Biomedical Waste Annual Training

In Florida, the Department of Health regulates the disposal of biomedical waste products, and as electrologists, we fall under their jurisdiction due to the probes that we use for needle electrolysis. Our Electrolysis Inspection forms list our requirement to have a sharps container on line 21. That inspection form can be accessed at this website:

http://www.floridahealth.gov/licensing-and-regulation/enforcement/_documents/electrolysis-facility1.pdf

Our electrolysis requirements include an inspection by the Department of Health for biomedical waste. That is a separate inspection from our biennial facility license. They require you to write a 'plan' for disposal and the protocols that you would use in the event of an accident. Even though our Electrolysis facilities are much different from most clinic and hospital settings, we are none-the-less on their list of biomedical waste generators. Clearly we are subject to a possible 'needle-stick' which hardly qualifies the use of a 'clean-up' plan. But occurances that could warrant a plan for clean-up could feasibly include an accident in our offices, where a person could have injured themselves by falling or getting a cut which would cause bleeding. Another example could be a menstrual accident. Essentially anything that could generate the loss of blood that would need to be cleaned up, would fall under your plan. Your plan will include your actions (and anyone else in your facility) on how you would process that type of occurance.

These are the official rules for Biomedical waste. For the purposes of this course, we have included the portions of this law that pertain to Electrolysis facilites and omitted referances to venues such as veternary, hospital, and acute care types of applications. All items that are emphasized by underlining, bold print, or highlighting has been done by the author of this course and is not a part of the original state rule/law. The entire rule for biomedial waste can be accessed here:

https://www.flrules.org/gateway/ChapterHome.asp?Chapter=64E-16

BIOMEDICAL WASTE
64E-16.002 Definitions

(2) Biomedical waste – Any solid or liquid waste which may present a threat of infection to humans, including nonliquid tissue, body parts, blood, blood products, and body fluids from humans and other primates; laboratory and veterinary wastes which contain human disease-causing agents; and discarded sharps. The following are also included:
(a) Used, absorbent materials saturated with blood, blood products, body fluids, or excretions or secretions contaminated with visible blood; and absorbent materials saturated with blood or blood products that have dried.
(b) Non-absorbent, disposable devices that have been contaminated with blood, body fluids or, secretions or excretions visibly contaminated with blood, but have not been treated by an approved method.

(3) Biomedical waste generator – A facility or person that produces biomedical waste. The term includes hospitals, skilled nursing or convalescent hospitals, intermediate care facilities, clinics, dialysis clinics, dental offices, health maintenance organizations, surgical clinics, medical buildings, physicians' offices, laboratories, veterinary clinics and funeral homes.

(4) Body fluids – Those fluids which have the potential to harbor pathogens, such as human immunodeficiency virus and hepatitis B virus and include blood, blood products, lymph, semen, vaginal secretions, cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluids. In instances where identification of the fluid cannot be made, it shall be considered to be a regulated body fluid. Body excretions such as feces and secretions such as nasal discharges, saliva, sputum, sweat, tears, urine, and vomitus shall not be considered biomedical waste unless visibly contaminated with blood.

(5) Contaminated – Soiled by any biomedical waste.

(6) Decontamination – The process of removing pathogenic microorganisms from objects or surfaces, thereby rendering them safe for handling.

(7) Department – The Department of Health or its representative county health department.

(8) Disinfection – A process which results in a minimum Log 6 kill against the vegetative organisms listed in Table 1, and a minimum Log 4 kill against Bacillus stearothermophilus spores utilizing steam or a minimum Log 4 kill against Bacillus Subtilis spores utilizing dry heat, chemicals, or microwave shredding.

(9) Facility – All contiguous land, structures, and other appurtenances which are owned, operated, and licensed as a single entity which may consist of several generating, treatment, or storage units.

(10) Hazardous waste – Those materials defined in Chapter 62-730, F.A.C.

(11) Health Care Provider – Any person who provides medical care or personal services, as that term is defined in Section 400.402, F.S., to another individual.

