

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Rick Scott
Governor

Celeste Philip, MD, MPH
Secretary and State Surgeon General

Vision: To be the Healthiest State in the Nation

Biomedical Waste Facility Permitting/Exemption Procedure

1. Complete the form DH4089 “**Application for Biomedical Waste Generator Permit/Exemption**”. You will find one following this page in your licensing packet. **Be sure to complete all blanks.** Should you have any questions please call our office for assistance.
2. To apply for a permit, you must include a check made out to the “**Department of Health – Manatee County**” in the amount of **\$85.00**.
3. If you are an existing permitted Biomedical Waste generator applying for an “**Exemption**”, a fee should not be submitted. However, you must include your **written documentation** for **each 30 day period**, for the **most recent 12 months**, showing that you produced **less than 25 pounds** of Biomedical Waste in **each** of those periods.
4. Mail the completed application and appropriate documentation (and fee, if required) to our mailing address: 410 6th Ave E, Bradenton, FL 34208.
5. Review the documents in the enclosed packet and begin completing your required Operating Plan and other required documents. Please call our department should you have questions.
6. You may begin Biomedical Waste operations at this point. Your permit will be delivered to you upon completion of a Satisfactory opening inspection. Opening inspections are done by appointment and are arranged upon receipt of the application.
7. The key components of a Biomedical Waste inspection are: Completed Operating Plan, Bloodborne Pathogen Spill Kit, Training Documentation, Transporter Documentation, Red Bag Documentation, Address Labels for the transporter bag, and Proper labeling of exam room red bag waste containers. We will also visually look at the locations of Sharps Containers, Red Bag Waste Containers and Storage Areas.
8. The best time to call our office for assistance or to confirm opening inspections is generally 8:00 A.M. to 4:30 P.M., Monday through Friday.

Biomedical Waste Program
Florida Department of Health -
Manatee County



DH USE Only: Check No. _____	Check Amount _____
Date Received _____	Receipt No. _____
Permit No. _____	Date Issued _____

Department of Health

Application for Biomedical Waste Generator Permit/Exemption

A biomedical waste generator is required to apply for an annual biomedical waste permit and abide by the requirements of Chapter 64E-16, Florida Administrative Code (F.A.C.). The initial permit fee is \$85.00. When the facility shall be in operation six (6) months or less before the annual renewal date, the initial fee shall be prorated on a quarterly basis. Permits expire September 30 of each year. The permit fee for renewal applications received by October 1 is \$85.00. The permit fee for renewal applications received after October 1 is \$105.00. State-owned and operated facilities are exempt from the permit fee. Submit the following information on this form to your local Department of Health Biomedical Waste Coordinator.

FOR CURRENTLY PERMITTED GENERATORS ONLY: A currently permitted biomedical waste generator, that produces **less than 25 pounds of biomedical waste** in each 30 day period, may claim an exemption from the fee and permitting requirements only of Chapter 64E-16, F.A.C. **A currently permitted biomedical waste generator applying for exemption from permitting must submit documentation from the previous 12 months showing the biomedical waste generated in each 30 day period during those 12 months was less than 25 lbs. Documentation must include the amount of waste generated in each 30 day period for the previous 12 months and may be in the form of a monthly log or receipts.**

- Application for (choose one):** _____ Permit _____ Exemption (attach appropriate documentation)
(Applicant must be a legal entity, i.e.: individual, partnership, corporation, association, or public body)
- Facility Name: _____
- Facility Address: _____
Street City State Zip Code
- Contact Person: _____ Telephone: _____
- Name of Facility Owner: _____
- Mailing Address of Facility Owner: _____
Street City State Zip Code
- Business Phone: _____ 24-Hour Emergency Phone: _____
- Name of Property Owner: _____
- Mailing Address of Property Owner: _____
Street City State Zip Code
- Type of Waste Generated: _____ Sharps _____ Non-sharps
- Method of Removal (Check One): _____
1. By applicant, to where: _____
2. By transporter, company name: _____
- Maximum weight of biomedical waste generated during any 30-day period: _____ lbs.
- Branch Offices: ____ Yes ____ No If yes, attach sheet with complete name, address and phone number of branch office(s).

