

# Healthcare Waste Regulatory Challenges

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# Overview

- What are “healthcare wastes”?
- What regulations and agencies affect healthcare waste?
- How to cope with it all! BMPs
- What are upcoming regulations and legislation which could potentially affect healthcare waste?



# Goals

- Identify the types of wastes generated throughout the hospital
- Identify the regulatory agencies overseeing the management of waste issues
- Provide for Best Management Practices
- Go over regulatory and legislative outlook for hospital environment

# HEALTHCARE WASTES

- Regulated Medical Waste

- Soft waste

- Gloves, gowns, tissue, blood and blood products
    - Special medical waste: CJD, pathological waste, trace chemotherapy

- Sharps waste

- Needles/syringes, pipettes, broken glass, culture slides and dishes

- Treatment: on site, off site

- Autoclaving/Rotoclave/Steam
    - Chemical treatment
    - Microwave/Macro wave
    - Incineration



- No federal RMW management regulations

- Each state is different
    - Can be at local level as well

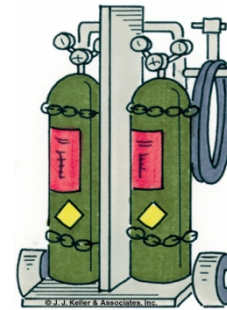


# HEALTHCARE WASTES

- **Select Agents**
  - Part of CDC list – Regulated by Department of Health and Human Services
  - Not regulated medical waste!
  - Must be treated prior to removal off site
- **Universal Waste**
  - Light bulbs
  - Batteries
  - Electronic Equipment
  - Regulated by Federal EPA Hazardous Waste Regulations
    - Regulated locally by most state environmental departments
    - Must check to see if adopted by each state

# HEALTHCARE WASTES

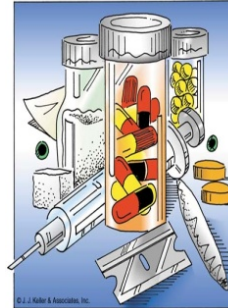
- Hazardous Materials – Hazardous Wastes
  - Chemotherapy and antineoplastic drugs
  - X-ray chemicals
  - Solvents
  - Radioactive materials
  - Mercury
  - Gases
  - Silver
  - Regulated Federally by EPA – Resource Conservation Recovery
    - Additional State requirements may apply
    - States may chose to have more stringent requirements



# HEALTHCARE WASTES

- Pharmaceutical drugs

- Hazardous
- Non-hazardous



- Cleaning supplies – hazardous and nonhazardous

- Corrosive and toxic hazardous materials
- Detergents
- Pesticides



- Laboratory wastes

- Solvents
- Mixing compounds



# REGULATORY AGENCIES

- Environment Protection Agency (EPA)
  - Resource Conservation and Recovery Act (RCRA)
  - Air and Radiation
  - Water
- Department of Transportation (DOT)
- Drug Enforcement Agency (DEA)
- Publicly Owned Treatment Works (POTW)
- Occupational Safety and Health Administration (OSHA)
- Board of Pharmacy
- Local & state regulators
- NJDEP



# REGULATORY AGENCIES

- EPA – Resource Conservation Recovery
  - Enforcement of waste regulations
  - Proper identification and management of all wastes
    - Proper disposal methods for all wastes
  - Proper training for all employees
  - Recordkeeping requirements
  - RCRA Requires proper handling of Hazardous Waste under 40 CFR 265
    - Hazardous pharmaceuticals
    - Hazardous chemicals such as solvents, cleaning supplies, metals such as mercury, silver and laboratory wastes
    - Oversees regulations related to Universal Waste



# REGULATORY AGENCIES

- EPA – Air and Radiation
  - Regulates incinerators
  - Radiation
- EPA – Water
  - Regulates water discharges
  - Regulates stormwater issues
  - Regulates POTWs

# REGULATORY AGENCIES

- DOT – Pipeline Hazardous Materials Safety Administration
  - Requires identification of hazardous materials for transport
  - Proper marking, labeling and containers for waste types
  - Proper documentation of transportation
  - Training for all employees; certified every 3 years