(12) Home User – An individual who generates biomedical waste as a result of self-care or care by a family member or other non health care provider.

(13) Leak resistant – Prevents liquid from escaping to the environment in the upright position.

(14) Outer container – Any rigid type container used to enclose packages of biomedical waste.

(15) Packages – Any material that completely envelops biomedical waste. This includes red bags, sharps containers and outer containers.

(16) Person – Any individual, partnership, corporation, association, or public body engaged in the generation, storage, transport, or treatment of biomedical waste.

(17) Point of origin – The room or area where the biomedical waste is generated.

(18) Public sharps collection program – A cooperative program designed as a non-profit community service to assist the home user in the safe disposal of discarded sharps.

(19) Puncture resistant – Able to withstand punctures from contained sharps during normal usage and handling.

(20) Restricted – The use of any measure, such as a lock, sign, or location, to prevent unauthorized entry.

(21) Saturated – Soaked to capacity.

(22) Sealed – Free from openings that allow the passage of liquids.

(23) Sharps – Objects capable of puncturing, lacerating, or otherwise penetrating the skin.

(24) Sharps container – A rigid, leak and puncture resistant container, designed primarily for the containment of sharps, clearly labeled with the phrase and international biological hazard symbol as described in Section 64E-16.004(2)(a), F.A.C., and manufactured with dyes meeting the requirements for incidental metals as described in Section 64E-16.004(2)(b)1.b., F.A.C.

(25) Sterilization – A process which results in a minimum Log 6 kill against Bacillus stearothermophilus spores utilizing steam or a minimum Log 6 kill against Bacillus Subtilis spores utilizing dry heat, chemicals, or microwave shredding.

(26) Storage – The holding of packaged biomedical waste for a period longer than three days at a facility or in a transport vehicle.

(27) Transfer – The movement of biomedical waste within a facility.

(28) Transport – The movement of biomedical waste away from a facility.

(29) Transport vehicle – A motor vehicle, as defined in Section 320.01, F.S., a rail car, watercraft or aircraft, used for the transportation of biomedical waste.

(30) Treatment – Any process, including steam, chemicals, microwave shredding, or incineration, which changes the character or composition of biomedical waste to render it noninfectious by disinfection or sterilization.

Inspectors for the Florida Health Department are directed to be sure that everyone in the state – including Electrologists – have a written plan in place, and receive annual training. Here is the portion of the law that specifies this directive:

64E-16.003 Facility Policies and Procedures

(1) All biomedical waste facilities shall comply with the following:
(a) Biomedical waste mixed with hazardous waste, as defined in Chapter 62-730, F.A.C., Hazardous Waste, shall be managed as hazardous waste.
(c) Any other solid waste or liquid, which is neither hazardous nor radioactive in character, combined with untreated biomedical waste, shall be managed as untreated biomedical waste.
(d) All surfaces contaminated with spilled or leaked biomedical waste shall be decontaminated as part of the cleaning process.

(2) Each biomedical waste facility shall implement a written operating plan to manage biomedical waste, in accordance with this chapter. This plan shall be available for review by the department and facility personnel.

The plan shall include the following:

- a description of training for personnel;
- procedures for segregating, labeling, packaging, transporting, storing, and treating, biomedical waste;
- procedures for decontaminating biomedical waste spills;
- and a contingency plan for emergencies.

A sample plan is provided by the state at this web address:

http://www.floridahealth.gov/environmental-health/biomedical-waste/_documents/CurrentDisclaimer_08.pdf

Facilities which have multiple specialty services shall include procedures specific to each specialty if procedures vary. Plans shall be updated when regulations, facility policies, or procedures change.
(a) Each facility or their designee shall train new personnel who handle biomedical waste as part of their work responsibilities. This training shall be provided prior to commencement of duties related to biomedical waste handling. Refresher training shall be completed annually by all personnel who handle biomedical waste. Training shall detail compliance with the facility's operating plan and Chapter 64E-16, F.A.C., and shall be maintained as a part of the operating plan.
(b) All biomedical waste management records shall be maintained for 3 years and shall be available for review by the department.

