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The sharpsPRO™

and

Medical Waste Regulations

Evolution of Regulating Medical Waste

The Resource Conservation and Recovery Act, commonly referred to as RCRA, is our nation's primary law governing the disposal of solid and hazardous waste. Congress passed RCRA on October 21, 1976 to address the increasing problems the nation faced from our growing volume of municipal and industrial waste.[1]

During the late 1980s, several instances of medical waste washed ashore the beaches of New Jersey prompting the immediate closure of 50 miles of beach. This got the attention of the public and Congress. Congress responded by implementing the Medical Waste Tracking Act in 1988, requiring the U.S. Environmental Protection Agency (EPA) to create a program to better track medical waste from cradle-to-grave so that it didn't end up fouling beaches or any other environments.

Through RCRA, Congress directed EPA to regulate all aspects of hazardous waste. As a result, EPA developed strict regulations for the treatment, storage, and disposal of hazardous waste. States may implement stricter requirements than the Federal regulations as needed.

State Medical Waste Regulations

RCRA State authorization is a rulemaking process through which EPA delegates the primary responsibility of implementing the RCRA hazardous waste program to individual states in lieu of EPA. This process ensures national consistency and minimum standards while providing flexibility to states in implementing

rules. State RCRA programs must be at least as stringent as the federal requirements, but states can adopt more stringent requirements as well.[2]

In some states, the department of health may play an important role (e.g., MO, OK) or even serve as the primary regulatory agency (e.g., CO). Where both agencies are involved, typically the department of health is responsible for on-site management and the environmental agency is responsible for transportation and disposal (e.g., LA, MO).[3]

Nearly all 50 states have enacted medical waste regulations to some extent. Some state hazardous waste regulations are based on the federal RCRA standards, thus making state regulations very diverse.

Medical Waste Agency Overview

The EPA has the authority to regulate medical waste management under RCRA but no longer plays a central role; instead, the states and other federal agencies have taken on that responsibility. One such "other federal agency" Occupational Safety and Health Administration (OSHA) is the primary authority for regulating work place standards and employee health and safety. OSHA prepared the blood-borne pathogens rules and regulations standard 29 CFR 1910.1030. The standard's requirements state what employers must do to protect workers who are occupationally exposed to blood or other potentially infectious materials, as defined in the standard. However, they also help to systematically manage wastes, which benefit the public and environment.

OSHA, whether it is the U.S. Department of Labor Occupational Safety & Health Administration or an OSHA state program (24 states operate their own program), regulates several aspects of medical waste, including management of sharps, requirements for containers that hold or store medical waste, labeling of medical waste bags/containers, and employee training.

In states with comprehensive medical waste regulations, there are often overlaps between state environmental/department of health rules and the OSHA bloodborne pathogens standard; however, there are few, if any conflicts. Instead, one set of rules may be vague or general, where the other is highly specific. In such cases, healthcare facilities are advised to follow the more detailed or stringent regulations. In states where comprehensive medical waste regulations do not exist, the OSHA rules fill an important gap. Since each state sets its own guidelines, requirements vary; however, most states have similar guidelines.

Another federal agency, Centers for Disease Control (CDC) provides experience and recommendations with the identification of infectious waste. CDC issues notices and advisories jointly with OSHA. Other government agencies such as Health and Safety, Toxic Substance Control Agency, and Sanitation department are responsible for requiring medical waste generators to comply with the necessary procedures and documentation required by law.

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Medical Waste Requirements Overview

The EPA defines the treatment of hazardous waste as "as any process that changes the physical, chemical, or biological characteristics of waste to minimize its threat to the environment." [4] Four basic processes are used in medical waste treatment: thermal, chemical, irradiative, and biological.[5] Currently, there are no federal or national efficacy standards for medical waste treatment technologies.

EPA does require that medical waste be sterilized prior to disposal to kill all pathogens in the wastes. Incineration and steam sterilization are the most frequently used sterilization treatments, however, other processes are effective. There are approximately 6,700 on site incinerators at hospitals throughout the country and approximately 60% of waste is treated on site. If the waste is no longer hazardous after treatment, the material may be disposed of at a sanitary landfill or in the sewer if locally approved.[6]

EPA has suggested guidelines for testing the sterility efficacy of dry heat thermal systems by using Biological indicators. Biological indicators, which are a resistant strain of bacteria, test the effectiveness of waste treatment technologies. The indicators are placed in the waste prior to treatment and their destruction indicates the success of the treatment. Biological indicator with qualitative and quantitative criteria is the microbial inactivation of B. Stearothermophilus.[7]

As an alternative to the incineration of medical waste, states generally accept methods of treatment by one of the following processes: decontamination by autoclaving, heating the waste to a minimum of 210°F, exposing the waste to chemicals such as sodium hypochlorite (household bleach) or chlorine dioxide; or by subjecting the waste to heated chemicals.[8]

The US Food and Drug Administration (FDA) regulates containers designed to store medical sharps waste. Medical sharps containers are classified by the FDA as a Class II medical device per regulation number 21 CFR 880.5570. A medical sharps container cannot be marketed until it receives clearance by the FDA thru the 510(k) premarket submission process.

The FDA has established guidelines and requirements for medical sharps containers; *GUIDANCE ON THE CONTENT AND FORMAT OF PREMARKET NOTIFICATION [510(k)] SUBMISSIONS FOR SHARPS CONTAINERS, October 1993.*

Summary

The regulation of medical waste has been evolving and is governed differently by federal and state agencies. The main regulatory requirements include:

- the medical waste must be sterilized prior to disposal
- complete traceability of all treated medical sharps waste
- if a medical sharps container is used, it must be FDA 510(k) cleared

The sharpsPRO™ system including the Model 100 and sharpsCAN™ meets all of these regulatory requirements for the treatment of medical sharps biohazardous waste:

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- The sharpsPRO™ uses a dry heat thermal treatment to sterilize and physically change the characteristics of the sharps waste.
- Biological indicator Microbial spore strips containing B. Stearothermophilus were successfully inactivated, thus demonstrating the validation of the sharpsPRO™ sterility effectiveness (dry heat thermal system).
- An independent test laboratory determined the sharpsCAN™ sharps container met OSHA's Bloodborne Pathogen Standard 29 CFR 1910.1030, exceeded the ASTM Puncture Resistance Standard F2132-01 (2008) and met CSA Z316.6-07 Toppling Resistance Standard.
- A 510(k) premarket submission including the standards testing and results was submitted to the FDA. The sharpsCAN™ received FDA clearance in July of 2013.
- The sharpsPRO™ also includes an automated cradle-to-grave tracking system insuring complete traceability of all treated medical sharps waste meeting standards in the EPA Medical Waste Treatment Act in 1988.

1. EPA, *History of RCRC, http://epa.gov/epawaste/laws-regs/rcrahistory.htm*

2. EPA, *RCRA State Authorization http://www.epa.gov.epawaste/laws-regs/state/index.htm*

3.Healthcare Environmental Resource Center, *Regulated Medical Waste Overview, http://www.hercenter.org/rmw/rmwoverview.cfm*

4. Jorge Emmanuel, PhD, CHMM, PE, *Non-incineration Medical Waste Treatment Technologies*, Health Care Without Harm (2001)

5. EPA, *Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies*

6. Harold M. Cota, Ph.D., P.E.David *Wallenstein, Hazardous Waste Management*, (1996)

7. *EPA, Wastes-Hazardous Waste-Treatment, Storage & Disposal (TSD),* http://www.epa.gov/solidwaste/hazard/tsd/index.htm

8. New York Department of Health, *Managing Regulated Medical Waste*, (2009)