**

**OEPA  
16  
LETTER**

**DOE-FN**



State of Ohio Environmental Protection Agency

7842

J-2959

STREET ADDRESS:

1800 WaterMark Drive  
Columbus, OH 43215-1099

TELE: (614) 644-3020 FAX: (614) 644-2329

MAILING ADDRESS:

P.O. Box 1049  
Columbus, OH 43216-1049

September 12, 1996

Re: Renewal of Registration  
Certificate as a Generator  
of Infectious Waste  
ID No.: 31-G-00711

DEPT OF ENERGY - FERNALD  
ATTN: ED SKINTIK  
7400 WILLEY RD  
FERNALD OH 45030

Dear Sir or Madam:

This letter serves as a reminder that your current registration certificate as a generator of infectious waste will expire at 11:59 p.m. on the expiration date listed on your certificate (11/22/96). If you continue to generate fifty (50) pounds or more of infectious waste in any one month, please apply for your renewal certificate at least thirty (30) days before that expiration date, so that we may process the application before the current registration expires.

If you no longer generate fifty (50) pounds or more of infectious waste in any one month, please submit a completed Reversion to Small Generator Form to the Ohio EPA at least thirty (30) days prior to expiration of your current certificate. If you do not wish to renew your registration, please submit a letter stating so within the same time frame to Ohio EPA, DSIWM, Infectious Waste Unit at the letterhead address.

Enclosed, please find a renewal application form. This application must be accompanied by a fee of \$300.00. The check should be made payable to the Treasurer, State of Ohio. Your new certificate will be valid for three (3) years from the issue date.

Please send your renewal application and fee to the Ohio EPA, Attn: Fiscal Administration, P.O. Box 1049, Columbus, Ohio 43216-1049.

If you have any questions concerning your renewal application, please contact the Infectious Waste Unit at the above address, or by telephone at (614) 644-2621.

Sincerely,

  
Alison M. Shockley, Supervisor  
Infectious Waste Unit  
Division of Solid & Infectious Waste Management

Enclosure

cc: Central File

George V. Voinovich, Governor  
Nancy P. Hollister, Lt. Governor  
Donald R. Schregardus, Director

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## GUIDANCE DOCUMENT FOR LARGE 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 50 pounds or more of infectious waste in any one month (large 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 is a list of the specific categories of infectious waste and the definition of an infectious agent.

### Categories of Infectious Waste

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 or autopsy or for diagnostic evaluation.
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 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 of. "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 during research, production of biologicals, or testing or pharmaceuticals, and carcasses and bedding of animals otherwise infected that may present a substantial threat to public health if improperly managed.
7. Sharp wastes used in the treatment or inoculation of human beings or animals. Also 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".
8. Any other 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 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.

George V. Voinovich, Governor  
Nancy P. Hollister, Lt. Governor  
Donald R. Schregardus, Director

### Definition of an Infectious Agent

"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. A statutory change has deleted the words "or animals" from the definition.

## **LARGE GENERATORS OF INFECTIOUS WASTE MUST MEET THESE REQUIREMENTS**

### **1. Have a Registration Certificate**

#### **WHEN TO APPLY:**

Generators who generate 50 pounds or more of infectious waste, must submit an application within 30 days after the last day of the month in which the generator first produced 50 pounds or more of infectious waste.

#### **OBTAINING AN APPLICATION:**

Contact the Division of Solid and Infectious Waste Management of the Ohio EPA at (614) 644-2621.

#### **SUBMITTING AN APPLICATION:**

Mail the completed application form and a check for the amount of the registration fee to Ohio EPA; Fiscal Administration; P.O. Box 1049; Columbus, OH 43216-1049.

#### **RENEWING REGISTRATION CERTIFICATES:**

Approximately two months before the generator certificate expires, the Ohio EPA will send out a renewal notification and application form to the address and contact person of the previous certificate. Generators are required to submit the renewal application at least 30 days before the current certificate expires.