64E-16.004 Storage and Containment

(1) Storage.

(a) Storage of biomedical waste at the generating facility shall not exceed 30 days. The 30 day period shall commence when the first non-sharps item of biomedical waste is placed into a red bag or sharps container, or when a sharps container containing only sharps is sealed.

(b) Storage of biomedical waste in a place other than at the generating facility shall not exceed 30 days. The 30 day storage period shall begin on the day the waste is collected from the generator.

(c) Indoor storage areas shall have restricted access and be designated in the written operating plan. They shall be located away from pedestrian traffic, be vermin and insect free, and shall be maintained in a sanitary condition. They shall be constructed of smooth, easily cleanable materials that are impervious to liquids.

(2) Containment.

(a) Packages of biomedical waste shall remain sealed until treatment, except when compacted in accordance with the requirements of this chapter as stated in Section 64E-16.006(2), F.A.C. Ruptured or leaking packages of biomedical waste shall be placed into larger packaging without disturbing the original seal.

(b) All packages containing biomedical waste shall be visibly identifiable with the international biological hazard symbol and one of the following phrases: “BIOMEDICAL WASTE”, “BIOHAZARDOUS WASTE”, “BIOHAZARD”, “INFECTIOUS WASTE”, or “INFECTIOUS SUBSTANCE”. The symbol shall be red, orange, or black and the background color shall contrast with that of the symbol or comply with the requirements cited in subpart Z of 29 C.F.R. subparagraph 1910.1030(g)(1)(C), Occupational Exposure to Bloodborne Pathogen Standard.

(c) Bags.

1. Biomedical waste, except sharps, shall be packaged and sealed at the point of origin in impermeable, red plastic bags or, at the discretion of the generator, into sharps containers. The international biological hazard symbol shall be at least six inches in diameter on bags 19" × 14" or larger, and at least one inch in diameter on bags smaller than 19" × 14". Each plastic bag shall meet the following physical properties:

a. Impact resistance of 165 grams and tearing resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag. Impact resistance shall be determined using ASTM D-1709-91, and tearing resistance shall be determined using ASTM D-1922-89.

(d) **Sharps containers**.

1. Sharps shall be discarded at the point of origin into single use or reusable sharps containers. Needles and scalpel blades shall not be placed directly into double-walled *corrugated* containers. Sharps containers must be sealed when full. A sharps container is considered full when materials placed into it reach the designated fill line, or, if a fill line is not indicated, when additional materials cannot be placed into the container without cramming or when no additional materials are to be placed in the container.

2. Permanently mounted sharps container holders shall bear the phrase and the international biological hazard symbol described in paragraph 64E-16.004(2)(a), F.A.C., if this information on the sharps container is concealed by the sharps container holder.

3. Reusable sharps containers shall only be emptied into a treatment cart or directly into a treatment unit. They shall be constructed of smooth, easily cleanable materials, and shall be decontaminated after each use.

4. The international biological hazard symbol shall be at least one inch in diameter on sharps containers.

(f) The international biological hazard symbol shall be at least six inches in diameter on outer containers 19" × 14" or larger, and at least one inch in diameter on outer containers less than 19" × 14".

We have many choices in sharps containers. Most Electrologists choose the smallest ones that they can obtain so they take up the least amount of space in their office. Here are some examples of commonly used sharps containers. If you choose to use the "Isolizer", you can dispose your sharps in your household/clinic trash.

64E-16.005 Labeling.

(1) Biomedical waste bags and sharps containers shall be labeled with the generator's name and address unless treatment occurs at the generating facility.

You can tape a business card with the name and address to your sharps container

(a) If a bag or sharps container is placed into a larger bag prior to transport, the label for the exterior bag shall comply with subsection 64E-16.005(1), F.A.C. Inner bags and inner sharps containers are exempt from the labeling requirements of subsection 64E-16.005(1), F.A.C.

