

201978



DOT/RSPA/OHMS  
DOCKETS UNIT

95 MAR 21 AM 9:46

March 20, 1995

Docket # HM-181-G) Notice # (94-11)

RSPA-1993-13541-23

Dockets Unit (DHM-30)  
Hazardous Materials Safety, Room 8421, RSPA  
U.S. Department of Transportation  
400 Seventh St., SW  
Washington, D.C. 20590-0001

Dear Sir/Madam:

ABB Sanitec, the manufacturer and distributor of the ABB Sanitec Microwave technology for the treatment of regulated medical waste welcomes the opportunity to comment on the Research and Special Programs Administration's (RSPA) notice of proposed rule making concerning the transportation of infectious substances, including regulated medical waste. RSPA should be commended for it's efforts in addressing this complex issue.

ABB Sanitec has been involved with regulated medical waste and the medical waste treatment technology industry for over 10 years. During that time, ABB has commented extensively on issues such as definitions, treatment, and destruction of regulated medical waste.

ABB Sanitec feels obligated to share it's experience and knowledge with RSPA's proposed changes regarding regulated medical waste.

**Regulated Medical Waste**

The intent of the DOT Hazardous Materials Regulations is to prevent the unreasonable risk to health and safety during the transportation of a hazardous material. With respect to Regulated Medical Waste, DOT is proposing to define RMW as a waste or reusable material, other than a culture or stock of an infectious substance, which contains an infectious substance, and is generated in the treatment or immunization of human beings or animals, research pertaining thereto, or the production or testing of biological products.

This definition has the potential to create confusion among health care workers because of its impracticality. The agents (infectious substances)

ABB Sanitec, Inc.



referenced in 42 CFR 72.3 of the regulations of the Department of Health and Human Services represent a substantial number of commonly isolated organisms from patients. They are, in many instances, part of the normal microbial flora of the human body. Additionally, other agents not on the list that cause or may cause severe, disabling, or fatal disease can be included based upon present epidemiological and infectious disease data (i.e., Human Immunodeficiency Virus - HIV, *Borrelia burgdoferi*- the causative agent of Lyme disease).

It is impractical to define a regulated medical waste based upon the mere presence of an infectious substance. This issue has been discussed extensively since 1980.

The EPA, in their Guide for Infectious Waste Management, 1986, reiterated the difficulty in establishing a definition for infectious waste. Several factors must be considered when establishing the definition including:

- a. Presence of a pathogen of sufficient virulence
- b. Dose
- c. Mode of transmission
- d. Portal of entry
- e. Resistance of host

From the Society for Hospital Epidemiology of America position paper on Medical Waste (January, 1992):

"As stated, infectious waste is waste that is capable of producing an infectious disease. This definition requires consideration of the factors necessary for induction of disease, which include dose, host susceptibility, presence of a pathogen, virulence of a pathogen, and the most common absent factor, a portal of entry. Therefore, for waste to be infectious, it must contain pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease. Because there are no tests that allow infectious waste to [easily] be objectively identified, responsible agencies such as the CDC, the EPA, or states define waste as infectious when it is suspected to contain pathogens in sufficient numbers to cause disease. Not only has this subjective definition resulted in conflicting opinions from the EPA, the CDC, and state



agencies on what constitutes infectious waste and how it should be treated, but it also gives undue emphasis to the mere presence of pathogens. "

In combination with these factors and knowledge of modes of transmission of infectious diseases, and the lack of a litmus test which can easily discern between items having and not having infectious substances, it is more practical to approach medical waste definitions from a relative risk of disease transmission perspective.

ABB proposes the following definition for regulated medical waste:

A regulated medical waste means a waste or reusable material, other than a Class 7 (radioactive) material, such as those listed below that are capable of causing infectious disease because there is reason to believe such waste has been contaminated by an organism that is known or suspected to be pathogenic to humans and such organism or material containing such organism is present in sufficient quantity to transmit disease and is generated in-

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

The following shall be considered regulated medical waste:

**Cultures and Stocks:** This waste shall include but not be limited to cultures and stocks of infectious substances and associated biologicals, including: cultures from medical or pathological laboratories; cultures and stocks of infectious substances from research and industrial laboratories; waste from the production of biologicals; discarded live or attenuated vaccines; and cultures dishes and devices used to transfer, inoculate, or mix cultures.

**Human Pathological Waste.** This waste means any human tissue, organ, or body part, except teeth and the contiguous structures of bone and gum, removed during surgery, autopsy or other medical procedures.



**Human Blood and Blood Products:** This means items containing free-flowing or visibly dripping or soaked with blood, serum, plasma, and other blood products or containers filled with such discarded fluids.

**Sharps:** This means discarded sharps (items that can cause percutaneous injury) that have been used in animal or human patient care or treatment or in medical, research or industrial laboratories, including hypodermic needles, syringes, with or without attached needle; needles with attached tubing; glass culture dishes and Pasteur pipettes, provided such glassware is known to have been in contact with an infectious substance.

**Animal waste:** Animal waste means discarded materials, including animal carcasses, body parts, body fluids, blood, or bedding originating from animals that were known to have been exposed to infectious substances during research, production of biologicals, or pharmaceutical testing.

**Isolation wastes:** This waste shall include, but not be limited to discarded materials contaminated with blood, excretions, exudates, and secretions from humans that are isolated to protect others from highly communicable diseases. A highly communicable disease is one listed in Biosafety Level 4 of the Centers for disease Control/National Institutes of Health Guidelines entitled "Biosafety in Microbiological and Biomedical Laboratories" and dated May, 1993.