#### **REVERSION TO SMALL GENERATOR STATUS:**

Once registered as a generator of infectious waste with the Ohio EPA, you must meet the large generator regulatory requirements for the duration of your registration cycle. If at the **END** of the cycle you believe that you may now meet the small generator status, please obtain and complete a "Reversion to Small Generator Form". If you do not still have a form, contact the Division of Solid and Infectious Waste at (614) 644-2621. You should complete and submit the form to the Ohio EPA - DSIWM; Infectious Waste Unit; P.O. Box 1049; Columbus, OH 43216-1049 at least 30 days before your current infectious waste generator registration certificate expires.

### **2. Segregation and Packaging of Infectious Wastes**

**SHARPS:** Used infectious sharps and unused discarded hypodermic needles, syringes, and scalpel blades must be placed into a sharps container. If such containers contain untreated sharps when transported off the premises, the container must be labelled with the international biohazard symbol.

**UNTREATED LIQUID OR SEMILIQUID INFECTIOUS WASTE:** Infectious wastes consisting of blood, blood products, body fluids, and excreta that are in liquid or semiliquid form may be disposed of into a sanitary sewer if the disposal is consistent with the permit for the system.

**ALL OTHER INFECTIOUS WASTES:** All other infectious wastes must be placed in plastic bags that are either red in color, or labelled with an international biohazard symbol that is at least 5 inches in diameter, such plastic bags must be:

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

**INFECTIOUS WASTE THAT IS ALSO A HAZARDOUS WASTE:** Any infectious waste or infectious waste mixture that meets the definition of 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 Ohio Administrative Code.

**INFECTIOUS WASTE THAT IS ALSO A RADIOACTIVE WASTE:** Any infectious waste that is also radioactive must be managed in accordance with applicable Ohio Department of Health and U.S. Nuclear Regulatory Commission regulations.

**3. Infectious Wastes Must Be Shipped Off Site for Treatment at a Licensed Infectious Waste Treatment Facility or Else Treated by the Generator of the Wastes at a Treatment Facility Owned or Operated by the Generator**

**INFECTIOUS WASTES SHIPPED OFF-SITE TO A LICENSED INFECTIOUS WASTE TREATMENT FACILITY:** A large generator of infectious waste may want to have all or part of his infectious waste treated at a licensed infectious waste treatment facility, at a facility holding a license under section 4717.17 and a permit issued under Chapter 3704. of the Ohio Revised Code, or to a facility in another state operating in compliance with that state's and federal regulations. If a generator chooses this option, he must follow all the requirements listed under Infectious Wastes Shipped Off-Site for Treatment at a Licensed Infectious Waste Treatment Facility (see attachment A).

**INFECTIOUS WASTES TREATED BY THE GENERATOR AT THE PREMISES WHERE GENERATED OR AT ANOTHER PREMISES OWNED OR OPERATED BY THE GENERATOR:** If a generator chooses to treat all or part of the infectious wastes he generates either at the premises where generated, or at another premises which is also owned or operated by him,, then he must follow the requirements listed under Large Generators Who Treat Their Own Infectious Wastes (see attachment B).

To receive a copy of the Infectious Waste Regulations, please send a check or money order in the amount of \$5.80 made payable to "Treasurer - State of Ohio" and a short note indicating you are requesting the infectious waste regulations to:

OHIO EPA - FISCAL ADMIN  
ATTN: VICKIE  
P.O. BOX 1049  
COLUMBUS, OH 43216-1049

**'ATTACHMENT A' TO  
GUIDANCE DOCUMENT FOR LARGE GENERATORS OF INFECTIOUS WASTE**

*Infectious Wastes Shipped Off-Site for Treatment at a Licensed Infectious Waste Treatment Facility*

**OTHER PACKAGING REQUIREMENTS:**

Bags of infectious wastes that are being transported to a licensed 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
  - labelled 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 disinfectant that is registered with the US EPA as a hospital disinfectant that is also tuberculocidal. Optionally, a ten per cent volume/volume of household bleach may be used instead of the registered hospital disinfectant.

**TRANSPORTED BY A REGISTERED TRANSPORTER:** Untreated infectious wastes must be transported by a business registered with the Ohio EPA, or in the instance that the wastes consist of dead animals or their parts, either by a person employed by a business that holds a valid license under Chapter 953. (Ohio Dept. of Agri) of the Revised Code or by a business registered with the Ohio EPA. Generators of infectious waste who wish to transport untreated infectious waste from a satellite facility to a main facility for centralized pick-up must also use a registered transporter.