Check Type of Facility:

<input type="checkbox"/>	01. Hospital	<input type="checkbox"/>	07. Dentist	<input type="checkbox"/>	13. Surgical Center/Walk-in Clinic
<input type="checkbox"/>	02. Funeral Home	<input type="checkbox"/>	08. Podiatrist	<input type="checkbox"/>	14. Blood Banks
<input type="checkbox"/>	03. Dialysis Clinic	<input type="checkbox"/>	09. Osteopath	<input type="checkbox"/>	16. Abortion Clinics
<input type="checkbox"/>	04. Nursing Home	<input type="checkbox"/>	10. Home Health	<input type="checkbox"/>	17. Other (specify)
<input type="checkbox"/>	05. Veterinarian	<input type="checkbox"/>	11. State Laboratory/Clinic	<input type="checkbox"/>	18. Tattoo/Body Piercing
<input type="checkbox"/>	06. Medical Doctor	<input type="checkbox"/>	12. Clinical Laboratory	<input type="checkbox"/>	

The undersigned owner/owner's representative hereby agrees to operate the biomedical waste generating facility described in this application in accordance with the requirements of Section 381.0098, Florida Statutes, and Chapter 64E-16, F.A.C. The information contained in this application, which serves as a basis for permitting or exemption, is true and correct. I understand that any misrepresentation of the facts in this application, or failure to comply with sanitary standards, is grounds for denial, administrative fine or revocation of the biomedical waste permit or exemption. Biomedical waste shall be handled within the facility in accordance with the generator's written operating plan. Operating plan must be in compliance with 64E-16, F.A.C.

Signature of Authorized Representative
DH 4089, 1/09

Name of Authorized Representative (print or type) _____ Date

BIOMEDICAL WASTE OPERATING PLAN

FACILITY NAME (1) _____

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ATTACHMENT A: BIOMEDICAL WASTE TRAINING ATTENDANCE

Use of this plan format is voluntary and not required by the Department of Health. It is provided as a service to assist biomedical waste facilities in complying with the requirements of Chapter 64E-16, F.A.C.

I. DIRECTIONS FOR COMPLETING THE BIOMEDICAL WASTE PLAN

Blank 1: Enter the name of your facility.

Blank 2: Enter where you keep your employee training records.

Blank 3: List the items of biomedical waste that are produced in your facility and the location where each waste item is generated.

Blank 4: Enter the name of the manufacturer of your facility's red bags. This company must be on the Department of Health (DOH) list of compliant red bags (this list can be obtained from the following website: www.doh.state.fl.us/environment/community/biomedical/red_bags.htm) or from your DOH biomedical waste coordinator OR you must have results supplied by the bag manufacturer from an independent laboratory that indicate that your red bags meet the bag construction requirements of Chapter 64E-16, Florida Administrative Code (F.A.C.). If your facility does not use red bags, enter N/A.

Blank 5: Indicate where the documentation for the construction standards of your facility's red bags is kept. or if your facility does not use red bags, enter N/A.

Blank 6: Indicate where unused, red biomedical waste bags are kept in operational areas (not in stock or in central storage) so that working staff can get them quickly when they need them. If your facility does not use red bags, enter N/A.

Blank 7: Enter the place where your biomedical waste is stored. 1. How is this area "Washable"?
2. Is this area "Out of the Client Traffic Area" (how)? 3. How is this area's access restricted?
If your biomedical waste is picked up by a licensed biomedical waste transporter but you have no storage area, indicate your procedure for preparing your biomedical waste for pick-up. If you have no pick-up and no storage area, enter N/A.

Blank 8: Enter all the required information about your registered biomedical waste transporter. The website www.doh.state.fl.us/environment/community/biomedical/transporters.htm has a list of such transporters. If you do not use a transporter, enter N/A.

Blank 9: Enter the name(s) of the employee(s) designated to transport your facility's untreated biomedical waste to another facility. If your facility does not transport your own biomedical waste, enter N/A.

Blank 10: Enter the name of the facility to which your facility transports your own untreated biomedical waste. If your facility does not transport your own biomedical waste, enter N/A.

Blank 11: Describe the procedure and products your facility will use to decontaminate a spill or leak of biomedical waste.

Blank 12: Enter the required information about the registered biomedical waste transporter who will transport your biomedical waste on a contingency basis.

Blank 13: If personnel from your facility also work at a branch office of your facility, enter the name of the branch office. If you have no branch office, enter N/A.

Blank 14: Enter the street address, city, and state of the branch office named in (13). If you have no branch office, enter N/A.

Blank 15: Enter the weekdays the branch office named in (13) is open. If you have no branch office, enter N/A.

Blank 16: Enter the normal work hours for each day the branch office named in (13) is open. If you have no branch office, enter N/A.

Blank 17: Indicate where a copy of this biomedical waste operating plan will be kept in your facility.

Blank 18: Indicate where the current biomedical waste permit or exemption document will be kept in your facility.

Blank 19: Indicate where your facility will keep its current copy of the biomedical waste rules, Chapter 64E-16, F.A.C.

Blank 20: Indicate where your facility will keep copies of its biomedical waste inspections from at least the last three (3) years.

Blank 21: If your facility transports your own biomedical waste, indicate where your transport log is kept. If you do not transport your own biomedical waste, enter N/A.