(2) The transporter may provide labels for bags or sharps containers that are generator-specific, such as bar codes or specific container numbers. Use of these generator-specific labels satisfies the requirements of paragraph 64E-16.005(1)(a), F.A.C.

64E-16.008 Biomedical Waste Transport

(Note: This section outlines the guidelines that collection agencies must practice to stay in compliance. This section has been included in this course because Electrologists may elect to pay a transporter to collect their properly packaged biomedical wastes.)

(1) No registered transporter may knowingly accept biomedical waste for transport unless it has been properly segregated, packaged, and labeled.

(2) Each registered transporter shall provide the generator with a receipt of pick-up.

(3) During transport, no registered transporter shall compact biomedical waste or allow it to leak into the environment.

(4) Transfer of biomedical waste from one transport vehicle to another is not allowed unless the transfer occurs at a permitted storage or treatment facility, except as provided in paragraph 64E-16.008(10)(a), F.A.C. Intermodal transfers of biomedical waste are allowed provided transport shipping seals remain intact.

(5) Any registered transporter who unknowingly fails to comply with subsections (3) or (4) of this section because such biomedical waste has not been properly segregated or separated from other solid wastes by the generating facility is not guilty of a violation under this rule.

(6) No registered transporter shall knowingly deliver biomedical waste for storage or treatment to a facility which does not have a valid permit issued by the department.

(7) All transport vehicles containing biomedical waste shall be visibly identified with the business name, registration number, a 24 hour telephone number, and placards showing the phrase and the international biological hazard symbol as described in paragraph 64E-16.004(2)(a), F.A.C. The symbol shall be at least six inches in diameter.

(8) All transport vehicles containing biomedical waste shall be fully enclosed and secured when unattended.

(9) Registered transporters shall notify the department within one working day by telephone and shall submit a follow-up report to the department within 10 days, in writing, if there is an accident that results in a spill of biomedical waste.

(10) In case of an emergency situation, including mechanical failure, the following is allowed:

(a) If the emergency occurs during transport, biomedical waste may be transferred to another transport vehicle, including a rental vehicle, without being at a storage or treatment facility.

(b) If a rental vehicle is used, the department shall be notified of its use on the first working day after the emergency. A copy of the written authorization from the rental agency stating awareness of the intended use of the vehicle shall be submitted to the department within seven days.

(c) Biomedical waste shall be removed and transported to a permitted storage or treatment facility within 24 hours of the emergency.

(d) Before return to the rental agency, the vehicle shall be decontaminated.

64E-16.011 Permits

(1) All biomedical waste facilities, except those facilities operating under a Department of Environmental Protection permit, shall obtain a permit from the department annually. Application forms and annual report forms used by the public may be obtained from the environmental health section of the county health department in the county of their location or from the Department of Health, Bureau of Facility Programs, 4052 Bald Cypress Way, Bin #A08, Tallahassee, Florida 32399-1710. All forms listed in this section are incorporated by reference.

Electrologists must apply for their exemption with their county health department. When you have received your exemption through the mail, it must be displayed in your facility.

(a) **A biomedical waste generator, who produces or treats less than 25 pounds of biomedical waste in each 30 day period, shall be exempt from all permit and fee requirements of this chapter.**

(b) Application for an initial biomedical waste generator permit or exemption from permitting shall be submitted to the department on form DH 4089, Application for Biomedical Waste Generator Permit/Exemption, 8/98. Biomedical waste treatment facilities which were constructed prior to December 31, 1995, or for which an operation permit was submitted to the Department of Environmental Protection prior to December 31, 1995, shall meet the requirements of this chapter at the time of renewal of their existing permit.

(f) Permits shall not be transferable from one person to another. In the event of an address or name change, an amended application for permit shall be submitted to the department. A permitted generator may work at a branch office for no more than six hours in any seven day period without applying for an additional permit. These

generators must notify the local county health department biomedical waste coordinator of the existence and operating hours of the branch office.