**TREATMENT SHIPPING PAPERS:** All shipments of untreated infectious waste that are being transported to a licensed treatment facility must be accompanied by a treatment shipping paper. Both generator copies of the treatment shipping paper are to be kept on file for 3 years. 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 transporter number two.

**BASIC STORAGE REQUIREMENTS:**

- Maintain the integrity of the packaging
- Maintain the infectious wastes in a nonputrescent state using refrigeration or freezing when necessary. Nonputrescent state 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 must be locked to prevent unauthorized access
- Unlocked storage access points must marked with either an "authorized personnel only" sign, or one that states "warning: infectious waste" and/or displays the international biohazard symbol
- No infectious wastes may be stored for more than 35 days. Storage begins when the any infectious waste is placed into the waste container. Sharps containers that are currently in use are exempt from the 35 day storage limit.

**MISCELLANEOUS INFECTIOUS WASTE REQUIREMENTS:** Large generators of infectious waste must also meet the following requirements:

All infectious wastes that have not been treated to render them noninfectious must be transported in shipments consisting only of untreated infectious wastes. The requirement pertains only to shipments of waste types. For example, untreated infectious waste may not be transported in the same shipment with solid waste, hazardous waste, radioactive waste, or treated infectious waste. Untreated infectious waste may be transported with other materials which are not wastes, provided that the infectious wastes are contained in a separate compartment. A "compartment" means a container able to be fixed in a stationary position within a vehicle.

Provide information on the major components of his infectious wastes to any person with whom the generator has contracted with to transport, treat, or dispose of the wastes after receiving a written request from these persons for this information.

Record in a log all spills of infectious waste from sharps containers or plastic bags, unless the quantity of the spills are less than one cubic foot of waste or less than one-half the contents of a container with a maximum capacity of two cubic feet. The log must be maintained for 3 years and contain the name of the facility, name of the employees involved, address of facility, date of the spill, date of the report, and a short summary of the events causing the spill and the procedure used to clean-up the spill.

Develop and implement a spill containment and clean-up procedure that meets the following minimum standards:

- The kit shall contain liquid impermeable and disposable overalls, boots, and caps made or "Tyvek" (registered trademark) or equivalent material and must either be oversized or fitted to workers. Personnel must also wear heavy neoprene or latex gloves, and protective eyewear. Boots that are made of thick rubber may optionally be used in place of other boots. Boots, gloves, and eyewear may be reused if fully disinfected between uses. Clean-up personnel must wear appropriate personal protective equipment depending upon the type and volume of waste spilled. It is in no way implied that the clean-up personnel have to wear every item in the spill kit for each spill.
- Limit the access of the spill area to authorized personnel.
- Place any broken containers and spilled materials in the appropriate infectious waste containers.
- Disinfect the contact area and handle any absorbent materials used to clean-up the area as infectious waste.
- Clean and disinfect any nondisposable items.
- Remove protective equipment 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.
- The name, address, and telephone number of the infection control manager or the infectious waste control manager and their back-up must also appear at the top of the spill containment procedure. A copy of the procedure must be readily available on the location to all people that are likely to handle infectious wastes, including janitorial services. Copies of the procedure must also be provided at the request of the Board of Health that has jurisdiction over the facility and to the Ohio EPA.

**'ATTACHMENT B' TO  
GUIDANCE DOCUMENT FOR LARGE GENERATORS OF INFECTIOUS WASTE**

**Large Generators Who Treat Their Own Infectious Wastes**

Large generators of infectious waste who treat the infectious wastes that they generate, regardless of whether or not the infectious wastes were generated on the same premises that the treatment facility is located, must abide by the following requirements.

