LION TECHNOLOGY INC.

The Essentials of Storing and Shipping Regulated Medical Waste

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Syringe Tide

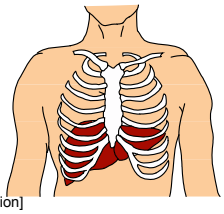
"…hypodermics on the shore…" Billy Joel, *Storm Front*, 1989

Concerns Regarding Medical Waste

- Mismanagement of medical waste can increase risk of exposure to blood and other potentially infectious materials
- Bloodborne pathogens can include:
  - Hepatitis B
  - AIDS
  - Infectious mononucleosis
  - Malaria
  - Syphilis
  - Ebola

Hepatitis B

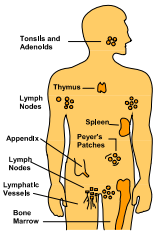
- Caused by the hepatitis B virus (HBV)
- The virus causes:
  - Inflammation of liver
  - Liver failure
  - Cirrhosis
  - Liver cancer
- In the U.S. approximately:
  - 2,890 cases (2011)
  - 5,800 deaths (2010)



[Source: Centers for Disease Control and Prevention]

Acquired Immunodeficiency Syndrome (AIDS)

- Caused by the human immunodeficiency virus (HIV)
- Attacks the immune system
- In the U.S. approximately:
  - 49,273 HIV diagnoses (2011)
  - 15,529 AIDS deaths (2010)



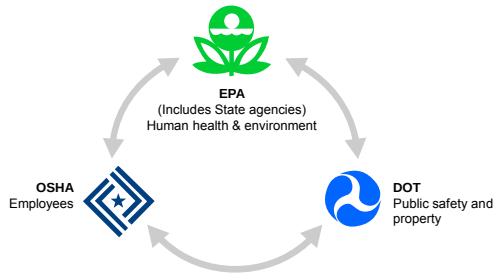
IMMUNE SYSTEM

[Source: Centers for Disease Control and Prevention]

General Definition

- The term "medical waste" varies by agency and regulation
- In general, waste from medical treatment or research related to humans and/or animals, including:
  - Sharps
  - Bandages
  - Blood and blood products
  - Isolation waste
  - Culture and stocks of infectious agents

Key Agencies



Medical Waste Tracking Act (MWTA) of 1988

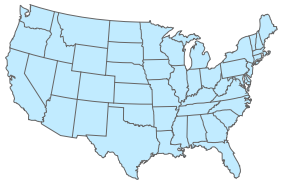
- Amended the Solid Waste Disposal Act
- Required the EPA to establish a 2-year pilot program in:
  - Connecticut
  - New Jersey
  - New York
  - Puerto Rico
  - Rhode Island

MWTA Regulations

- The regulations (40 CFR 22 and 259), effective June 24, 1989, established:
  - A definition of "medical waste"
  - Cradle-to-grave tracking system
  - Management standards for segregation, packaging, labeling and marking, and storage
  - Recordkeeping obligations

Current Management of Regulated Medical Waste

- The Federal program sunset on June 21, 1991:
  - Not defined as federally-regulated hazardous waste
  - No solid waste guidelines
- Management is now left to the states
  - Varies greatly



State Medical Waste Management

- Common differences include:
  - Definition
  - Storage requirements, including accumulation time
  - Tracking offsite shipments
  - Standards for treatment (e.g., autoclaving, incineration) and disposal
  - Permitting and/or licensing

Bloodborne Pathogen Standard

- The Occupational Safety and Health Administration (OSHA) regulates employee exposure to:
  - Blood
  - Other potentially infectious materials (body fluids, tissues/organs, HIV- or HBV-containing culture medium)
- Includes, but not limited to medical waste

[29 CFR 1910.1030]

OSHA

Bloodborne Pathogen Standard

- The bloodborne pathogen standard contains requirements for:
  - Written control plan
  - Engineering and work practice controls
  - Personal protective equipment
  - Labeling
  - Training
  - Recordkeeping