# REGULATORY AGENCIES



- DEA

- Proper management of all pharmaceuticals which are considered controlled substances
- These pharmaceuticals are not considered a waste but must be managed appropriately for final destruction
- Hospital/entity which is a registrant must be responsible for proper inventory tracking

# REGULATORY AGENCIES

- POTW – Publicly Owned Treatment Works
  - Management of materials being flushed or poured down the drain
  - Restrictions on types of chemicals, blood or other fluids and/or pharmaceuticals
  - Mostly managed locally
  - Bound by Federal EPA standards under Water Division and often further regulated by State regulatory agencies

# REGULATORY AGENCIES

- OSHA
  - Oversees management and safety of employees in workplace
  - Bloodborne Pathogens
  - Exposure to hazardous materials
  - Requires plan development, identification of engineering and workplace practice controls
  - Requires training



# REGULATORY AGENCIES

- Local and State
  - Department of Environmental Quality
  - Department of Health
  - County, City departments
  - Mandates management of regulated medical waste
  - May have additional requirements for hazardous and universal waste
  - State Board of Pharmacy

# REGULATORY AGENCIES - NJDEP

- NJDEP – New Jersey Department of Environmental Protection.
  - TITLE 7. ENVIRONMENTAL PROTECTION, CHAPTER 26. SOLID WASTE, SUBCHAPTER 3A. REGULATED MEDICAL WASTE
  - Regulates responsibility for generators, transporters and treaters of RMW in NJ and outlines specific requirements for:
    - Packaging, labeling and segregation of RMW
    - Shipping documents
    - Recordkeeping requirements
    - Training requirements
  - Several guidance documents are available for generators and transporters



# REGULATORY AGENCIES - NJDEP

## KEY DEFINITIONS:

- RMW is defined as any solid waste, generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto or in the production or testing of biologicals, that is not excluded or exempted under N.J.A.C. 7:26-3A.6(b) and that is listed or meets any waste characterization criteria described in ***the table at N.J.A.C. 7:26-3A.6(a)***. Refer to the rule for excluded wastes (N.J.A.C. 7:26-3A.6(b)).
- "Generator" means any person, by site, whose act or process produces RMW as defined in N.J.A.C. 7:26-3A.6) or whose act first causes a RMW to become subject to regulation. Noncontiguous properties owned or operated by the same person are separate sites and in the case where more than one person (for example, doctors with separate medial practices) are located in the same building and office, each individual business entity is a separate generator for the purposes of this subchapter. However, households utilizing home self-care exclusively are not generators.

# REGULATORY AGENCIES - NJDEP

## KEY REGULATORY REQUIREMENTS FOR GENERATORS TO KEEP IN MIND:

- Tracking waste:
  - Each generator shipping RMW off-site is responsible for initiating the New Jersey RMW Tracking Form
  - All medical waste generators, no matter how small the amount produced, with the exception of home self-care medical waste, must register with the NJDEP and pay the appropriate fees (N.J.A.C. 7:26-3A.8(a))
  - Generators are responsible for maintaining all shipping records for 3 years
  - Generators should contact transporter if documentation not returned within 35 days and notify NJDEP if not returned within 45 days
  - Annual Report requirements

# REGULATORY AGENCIES - NJDEP

## KEY REGULATORY REQUIREMENTS FOR GENERATORS TO KEEP IN MIND:

- Waste must be segregated into one of three categories:
  - 1. Sharps (Classes 4 and 7 as defined at N.J.A.C. 7:26-3A.6(a)) including sharps containing residual fluids;
  - 2. Fluids (quantities greater than 20 cubic centimeters); and
  - 3. Other RMW.
- Waste must be identified by the different classes as identified under the table:
  - Cultures and Stocks
  - Pathological Wastes
  - Human blood and blood products
  - Sharps
  - Animal Waste
  - Isolation waste
  - Unused Sharps

# REGULATORY AGENCIES - NJDEP

## KEY REGULATORY REQUIREMENTS FOR GENERATORS TO KEEP IN MIND:

- Specific packaging requirements and container specification
- Storage: non-putrescent, secured, limited access, max 1 year
- Labeling requirements:
  - Water-resistant label affixed to or printed on the outside of the container. The label shall include the words "Medical Waste," or "Infectious Waste," or display the universal biohazard symbol
  - Haulers information
  - Inner bag