**EXTRA PACKAGING REQUIREMENTS:** Infectious wastes that are being treated to render them noninfectious on the same premises where they were generated do not need to be double bagged or placed into a sturdy, rigid, tightly closed container. However, if the infectious wastes are to be transported from one premises where generated to another premises for treatment, then the wastes require these packaging requirements:

**Bags of infectious wastes that are being transported to a treatment facility must be:**

- Placed inside a second sealed, or tied, 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.
  - labelled 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 disinfectant that is registered with the US EPA as a hospital disinfectant that is also tuberculocidal. Optionally, a ten per cent volume/volume of household bleach may be used instead of the registered hospital disinfectant.

**USE OF A REGISTERED TRANSPORTER:** Large generators of infectious waste who need to transport untreated infectious wastes generated at a satellite facility to another facility or premises which he also owns or operates must use a registered transporter. Ohio statute and Ohio EPA rules provide that large generators who hold a valid registration certificate as a generator of infectious waste can register as transporters of infectious waste without being required to pay the registration fee if they only transport their own infectious waste. Large generators of infectious waste who wish to register vehicles to transport infectious waste can obtain a registration application by contacting the Ohio EPA's Division of Solid and Infectious Waste at (614) 644-2621.

**USE OF TREATMENT SHIPPING PAPERS:** Infectious wastes that are being transported from the premises where generated to another premises owned or operated by the generator that treats infectious wastes do not need to be accompanied by treatment shipping papers.

**STORAGE REQUIREMENTS FOR INFECTIOUS WASTE:**

- Maintain the integrity of the packaging;
- Maintain the infectious wastes in a nonputrescent state using refrigeration or freezing when necessary. Nonputrescent state means that the infectious waste is not allowed to undergo biological degradation which is commonly characterized by the formation of malodorous products; and
- Outside storage areas must be locked to prevent unauthorized access;
- Storage access points must be marked with either an "authorized personnel only" sign, or one that states "warning: infectious waste" and/or displays the international biohazard symbol;

No infectious wastes may be stored for more than 35 days. Sharps containers that are currently in use are exempt from the 35 day storage limit.

Additional storage requirements apply to generators who treat their own infectious waste since they are also defined as infectious waste treatment facilities. Infectious waste can be stored for 14 days once the waste has been transferred to the treatment area.

**MISCELLANEOUS INFECTIOUS WASTE REQUIREMENTS:** Large generators of infectious waste must also meet the following requirements:

All infectious wastes that have not been treated to render them noninfectious must be transported in shipments consisting only of untreated infectious wastes. This requirement pertains only to shipments of waste types. For example, untreated infectious waste may not be transported in the same shipment with solid waste, hazardous waste, radioactive waste, or treated infectious waste. Untreated infectious waste may be transported with other materials which are not wastes, provided that the infectious wastes are contained in a separate compartment. A "compartment" means a container able to be fixed in a stationary position within a vehicle. A container can range from the entire cargo area of a vehicle to a fixed container.

Provide information on the major components of his infectious wastes, the method of treatment, and his system for distinguishing between packages that contain treated and untreated infectious wastes to any person with whom the generator has contracted with to transport, treat, or dispose of the wastes after receiving a written request from those persons for this information.

Record in a log all spills or accidents of infectious waste from sharps containers or plastic bags, unless the quantity of the spills are less than one cubic foot of waste or less than one-half the contents of a container with a maximum capacity of two cubic feet. The log must be maintained for 3 years and contain the name of the facility, name of the employees involved, address of facility, date of the spill, date of the report, and a short summary of the events causing the spill and the procedure used to clean-up the spill.

Develop and implement a spill containment and clean-up procedure that meets the following minimum standards:

- The kit must contain the following items: liquid impermeable and disposable overalls, boots, and caps made of "Tyvek" (registered trademark) or equivalent material that are either oversized or fitted to workers; heavy neoprene or latex gloves; and protective eyewear. Boots that are made of thick rubber may optionally be used in place of disposable boots. Boots, gloves, and eyewear may be reused if fully disinfected between uses. Clean-up personnel are encouraged to wear the appropriate items in the spill kit when managing a spill. **Note:** It is in no way implied that all personal protective items in the spill kit must be worn to clean-up every spill.
- Limit the access of the spill area to authorized personnel.
- Place any broken containers and spilled materials in the appropriate infectious waste containers.
- Disinfect the spill area and handle any absorbent materials used to clean-up the area as infectious waste.
- Clean and disinfect any nondisposable items.
- Remove protective equipment 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.
- The name, address, and telephone number of the infection control manager or the infectious waste control manager and their back-up must also appear at the top of the spill containment procedure.

infectious wastes, including janitorial services. Copies of the procedure must also be provided at the request of the Board of Health that has jurisdiction over the facility and to the Ohio EPA.