Exposure Control Plans

- Written plan intended to eliminate or minimize employee exposure to bloodborne pathogens
- Contents:
  - Exposure determination
  - Schedule and method of implementing this standard
  - Description of how exposure incidents will be evaluated
- Reviewed and updated at least annually

[29 CFR 1910.1030(c)]

Exposure Determination

- Three lists that show which employees and activities are exposed to bloodborne pathogens:
  1. Job classifications where ALL employees have occupational exposure
  2. Job classifications where SOME employees have occupational exposure
  3. Tasks and procedures that are creating the occupational exposures for group 2
- Exposure determination must be made WITHOUT regard to personal protective equipment

[29 CFR 1910.1030(c)(2)]

Post-Exposure Follow-up

- Confidential medical evaluation available immediately
- Written opinion from healthcare provider within 15 days
- Employee access to Hepatitis B vaccine within 10 days
- Documentations retained as part of employee's exposure records

[29 CFR 1910.1030(f)]

Universal Precautions

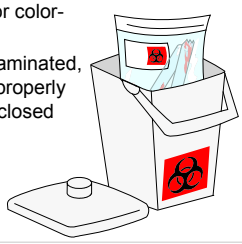
- Treat ALL human blood and certain body fluids as if they are known to be infectious
- Prevent ALL contact with blood or other potentially infectious materials
- Achieved by:
  - Engineering controls
  - Workplace controls
  - Personal protective equipment

[29 CFR 1910.1030(b) and (d)]

Engineering and Work Practice Controls
Storage

"Do's" in potential exposure areas

- Store infectious materials in leak-proof containers, labeled or color-coded and closed
- If container becomes contaminated, use secondary container, properly labeled, color-coded, and closed



[29 CFR 1910.1030(d)(2)(xiii)]

Regulated Medical Waste Storage

- Must be placed in containers that are:
  - Closable
  - Constructed to contain the materials placed in them
  - Constructed to prevent leakage
  - Properly labeled or color-coded
  - Closed before they are moved
  - Placed in secondary containers prior to removal

[29 CFR 1910.1030(d)(4)(iii)(B)]

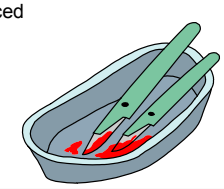
Contaminated Sharps

- Contaminated sharps must be disposed of in specially designed containers
  - Closeable
  - Puncture-resistant
  - Properly labeled or color-coded
  - Leak-proof
- Once placed in container, contaminated sharps cannot be retrieved

[29 CFR 1910.1030(d)(2)(viii), and (d)(4)(iii)(4)]

Reusable Sharps

- Reusable sharps that are contaminated must be stored in a way to:
  - Ensure safe handling
  - Prevent employees from reaching into a container where sharps have been placed



Labeling and Color Coding

- Warning labels must be:
  - Affixed to any container used to store or ship blood or other potentially infectious materials
  - Fluorescent orange or orange-red with the biohazard symbol in a contrasting color
- Red bags or containers may be substituted for labels

[29 CFR 1910.1030(g)]

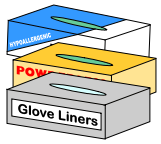
Personal Protective Equipment

- Must not permit infectious material to pass through
- Must protect under normal conditions of use
- Must protect for entire duration of time that it is being used

[29 CFR 1910.1030(d)(3)(i)]

Personal Protective Equipment

- Employers must:
  - Provide and pay for PPE
  - Make PPE accessible
  - Require employees to use PPE
  - Provide correct sizes
  - Provide alternatives if employees have allergy problems



[29 CFR 1910.1030(d)(3)(i) – (iii)]

Gloves

- Must be worn if it can be reasonably anticipated that the employee will have contact with…
  - Blood
  - Other potentially infectious material
  - Mucous membranes
  - Non-intact skin