Attachment A: Enter the required information to document training sessions.

II. PURPOSE

The purpose of this Biomedical Waste Operating Plan is to provide guidance and describe requirements for the proper management of biomedical waste in our facility. Guidelines for management of biomedical waste are found in Chapter 64E-16, Florida Administrative Code (F.A.C.), and in section 381.0098, Florida Statutes.

III. TRAINING FOR PERSONNEL

Biomedical waste training will be scheduled as required by paragraph 64E-16.003(2)(a), F.A.C. **Training sessions will detail compliance with this operating plan and with Chapter 64E-16, F.A.C.** Training sessions will include all of the following activities that are carried out in our facility:

- Definition and Identification of Biomedical Waste
- Segregation
- Storage
- Labeling
- Transport
- Procedure for Decontaminating Biomedical Waste Spills
- Contingency Plan for Emergency Transport
- Procedure for Containment

Training for the activities that are carried out in our facility is outlined above.

Our facility must maintain records of employee training. These records will be kept (2) _____

Training records will be kept for participants in all training sessions for a minimum of three (3) years and will be available for review by Department of Health (DOH) inspectors.

An example of an attendance record is appended in Attachment B.

IV. DEFINITION, IDENTIFICATION, AND SEGREGATION OF BIOMEDICAL WASTE

Biomedical waste is any solid or liquid waste which may present a threat of infection to humans. Biomedical waste is further defined in subsection 64E-16.002(2), F.A.C.

Items of sharps and non-sharps biomedical waste generated in this facility and the locations at which they are generated are:

(3) _____

If biomedical waste is in a liquid or semi-solid form and aerosol formation is minimal, the waste may be disposed into a sanitary sewer system or into another system approved to receive such waste by the Department of Environmental Protection or the DOH.

V. CONTAINMENT

Red bags for containment of biomedical waste will comply with the required physical properties.

Our red bags are manufactured by

(4) _____

Our documentation of red bag construction standards is kept

(5) _____

Working staff can quickly get red bags at

(6) _____

Sharps will be placed into sharps containers at the point of origin.

Filled red bags and filled sharps containers will be sealed at the point of origin.

Red bags, sharps containers, and outer containers of biomedical waste, when sealed, will not be reopened in this facility. Ruptured or leaking packages of biomedical waste will be placed into a larger container without disturbing the original seal.

VI. LABELING

All sealed biomedical waste red bags and sharps containers ***will be labeled with this facility's name and address prior to offsite transport.*** If a sealed red bag or sharps container is placed into a larger red bag prior to transport, placing the facility's name and address only on the exterior bag is sufficient.

Outer containers must be labeled with our transporter's name, address, registration number, and 24-hour phone number.

VII. STORAGE

When sealed, red bags, sharps containers, and outer containers will be stored in areas that are restricted through the use of locks, signs, or location. The 30-day storage time period will commence when the first non-sharps item of biomedical waste is placed into a red bag or sharps container, or when a sharps container that contains only sharps is sealed.

Indoor biomedical waste storage areas will be constructed of smooth, easily cleanable materials that are impervious to liquids. These areas will be regularly maintained in a sanitary condition. The storage area will be vermin/insect free. Outdoor storage areas also will be conspicuously marked with a six-inch international biological hazard symbol and will be secure from vandalism.

Biomedical waste will be stored and restricted in the following manner:

(7) _____

VIII. TRANSPORT

We will negotiate for the transport of biomedical waste only with a DOH-registered company. If we contract with such a company, we will have on file the pick-up receipts provided to us for the last three (3) years. Transport for our facility is provided by:

- a. The following registered biomedical waste transporter:

Company name (8) _____

Address _____

Phone _____

Registration number _____

Place pick-up **receipts** are kept _____

OR

- b. An employee of this facility who works under the following guidelines:

We will transport our own biomedical waste. For tracking purposes, we will maintain a log of all biomedical waste transported by any employee for the last three (3) years. The log will contain waste amounts, dates, and documentation that the waste was accepted by a permitted facility.