**REQUIREMENTS FOR THE TREATMENT OF INFECTIOUS WASTE:** Large generators of infectious waste who treat the infectious waste that they produce are considered to be infectious waste treatment facilities and must follow all the applicable requirements contained in Rule 3745-27-32 of the Administrative Code. The remainder of this guidance document contains the requirements for chemically treating waste cultures and the applied heat encapsulation method for treating sharps. If you treat infectious waste by either autoclaving or incineration, please obtain either "Infectious Waste Treatment Facility Guidance Document - Autoclaving" or "Infectious Waste Treatment Facility Guidance Document - Incineration" by contacting the Ohio EPA's Division of Solid and Infectious Waste Management at (614) 644-2621.

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

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. Please note that cultures of infectious agents that are recommended by the Centers for Disease Control to be handled in accordance with class III or IV biosafety level practices shall not be treated by this chemical method.

Once treated, the cultures may be disposed into the solid waste stream (general trash), but a disposal shipping paper must accompany the load of solid 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. A master copy of the disposal shipping paper that would need to go to a printer for preparation can be obtained by contact the Ohio EPA Infectious Waste Unit by telephone at (614) 644-2621.

In addition to the operational requirements listed above, large generators who treat cultures on-site must:

- Maintain a spill containment and clean-up kit in the general area where the cultures are treated. The kit must contain the following items:
  - 1) Enough material to absorb 10 gallons of liquid.
  - 2) One gallon of disinfectant. The disinfectant must either be a hospital disinfectant that is also tuberculocidal.
  - 3) Minimum ten biohazard bags that can be used as overpack bags if another container breaks.
  - 4) Personal protective equipment consisting of: one set of liquid impermeable and disposable overalls, boots, and caps made of "Tyvek" (registered trademark) or equivalent material that are either oversized or fitted to workers; heavy neoprene or latex gloves; and protective eyewear. Boots that are made of thick rubber may optionally be used in place of disposable boots. Boots, gloves, and eyewear may be reused if fully disinfected between uses.
  - 5) Safety equipment consisting of: a fire extinguisher; boundary tape; and a first aid kit, unless emergency medical care is available on the premises.
- Subsequent to a spill of infectious waste the large generator shall:
  - Have the clean-up personnel utilize the appropriate personal protective equipment.
  - 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 nondisposable items.
- Remove protective equipment 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.

**Applied Heat Sharps Encapsulation on the Site Where The Sharps Were Generated**

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.

Once treated, the resulting solid mass may be disposed into the solid waste stream (general trash), but a disposal shipping paper must accompany the load of solid 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. A master copy of the disposal shipping paper that would need to go to a printer for preparation can be obtained by contact the Ohio EPA Infectious Waste Unit by telephone at (614) 644-2621.

In addition to the operational requirements listed above, large generators who encapsulate sharps on-site must:

- Maintain a spill containment and clean-up kit in the general area where the cultures are treated. The kit must contain the following items:

- 1) Enough material to absorb 10 gallons of liquid.

- 2) One gallon of disinfectant. The disinfectant must either be a hospital disinfectant that is also tuberculocidal.
- 3) Minimum ten biohazard bags that can be used as overpack bags if another container breaks.
- 4) Personal protective equipment consisting of: one set of liquid impermeable and disposable overalls, boots, and caps made of "Tyvek" (registered trademark) or equivalent material that are either oversized or fitted to workers; heavy neoprene or latex gloves; and protective eyewear. Boots that are made of thick rubber may optionally be used in place of disposable boots. Boots, gloves, and eyewear may be reused if fully disinfected between uses.
- 5) Safety equipment consisting of: a fire extinguisher; boundary tape; and a first aid kit, unless emergency medical care is available on the premises.