[29 CFR 1910.1030(d)(3)(ix)]

Workplace Cleanliness

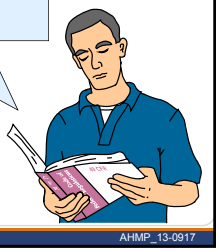
- Employers must implement a written schedule for cleaning and decontamination based on:
  - Location within the facility
  - Surfaces to be cleaned
  - Types of contamination present
  - Tasks or procedures performed in particular locations
- Anything that comes into contact with blood or potentially infectious material has to be cleaned and decontaminated

[29 CFR 1910.1030(d)(4)(i)-(ii)]

Definition of a Hazardous Material

Hazardous material is defined as "…a substance or material that the Secretary of Transportation has determined is capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and has designated as hazardous…"

Definition also includes certain other materials regulated by the EPA and others



[49 CFR 171.8]

Infectious Substances
Division 6.2

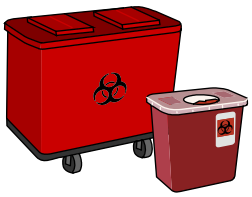
- An infectious substance is a material that is known or reasonably expected to contain a pathogen
- Infectious substances are assigned to one of two categories:
  - Category A
  - Category B

Infectious Substances
Division 6.2

- Category A - those infectious substances that are capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs
- Category B - those infectious substances that are NOT generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs

Regulated Medical Waste

"…Waste or reusable material derived from the medical treatment of an animal or human, which includes diagnosis or immunization, or from biomedical research, which includes the production and testing of biological products…"



[49 CFR 173.134(a)(5)]

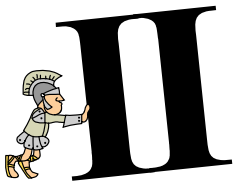
Classification of Regulated Medical Waste

If a regulated medical waste contains a Category A infectious substance, it MUST be classed as a Category A infectious substance

- Not considered to be a "regulated medical waste" for the purposes of hazmat shipping!

Classification of Regulated Medical Waste

All regulated medical wastes are classified as Packing Group II materials

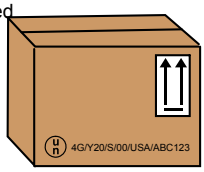


Proper Shipping Names for Regulated Medical Waste

- Acceptable proper shipping names:
  - Regulated medical waste, n.o.s.
  - Clinical waste, unspecified, n.o.s.
  - (BIO) Medical waste, n.o.s.
  - Biomedical waste, n.o.s.
  - Medical waste, n.o.s.
- All are assigned UN 3291

Standards for Non-bulk Packagings

- Non-bulk packagings used to transport regulated medical wastes must be UN standard packagings that have been tested to meet Packing Group II performance levels
- Exception for packages transported by private or contract carriers



[49 CFR 173.197(b)]

Non-bulk Packagings for Sharps

- Must be puncture-resistant
- Must be securely closed in conformance with the instructions provided by the packaging manufacturer

[49 CFR 173.197(b)]

Plastic Film Inner Packagings

Plastic film bags are authorized as inner packagings for large packagings, carts, and BOPs if the material is:

- Solid, or
- Waste material containing absorbed liquid IF there is sufficient absorbent to absorb and retain all the liquids during transport

[49 CFR 173.197(e)(1)]

Plastic Film Inner Packagings

Plastic film bags used as inner packagings must:

- Not exceed a volume of 175 L (46 gal.)
- Be marked and certified by the manufacturer as having passed the tests prescribed for tear resistance

Plastic Film Inner Packagings

Plastic film bags used as inner packagings must:

- Be closed with a minimum of trapped air to prevent leakage
- Not leak if held inverted for 5 minutes
- Not weigh more than 10 kg (22 lbs.) when using with carts or BOPs

Reusing Sharps Containers

Sharps containers may only be reused if they are:

- Certified by the FDA for reuse
- Permanently marked for reuse
- Disinfected prior to reuse
- Have a capacity between 7.57 L (2 gal.) and 151.42 L (40 gal.)