1. In the event of a change of ownership of the facility or a newly constructed facility, an application for an initial permit shall be submitted to the department within 30 days of the commencement of business.

2. When a facility is leased by the owner to a second party for operation, the second party shall apply to the department for an initial permit within 30 days of the commencement of business. The second party shall be held responsible for the operation and maintenance of the facility.

(g) Permits shall expire on September 30 each year. The permit, or a copy thereof, shall be maintained within the facility and shall be made available for review by department personnel.

(2) Persons engaged in a sharps collection program with single or multiple facility locations may operate under a single permit provided:

(a) The sharps collection program is open to the general public;

(b) A list identifying the location of each facility is attached to the application; and

(c) Each facility meets the applicable permit requirements.

64E-16.013 Enforcement and Penalties

(1) According to Section 381.0025, F.S., any person who generates, transfers, treats, stores, transports or disposes of biomedical waste in violation of this chapter; or who interferes with, hinders, or opposes any employee of the department in the discharge of his duties, or who impersonates an employee of the department, is chargeable with a misdemeanor of the second degree, punishable as provided in Sections 775.082 and 775.083, F.S.

(2) For violation of any provision of Chapter 64E-016, F.A.C., the department shall deny, suspend or revoke any biomedical waste permit or impose an administrative fine of up to $2500 per day for each violation of this chapter or pursue other enforcement action authorized by law. In determining the type and degree of enforcement action necessary, the department shall take into consideration the following:

(a) The gravity of the violation, including the probability that death or serious physical harm to any person may result or has resulted, the severity of the actual or potential harm, and the extent to which the provisions of the applicable statutes or rules were violated.

(b) Actions taken by the owner or operator to correct violations.

(c) Any previous violations.

SUMMARY

- Electrologists are required to properly dispose of their sharps containers, which are considered biomedical waste.
- Due to the low volume of biomedical waste that is generated in Electrology facilities, they are granted an exemption for the required permit.
- Electrologists must prepare a plan that defines the protocols that will be implemented in the event of a biomedical spill or accident. The plan must also clearly explain the process that you will undertake for the disposal of your biomedical waste sharps container.

Here is an example of a biomedical waste plan that has been successfully used in an Electrology facility. Areas that you should customize are printed in red.

Date

RE: POLICY AND PROCEDURE IN COMPLIANCE WITH CHAPTER 64E-16.003 (2) FLORIDA ADMINISTRATIVE CODE, JUNE 1997—BIOMEDICAL WASTE

DEFINITION OF BMW:

My facility, Name of your facility, is an electrology facility which only generates biomedical waste in the form of sharps. Less than 25 pounds of biomedical waste is generated in a 30-month period, let alone a 30-day period. No "non sharps" are generated. Very fine needles (also known as wires or probes) in various sizes are used. They are inserted into a hand-held probe holder. There is no attached syringe-type apparatus that is disposed of with the needle.

HANDLING OF BMW:

A. POINT OF ORIGIN AND SEGREGATION

The point of origin of the bmw that is generated in my facility is in the treatment room. Single-use disposable needles (probes) are used. After removing a needle from its blister pack with forceps, it is placed into a probe holder. This needle is inserted into the hair follicle conducting an electric current to destroy the reproductive cells of that hair follicle. After treatment, the needle is removed from the probe holder using forceps and placed into a sharps container that is placed on a flat counter top within my immediate reach.

B. CONTAINMENT, GENERAL HANDLING OF CONTAINERS, STRUCTURE OF CONTAINERS

The sharps container that is used is a small (less than 300ml) container that is clearly labeled with the phrase and international biological hazard symbol as described in section 64E-16.004 (2)(a), F.A.C., and manufactured with dyes meeting the requirements for incidental metals as described in section 64E-16.004(2)(b) 1.b., F.A.C. The sharps container is kept on a stable, flat surface. At no time is it removed from this location prior to transport.