- Subsequent to a spill of infectious waste the large generator shall:

- Have the clean-up personnel utilize the appropriate personal protective equipment.
- 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 nondisposable items.
- Remove protective equipment 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.

For further information regarding the Ohio EPA Division of Solid and Infectious Waste Management's regulations on large 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.

To obtain a copy of the current infectious waste regulations, please send a check or money order in the amount of \$5.80 payable to "Treasurer - State of Ohio" and a short note indicating you are requesting the infectious waste regulations to:

OHIO EPA - FISCAL ADMIN  
ATTN: VICKIE  
P.O. BOX 1049  
COLUMBUS, OH 43216-1049



## OhioEPA

### DISTRICT OFFICES

**CDO** Central District Office  
3232 Alum Creek Drive  
Columbus, Ohio 43207-3417  
(614) 728-3778  
1-800-686-2330

**NEDO** Northeast District Office  
2110 E. Aurora Road  
Twinsburg, Ohio 44087  
(216) 963-1200  
1-800-686-6330

**NWDO** Northwest District Office  
347 North Dunbridge Road  
Bowling Green, Ohio 43402  
(419) 352-8461  
1-800-686-6930

**SEDO** Southeast District Office  
2195 Front Street  
Logan, Ohio 43138  
(614) 385-8501  
1-800-686-7330

**SWDO** Southwest District Office  
401 East Fifth Street  
Dayton, Ohio 45402-2911  
(513) 285-6357  
1-800-686-8930

Toll free numbers are for citizens with questions or concerns about environmental issues. The regulated community should use the business line for routine business. Spills and emergencies should be reported to 1-800-282-9378.

OHIO ENVIRONMENTAL PROTECTION AGENCY  
DIVISION OF SOLID AND INFECTIOUS WASTE MANAGEMENT  
INFECTIOUS WASTE  
GENERATOR REGISTRATION CERTIFICATE  
APPLICATION FORM

INSTRUCTIONS: Please type or legibly print all required information on all sides of this form. All information shall be completed in accordance with the provisions of Section 3734.021 of the OHIO REVISED CODE.

NOTE: This application will not be processed if: incomplete information, no original signature, or incorrect fees are submitted. Submit to:

OHIO EPA  
Fiscal Administration  
P.O. Box 1049  
Columbus, OH 43216-1049

For Office Use Only  
Registration No. \_\_\_\_\_  
Date Received \_\_\_\_\_  
Fee Paid \_\_\_\_\_ Date \_\_\_\_\_  
Check No. \_\_\_\_\_ Date \_\_\_\_\_

NATURE OF APPLICATION: (please check one)

\_\_\_\_\_ Initial application for generator certificate.  
\_\_\_\_\_ Renewal application. Enter current registration number: \_\_\_\_\_ G \_\_\_\_\_

REGISTRANT INFORMATION:

Registrant Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_  
(City) (State) (ZIP) (Telephone)  
Contact Person: \_\_\_\_\_ (Telephone)  
Health District in which Registrant is Located: \_\_\_\_\_

Registrant is the entity under which all generator and/or generator treatment facilities are registered.

Premises are all location(s), operated by the registrant in the state of Ohio, at which infectious wastes are generated and/or treated by the registrant.

Attach a PREMISES INFORMATION FORM for each premises operated by the registrant where infectious wastes are generated and/or treated by the registrant. The premises information form may be photocopied.

Number of forms attached \_\_\_\_\_

# INFECTIOUS WASTE GENERATOR REGISTRATION CERTIFICATE APPLICATION FORM

Application must be signed by:

- 1) In the case of a corporation, by a principal executive officer of at least the level of vice-president, or his duly authorized representative, who is responsible for the overall operation of the facility;
- 2) In the case of a partnership, by a general partner;
- 3) In the case of sole proprietorship, by the proprietor;
- 4) In the case of a municipal, state, federal, or other government premise, by the principal executive officer, the ranking elected official, or another duly authorized employee.

A non-refundable application fee of \$300.00, regardless of the number of premises being registered, payable to **TREASURER - STATE OF OHIO** must accompany this application.