[49 CFR 173.197(e)(3)]

Transportation by Private or Contract Carrier

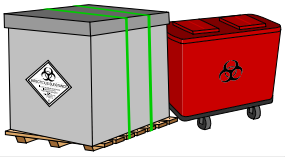
Excepted from standard packaging requirements if it:

1. Is packaged in a rigid, non-bulk packaging
2. Meets the general packaging requirements of 49 CFR 173.24 and 173.24(a)
3. Meets the packaging requirements of 29 CFR 1910.1030 (OSHA's Bloodborne Pathogen Standard)
4. Does not contain a waste concentrated stock culture of an infectious substance
5. Contains sharps containers that are securely closed

[49 CFR 173.134(c)(1)]

Larger Packagings

- Additional requirements for:
  - Large packagings
  - Non-specification bulk packaging (i.e., wheeled carts and bulk outer packagings (BOPs))



[49 CFR 173.197(c)(2) and (e)(2)]

Marking Non-Bulk Packages

- Each non-bulk package must be marked with:
  - Proper shipping name
  - Identification number
  - Name and address of shipper or consignee

[49 CFR 172.301]

Marking Bulk Packages

- Mark the identification number
- BIOHAZARD marking
- Two opposing sides if the capacity < 1,000 gallons
- Each side and end if capacity ≥ 1,000 gallons

[49 CFR 172.332, 172.323, and 172.336]

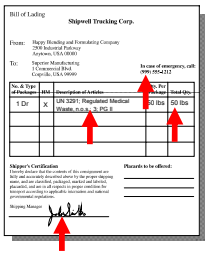
Labeling

- Non-bulk packages containing regulated medical wastes must be labeled with the 6.2 Infectious Substances label
- Labels are required on bulk packages with maximum capacities of less than 18 m3 (640 ft.3) unless those packages are placarded

[49 CFR 172.400]

Shipping Papers

- Shipping papers must contain:
  - Basic description for each material
  - Total quantity of each material
  - Shipper's certification
- Emergency response information



[49 CFR 172.201(a)(1); 172.602; 172.604]

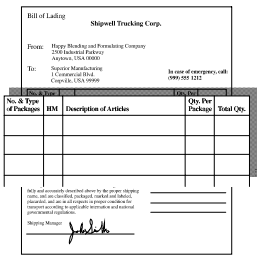
Basic Description Examples

UN3291, Regulated Medical Waste, 3, PG II

UN3291; REGULATED MEDICAL WASTE; 3; PG II

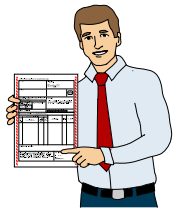
UN3291 Clinical waste unspecified nos 3 PG II

UN3291 Clinical waste unspecified nos 3 II

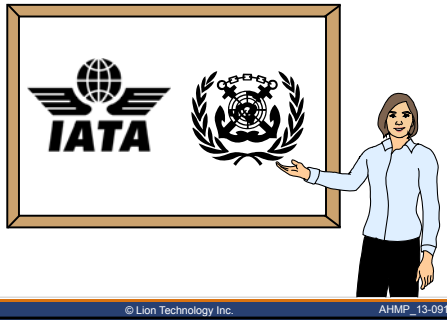


State-Specific Issues

- Some state solid waste programs require tracking document or specific medical waste manifest
- Must comply with both generator and destination states and DOT requirements

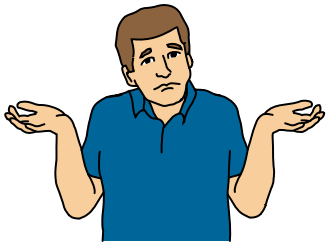


Additional IATA and IMDG Requirements



Thank You!

Any questions?



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