LABELING/STORAGE

Due to the small amount of bmw that is generated within this facility, as to date I have not had to transport any bmw. When it becomes necessary to transport this bmw, the sharps container will be clearly labeled listing the name and location where it was generated.

TRANSFER/TRANSPORT

When it becomes necessary, the sharps container from this facility will be placed into a sealed, single walled, 200 pound per square inch corrugated box. This box will be clearly labeled as follows: Name, address, and telephone number of your facility. The box with the sharps container will be placed in the trunk of my car and transported to Location, address, and phone number of facility where you will take your packaged sharps container, such as a hospital or clinic. A written receipt of the bmw will be obtained from the facility name above at that time.

SPILLS/LEAKS OF BIOMEDICAL WASTE

In the event of an accidental spill of the sharps container or dropping of a used needle, with gloves on, I will use a forceps to pick up the spilled needles/probes and place them into the sharps container. Any areas that would become contaminated by contact of the used needles will be disinfected with a hospital grade tuberculocidal disinfectant, which is kept on the premises.

RECORDS

Pursuant to subsection 64E-16.003(2), F.A.C., all bmw records shall be maintained for three (3) years. These records will include inspection reports, exemption letters and any receipt of transported bmw. These records will be kept in the treatment room in this facility.

TRAINING

There are no employees at this facility and therefore no training program has been outlined.

EXAMINATION

Biomedical Waste

Circle the correct answer to the following questions and return them to the testing center. You must complete eight (5) out of ten (7) questions correctly. This home study unit is worth 1 credit hour.

1.) Which of the following is NOT required to be displayed on a sharps container?
- a. Description of contents in the sharps container
- b. Name of facility
- c. Phone number of facility
- d. Universal biomedical symbol

2.) What is a biomedical generator?
- a. A mechanical device that destroys biomedical waste
- b. Mobile health care units, such as bloodmobiles
- c. A funeral home that practices embalming
- d. A facility or person that produces biomedical waste

3.) How many years shall biomedical records be maintained and available for the department to review?
- a. 1 year
- b. 3 years
- c. 5 years
- d. 7 years

4.) Electrologists are eligible for a biomedical waste exemption for permits and fees because:
- a. The industry is older than these laws and are therefore 'grandfathered'.
- b. The industry does not generate products saturated with blood
- c. The industry does not generate more than 25 pounds of waste per month
- d. The industry does not fall under OSHA guidelines

5.) A sharps container can be
- a. A glass jar whose contents are clearly visible
- b. A rigid, leak and puncture resistant container with a biological hazard symbol
- c. A sturdy cardboard box with a biological hazard symbol
- d. Sterilization bags with color change indicators

6.) Permits are transferable when the facility changes address
- a. True
- b. False

7.) Body excretions such as feces and secretions such as nasal discharges, saliva, sputum, sweat, tears, urine, and vomitus shall not be considered biomedical waste unless visibly contaminated with blood.
- a. True
- b. False

INSTRUCTIONS FOR SUBMITTING

EXAMINATION ANSWERS

- **Please take the final exam on line!**

- **Use the same link that took you to the page that was emailed to you to access the course. You can also use the "back" arrow (⟵) on the top left corner of the PDF page to go back to the 'home' page to take the exam.**

- **At the bottom of that page is a "start exam now" button for you to click for taking the exam on the 'Judy Adams Training Center of America' website on the internet.**

- **When prompted, be sure to spell your name *exactly* the way you want it to appear on your certificate of completion.**

- **As soon as you have completed the exam, you will be sent an email with a link to a PDF file so you can print your certificate. You can also save that PDF file for your reference. You also have an option of printing your certificate as soon as you pass the exam – before you even get your email with the link.**

- **The license number (if applicable) that you provide is the number that will be used to enter your hours/credit into CEBroker**

- **"Judy Adams Training Center of America" will be copied on your certificate and will then enter your hours into CEBroker for you!**

Thank you!