



Fact Sheets and Information Papers

Regulated Medical Waste Management

August 2004

Background: The MEDCOM Regulation 40-35 defines regulated medical waste (RMW) as waste that is potentially capable of causing disease in man and may pose a risk to both individuals and community health if not handled or treated properly. The U.S. Department of Transportation (DOT) considers RMW a hazardous material during transport. The DOT defines RMW (per 49 CFR 173.134) as “a waste or reusable material known or suspected to contain an infectious substance in (World Health Organization) Risk Group 2 or 3, and generated in -

- (i) The diagnosis, treatment or immunization of human beings or animals;
- (ii) Research on the diagnosis, treatment or immunization of human beings or animals; or
- (iii) The production or testing of biological products.”

The World Health Organization risk groups are defined by criteria based on the severity of the disease, the mode and ease of transmission, the degree of risk to both an individual and a community, and availability of preventative measures or treatments.

Point of Generation: In 1992 the Environmental Protection Agency granted states permission to manage medical waste at the point of generation to the point of disposal. States have jurisdiction to develop and manage their own regulations. State regulations can be accessed via the Fact Sheet “State Medical Waste Points of Contact” which is also available on the same web site where this Fact Sheet was obtained. It is important to know that the requirements of some states for the management of RMW exceed those required by MEDCOM 40-35 and these requirements must be followed in order to prevent the risk of liabilities and fines from state regulatory agencies. Some state’s requirements are less stringent than those found in MEDCOM 40-35. In these states, you are required to follow the more stringent requirements of MEDCOM 40-35. MEDCOM 40-35 can be obtained at <http://chppm-www.apgea.army.mil/hmwp/>.

Treatment: All RMW must be treated in some manner to eliminate its infectious nature prior to disposal. The method of treatment may determine the type of packaging used to transport the RMW to the treatment and disposal facility. The most common treatment methods are:

Autoclave or steam sterilization: Special bags or tape are available for use in autoclaves that react during the process to indicate that the waste has been treated. Such waste may then be disposed of as solid waste. Check with the Preventive Medicine Service or research the State regulations to determine if any additional requirements exist for treating RMW, i.e., grinding, shredding, etc.

Incineration: With few exceptions, incineration of RMW is usually accomplished under contract at an off-site, permitted facility. Chemotherapy wastes and most pathological wastes must be incinerated and as such, are usually treated off-site. Many facilities place these wastes in one-way cardboard boxes to facilitate disposal. Use of one-way packaging minimizes the handling of

the bags and reduces the exposure to personnel. Be sure the containers for pathological and chemotherapy wastes are properly labeled and marked so they are routed to the proper treatment facility.

Contract: Many facilities contract out RMW transport, treatment, and disposal. If your facility contracts its RMW transport, treatment, and disposal, you should research the contractor’s qualifications carefully. When developing the scope of work for a RMW disposal contract, we recommend facilities avoid generic comments such as: “The vendor must comply with all Federal, State, and local laws and regulations”. This type of requirement is usually not sufficient. Contractors may have a different interpretation that may result in noncompliance of the laws and regulations. Be as specific as possible.

Packaging for Transport on Public Roadways: According to the DOT, RMW is considered a hazardous material during transport. Per 49 CFR 173.197, RMW must be placed in packaging that conforms to the specific performance requirements based on who transports the waste and what type of packaging will be used. The packages that can be used for transport are Non- bulk packagings, Large packagings, and Non-specification bulk packaging which includes Wheeled Carts and Bulk Outer Packagings (BOPs)

Non-bulk packaging: Non-bulk package is defined by the DOT as a packaging having a volume equal to or less than 450L for a liquid or 400kg or less for a solid. Non-bulk packaging used for transport must meet PG II performance standards as defined in 49 CFR Subpart M 178.600-178.608) and be marked with a UN specification marking unless the package is being transported by private or contract carrier (see NOTE below). Packages containing sharps must be puncture resistant. An example of a UN specification marking is illustrated in Figure 1. UN specification packaging has been put through a series of rigorous tests as required by. Testing of packagings is accomplished by DOT authorized testing facilities, usually at the request of the packaging manufacturer. Testing is not done by healthcare facilities.

NOTE: When nonbulk packagings are being shipped using private or contract carrier, UN specification packagings are not required per 49 CFR 173.197(c) as long as the packagings conform to 173.24 and 173.24(a)



Figure 1.

Bulk Packagings. Bulk package is defined by the DOT as a packaging having a volume greater than 450L for a liquid or 400kg for a solid . Three options are available for bulk packagings of regulated medical waste. Large packaging, bulk outer packaging and wheeled carts.