Name of employee(s) who is(are) assigned transport duty:

(9) _____

Biomedical waste will be transported to:

(10) _____

IX. PROCEDURE FOR DECONTAMINATING BIOMEDICAL WASTE SPILLS

(11) _____

X. CONTINGENCY PLAN

If our registered biomedical waste transporter is unable to transport this facility's biomedical waste, or if we are unable temporarily to treat our own waste, then the following registered biomedical waste transporter will be contacted:

Company name (12) _____
Address _____
Phone _____
Registration number _____

XI. BRANCH OFFICES

The personnel at our facility work at the following branch offices during the days and times indicated:

- 1) Office name (13) _____
Office address (14) _____

Days of operation (15) _____
Hours of operation (16) _____

- 2) Office name (13) _____
Office address (14) _____

Days of operation (15) _____
Hours of operation (16) _____

XII. MISCELLANEOUS

For easy access by all of our staff, a copy of this biomedical waste operating plan will be kept in the following place:

(17) _____

The following items will be kept where indicated:

- a. Current DOH biomedical waste permit/ exemption document
(Must be posted conspicuously, copy may be filed or stored)
(18) _____

- b. Current copy of Chapter 64E-16, F.A.C.
(19) _____

- c. Copies of biomedical waste inspection reports from last three (3) years
(20) _____

- d. Transport log
(21) _____

DECONTAMINATING BIOMEDICAL WASTE SPILLS

PLEASE NOTE: If you choose to use this procedure, indicate so in your plan.
 If you choose to use pre-packaged OSHA Bloodborne Pathogen Spill Kits, delete this page and indicate which kits you use in your plan.

PROCEDURE:

1. Broken glass is never to be picked up with the hands.
 Glass should be removed using a dustpan and whiskbroom only.
2. Biomedical Waste clean-up kit(s) is\are located:
 _____.
3. Isolate area from patients and staff.
4. Put on protective gloves and clothing.
5. Sweep up glass/sharps using whiskbroom and dustpan or with scoop and scraper.
6. Place all contaminated glass or sharps into sharps containers.
7. Disinfect area with a **tuberculocidal disinfectant**.
 The disinfectant to be used is: _____ (Per OSHA).
8. Put paper towels over spill area and wait until absorbed.
9. Put on new gloves and wash area thoroughly with soap and water.
10. Discard gloves and towels into Biomedical Waste Container (with Red Bag).
11. Wash hands thoroughly with Anti-Bacterial soap.

Report to: _____
 (Someone in charge at your facility)

CONTENTS: 1. Place a “check” in the box for each item you choose to include.
 2. List any other items you wish to include in the boxes labeled “other”.

	Household Bleach (1 part Bleach, 9 parts water is 10 %)
	Alternate Tuberculocidal disinfectant (named above)
	Dust Pan
	Red Bags
	Disinfectant
	Mask
	Anti Bacterial Soap
	Whisk Broom
	Paper Towels
	Gown
	Gloves
	Sharps Container
	Transfer\Transport Container
	Other:

SAMPLE

ATTACHMENT A: BIOMEDICAL WASTE TRAINING ATTENDANCE

Facility Name: _____

Trainer's Name: _____

Duration: _____ (How long was this training?)

Content: _____

Purpose: **Initial Assignment** **Annual** **Update**
 {FULL TRAINING – First Time} {FULL TRAINING – NOT First Time} {Partial Training}

NOTE: Mark ONLY ONE Purpose for each page. A page can be used for multiple years.

Print Participant's Name

Signature

Date

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

SAMPLE

ATTACHMENT A: BIOMEDICAL WASTE TRAINING ATTENDANCE

Facility Name: _____

Trainer’s Name: _____

Training Coverage: **64E-16 FAC Training:** **online** **video** **self-taught**
Review of site specific Biomedical Waste Management Plan

I = Initial Assignment (First Time Training) A = Annual Training U = Update Training*

TYPE	PRINT NAME	SIGN NAME	DATE

CODE TRAINING OPTIONS

Option 1: To order the State biomedical waste training video, please print this page, cut off the order form below, and send it with a check or money order payable to the *State Treasurer of Florida*, in the amount of \$22.00 for each video, to:

**Bureau of Community Environmental Health
4052 Bald Cypress Way, Bin # A08
Tallahassee, FL 32399-1710**

The video is available on VHS tape or on a CD or a DVD.

Please send _____ copy(ies) of the biomedical waste training video @ \$22.00 each in:

_____ VHS format _____ CD format _____ DVD format

to

Name: _____

Street/P.O. Box: _____

City, State, Zip: _____

Name of Contact Person: _____

Phone Number of Contact Person: _____

**Bureau of Community Environmental Health
4052 Bald Cypress Way, Bin #A08
Tallahassee, FL 32399-1710**

OPTION 2: To view a PowerPoint Slide Presentation of the Biomedical Waste Code online, go to: [http://manatee.floridahealth.gov/programs-and-services/environmental-health/biomedical-waste/ documents/MCHD_BMW_Training.pdf](http://manatee.floridahealth.gov/programs-and-services/environmental-health/biomedical-waste/documents/MCHD_BMW_Training.pdf)

OPTION 3: Training yourself and employees in-house by reading through the code.

OPTION 4: Private consultants are available that provide this training in many areas.

Document your code training option on your training attendance sheets.