# THE JOINT COMMISSION



- TJC
  - Not a regulatory agency
  - Accrediting body for hospitals
  - Wide variety of requirement for proper management of environment of care
  - Audits frequently and unannounced
  - Crosses all different agency requirements

# BEST MANAGEMENT PRACTICES

- Identify the types of hazardous materials from all departments
- Identify what is being disposed of
- Who/what departments – compartmentalize identification of needs
- What types of employees are affected
  - Training needs
  - Minimum standards



# BEST MANAGEMENT PRACTICES



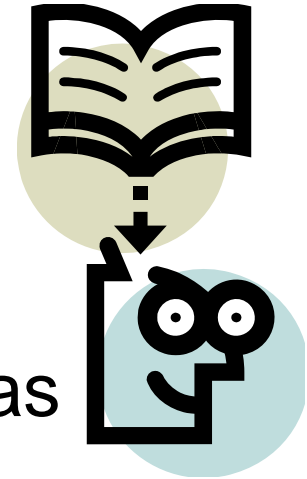
- Once all waste is identified:
  - What waste minimization is possible?
    - How best to implement waste minimization and sustain it?
  - What resources are needed?
  - What training is needed and for who?
  - Who are the best companies to work with to help you keep compliant?
  - How best to work with local regulators?



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# BEST MANAGEMENT PRACTICES

- Create a plan
- Look at overlapping regulations and consolidate
- Create a compliance calendar
  - Ensures proper recordkeeping
- Create checklists
  - Audit against checklists; Update lists as conditions change
- Review inventories to ensure compliance





# BEST MANAGEMENT PRACTICES

- Purchase less harmful chemicals
  - Look for alternative products
  - Less/no mercury
  - Reduce silver content
- Look for recycling options
  - Outlets for proper disposal and recycling
- Work with lab and radiation departments to identify ways to minimize waste



# BEST MANAGEMENT PRACTICES

- Specialize employee jobs if possible
  - Minimizes exposure to employees
  - Minimizes regulatory/training/recordkeeping requirements
  - Better control of environment
  - Reduce liability

# UPCOMING REGULATIONS AND LEGISLATION

- EPA
- OSHA
- DEA
- STATE
- RESOURCES

# UPCOMING EPA

- Universal Waste Rule – Office of Resource Conservation and Recovery
  - EPA has stated they are not planning on this
- Office of Water Science
  - Best Management Practices for RX Disposal
    - Proposed in Aug 2010
      - Still awaiting final
      - Many commenter's

# UPCOMING EPA

- Hospital Medical Infectious Waste Incinerator Rule – Air and Radiation
  - Signed September 15<sup>th</sup>, 2009; state plans 2010
  - More stringent requirements
  - Potential shut down of more incinerators limiting capacity for medical waste incineration
  - Increased capital for compliance
  - Still some states have mandatory requirements for incineration of certain materials

# UPCOMING OSHA

- Clarification of Personal Protective Equipment requirements
- BBP Standard Review
  - FR came out in May 2010; comments all received
  - No regulatory action taken at this time
  - Continuation of BBP regulations
- Infectious Diseases
  - FR came out in May – comments closed Aug 4<sup>th</sup>
  - Many commenter's – not much support
  - Confusing or redundant to many
  - OSHA held meeting earlier 2011 to get further comments

# UPCOMING DEA

- Safe Drug Disposal Act of 2009 – HB 5809
  - Passed and signed into law
  - Amend controlled substances act to provide for detailed disposal of state controlled take back disposal programs
  - Awaiting draft regulations from DEA
  - Currently more related to home take back programs
- Could have impact on controlled substances in general

# UPCOMING STATE



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- Water - No flush campaigns
- Sharps – Home generated waste take back programs
- Pharmaceutical
  - Universal Waste
  - Home generated waste take back programs
- Waste Regulations
  - Changes in state RMW regulations



# RESOURCES

- Practice Green Health
- Product Stewardship Institute
- Regulatory Websites
- Local and State regulators
- Industry waste service providers

# CONCLUSION

- Many regulations and factors affecting hospital waste
- Stay on top of regulations!
- Work with service providers
- New administration – new rules
- Complicated web of requirements – don't get stuck – get help!



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***THANK YOU!!!!***

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