Large packagings: Large packagings are bulk packages designated for mechanical handling. Large Packagings for RMW must meet UN specifications for performance and be marked with a marking like that shown in Figure 1. Solid RMW must be contained in inner packagings consisting of film bags which have been tested in accordance with ASTM D 1709, *Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method* and ASTM D 1922 *Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method*. Liquid RMW must be contained in rigid inner packaging

Non specification bulk packagings: Allowable packagings include wheeled carts or bulk outer packagings (BOPs) as long as the RMW is contained in the inner packagings described under Large Packagings. These require package testing but are not marked with the UN specification marking similar to that seen in Figure 1.

Wheeled carts: Wheeled carts are solid, one-piece bodied containers not exceeding 1,655 liters (437 gallons); are made of rigid plastic, fiberglass, or metal with a fitted lid; and must meet the requirements of the drop test for solids at the PG II level as outlined in 49 CFR 178.603.

Bulk outer packagings (BOPs) BOPs are constructed of metal or fiberglass, fitted with a weatherproof closure to prevent entry and release of liquids during use, and meet the requirements outlined in 49 CFR 173.197(d)(3). Carts will most likely be the primary bulk packaging used for RMW.

When filled with RMW, weight restrictions for inner packagings and sharps containers are also now in place. Sharps containers that exceed 76 liters (20 gallons) in volume must be capable of passing the UN specification performance tests outlined in 49 CFR Subpart M (178.600-178.608) at the PG II performance level.

Labels and Markings: The 49 CFR 173.134 states that RMW containers must either have a DOT Infectious Substance label (Fig 2) or an OSHA Biohazard marking (Fig 3).



Fig 2. Infections Substance Label



Fig 3 Biohazard Marking

Most contractors use the biohazard marking. Also, ensure that all labels and markings, like the orientation marking (i.e., red or black arrows indicating which end is up), shipping information, etc., are marked on the outer packaging. Per 49 CFR 172.323, large packagings, carts, or BOPs must be marked with an OSHA Biohazard marking in addition to the proper shipping name and UN identification number, e.g., Regulated Medical Waste, UN3291.

NOTE: Check with your state to see if other markings are required.

If large packagings, carts or BOPs are used, each inner packaging must be durably marked or tagged with the name and location (city and state) of the generator, unless the entire contents of the large packaging originates at a single location and is delivered to a single location. If the RMW generated meets the requirements for a single location, then the markings requirements for any outer packaging of RMW would apply.

Shipping Papers: As with other shipments of hazardous materials, the 49 CFR 172.204 states that each person who offers hazardous materials for transport must certify that the material is offered in accordance with the DOT requirements. This certification statement commits the government to liability in case of an incident involving the shipment.

Training:

Handlers of RMW within a treatment facility: If you handle RMW, you are required by law to have training: under OSHA Regulations 29 CFR 1910.1200 (HAZCOM and HAZWOPER) and 29 CFR 1910.1030 (Bloodborne Pathogen Standard)].

Hazmat Employee: The DOT defines a HAZMAT employee as a person who directly affects hazardous materials transportations safety. This includes all employees who are involved in preparing Regulated Medical Waste for transport. These employees are required to complete General Awareness, Function Specific, Safety and security training as required by 49 CFR 172. This training must be completed within 90 days of employment or a change of job function. This training can be accomplished by attending the USACHPPM Transport of Medical Waste Course that focuses on the requirements for transport of Regulated Medical Waste and includes state requirements. Anyone who signs RMW manifests must attend this course and must complete refresher training every two years per DOD 4500.9-R Part II, Chapter 204. In addition, DOD 4500.9-R Part II, Chapter 204 requires all certifying official to be designated in writing by the activity commander and successfully complete a formal training course from a DOD-approved school. Those schools are specified in DOD 4500.9-R. The other DOD schools focus on other hazardous materials and do not address biomedical materials in detail.

Safety: Most accidents occur during the collection of RMW. Some safety tips for your personnel are:

1. Ensure personnel are properly trained.
2. Use personal protective equipment such as, safety glasses or goggles, gloves, aprons, and safety shoes.

3. Do not compress or compact untreated RMW. Don't use your feet or hands to compress or compact the RMW in the collection cart or bins. There are dangers such as needlesticks or cuts from sharp objects, splashes from bursting the bag, etc, associated with compressing or compacting RMW.

4. Hold bag away from body. Don't place the bag over your shoulder to carry it. This presents a safety hazard of punctures and splashes.

5. Do not overfill containers. Most RMW contracts have limits on how much a sealed container can weigh. Also, overfilled containers present lifting hazards and increase the chances of the contents rupturing the container.

6. Clean collection carts. Collection carts should be cleaned and disinfected as directed by the Infection Control Officer of your facility or other standing operating procedures approved by your organization.

7. Ensure spill kits are available and personnel know how to use them. Restock as needed.

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