Please note: The registrant shall allow the Director of the Ohio EPA, or an authorized representative, upon presentation of credentials to:

- 1) Enter into the registrant's vehicle upon the registrant's premises where a regulated facility or activity is located or conducted, or where records must be kept in accordance with Ohio Revised Code Chapter 3734 and rules promulgated thereunder.
- 2) Have access to and copy, at any reasonable time, any records that must be kept in accordance with Ohio Revised Code Chapter 3734 and rules promulgated thereunder.
- 3) Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, operations, or vehicles regulated or required in accordance with Ohio Revised Code Chapter 3734 and rules promulgated thereunder.

I CERTIFY UNDER PENALTY OF LAW THAT I HAVE PERSONALLY EXAMINED AND AM FAMILAR WITH THE INFORMATION SUBMITTED IN THIS APPLICATION AND ALL ATTACHMENTS AND THAT, BASED ON MY INQUIRY OF THOSE PERSONS IMMEDIATELY RESPONSIBLE FOR OBTAINING THE INFORMATION CONTAINED IN THE APPLICATION, I BELIEVE THAT THE INFORMATION IS TRUE, ACCURATE AND COMPLETE. I AM AWARE THAT THERE ARE SIGNIFICANT PENALTIES FOR SUBMITTING FALSE INFORMATION, INCLUDING THE POSSIBILITY OF FINE AND IMPRISONMENT.

Full Name:

\_\_\_\_\_ (Type or Print)

Official Title:

Signature:

Date: \_\_\_\_\_

Only applications containing original signatures will be processed; facsimiles (photocopies) of signatures can not be accepted.

OHIO ENVIRONMENTAL PROTECTION AGENCY  
DIVISION OF SOLID AND INFECTIOUS WASTE MANAGEMENT

INFECTIOUS WASTE PREMISES INFORMATION FORM

INSTRUCTIONS: Please type or legibly print all required information on all sides of this form. All information shall be completed in accordance with the provisions of Section 3734.021 of the OHIO REVISED CODE.

Premises information form may be photocopied.

<u>For Office Use Only</u>	
Registration No.	_____
Date Received	_____

Registrant Name: _____
------------------------

PREMISES INFORMATION:

Premises Name: _____
Address: _____
_____ (City) _____ (State) _____ (ZIP Code) _____ (Telephone)
Health District in which premises is located: _____
Type of Business: _____

CONTACT PERSON:

Name: _____
Telephone: (____) _____ EXT _____

INFECTIOUS WASTE HANDLING INFORMATION:

Are infectious wastes accepted from other generators for on-site or off-site treatment?	Yes _____	No _____
Are infectious wastes treated on-site?	Yes _____	No _____
Please indicate method of treatment.	_____ Incineration	_____ Autoclaving
_____ Chemical treatment of cultures	_____ Other	
Are infectious wastes sent off-site for treatment at a commercial infectious waste treatment facility?	Yes _____	No _____
Please indicate method of treatment?	_____ Incineration	_____ Autoclaving
Other _____		

# INFECTIOUS WASTE PREMISES INFORMATION FORM

## BUSINESS OWNER:

Name:	_____			
Address:	_____			
	_____			
(City)	(State)	(ZIP Code)	( )	(Telephone)

## PROPERTY OWNER:

Name:	_____			
Address:	_____			
	_____			
(City)	(State)	(ZIP Code)	( )	(Telephone)
Please give a brief description of ownership or lease agreement:				
_____				
_____				

**NOTE:** Submit premises information form(s) along with the infectious waste generator registration certificate application form and the application fee to:

**OHIO EPA  
Fiscal Administration  
P.O. Box 1049  
Columbus, OH 43216-1049**

For more information please call the Ohio EPA, Division of Solid and Infectious Waste Management, Infectious Waste Unit at (614) 644-2621. To receive a copy of the Infectious Waste Regulations, please send a check or money order, made payable to Treasurer - State of Ohio, for the amount of \$4.75 to:

Ohio EPA  
Legal Records Section  
P.O. Box 1049  
Columbus, Ohio 43216-1049