Providing examples as above assists generators of regulated medical waste in establishing a bench mark or a point of reference for professional staff to objectively determine whether a waste material is a regulated medical waste. Given the ubiquitous nature of microorganisms and knowledge of disease transmission, a criteria alone definition is ambiguous and confusing. A combination criteria and list based definition provides broader guidance to all involved with regulated waste management.

### **Treated and Physically Altered Waste**

ABB Sanitec supports the proposed exception for treated medical waste. However, limiting the exception only to treated waste does not meet the intent or spirit of the law. As stated in the Federal Register of December 21 1994, page. 65865, "Under the Federal hazardous material transportation



law, RSPA must regulate the transportation of materials that may pose an unreasonable risk to health and safety or property." There are two hazards associated with regulated medical waste: infectious hazards and physical hazards. Removal of one hazard does not negate the other. Strong consideration must be given to understanding the factors associated with controlling infectious diseases. The infection control equation includes:

- a. Presence of an organism
- b. Reservoir
- c. Portal of Exit
- d. Mode of Transmission
- e. Portal of entry
- f. Susceptible host

Treatment of regulated medical waste can control the first factor. However, removing the possibility for any mode of transmission (direct contact, inhalation, percutaneous injury, and/or ingestion) removes all unreasonable risk. While treatment parameters may reduce and eliminate the infectious hazard, in actuality, the physical hazard is what contributes to disease transmission and normally raises the concerns of employees and the public. While aesthetics has been used as an argument in the past, the real reason to alter the treated medical waste prior to disposal is to remove any physical hazards should treated medical waste be disposed of improperly.

The abstract "Exposure to Blood and/or Body fluids in a Medical Waste Disposal Facility" (attached) clearly demonstrates the risk items which can cause percutaneous injury pose to employees of a medical waste disposal facility. This risk and other risks remain if only treatment is performed. Most alternative treatment technologies have focused upon the following two factors to eliminate the hazards of regulated medical waste - remove the infectious hazard and remove the physical hazards. Once this is accomplished, the end waste product can be considered municipal solid waste.

RSPA has not even considered the physical hazards posed by many items such as hypodermic needles in the regulated medical waste stream.



ABB recommends the exception be rewritten as follows:

*(b) Exceptions.*

*(iv) A material, including waste, which previously may have contained an infectious substance or was considered a regulated medical waste that has been treated to reduce or remove the infectious substance and has been physically altered to remove physical hazards.*

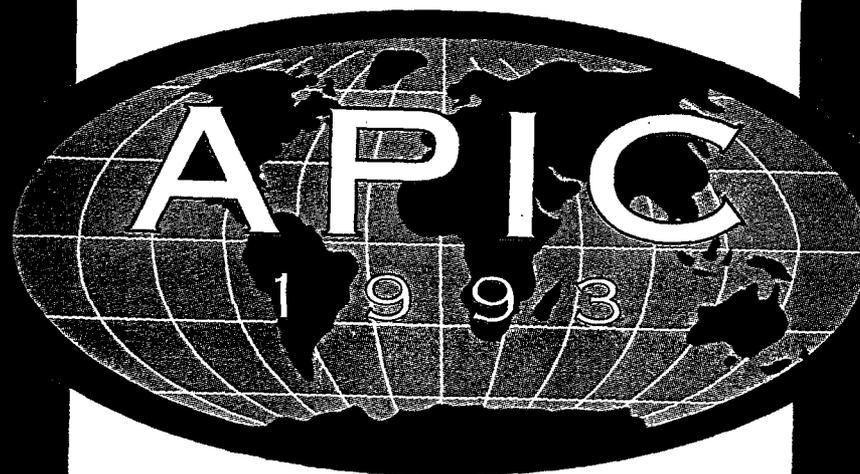
This definition is more comprehensive because it serves to protect the employees not only in health care but in solid waste management and it will protect the safety and health of the public.

Thank you again for the opportunity to comment. If I can be of any further assistance, please contact me.

Sincerely,

Edward Krisiunas, MT(ASCP), CIC  
Acting Regulatory Affairs Manager

ASSOCIATION FOR PRACTITIONERS  
IN INFECTION CONTROL, INC.  
— 20TH ANNUAL —  
EDUCATIONAL CONFERENCE  
AND INTERNATIONAL MEETING



A GLOBAL VIEW

MARRIOTT WORLD CENTER  
ORLANDO, FLORIDA  
MAY 23-28, 1993



**EXPOSURE TO BLOOD AND/OR BODY FLUIDS IN A MEDICAL WASTE DISPOSAL FACILITY. E. Krisiunas, MT(ASCP), CIC. Safe Way Disposal Systems, Inc., Middletown, CT.**

Much data has been collected and reported concerning exposures to blood and/or body fluids by workers in traditional healthcare settings. However, data concerning such exposures beyond these settings are limited. This study examines exposures of workers to blood and/or body fluids in a medical waste disposal facility.

Data were collected by reviewing OSHA 200 logs and accident report forms over a period of six (6) years. As of December 31, 1992, 15 employees had experienced 20 exposures to blood and/or body fluids. All 20 exposures were due to percutaneous injuries. 15/20 (75%) injuries were caused by exposure to needles; 4/20 (20%) contact with broken glass; and 1/20 (5%) contact with a sharp other than needles (scalpel blade).

Needlestick injuries resulted primarily from handling inappropriately packaged items (needles discarded into non-puncture resistant boxes). Other injuries (contact with broken glass) occurred when cleaning spills of medical waste.

Hospitals were primarily responsible for inappropriate packaging from 1988 - 1990 (7/7 exposures). During 1991 and 1992, other healthcare facilities, (i.e., physician offices, dental offices, labs) were more responsible for inappropriate packaging (6/8 exposures).

The most common exposure route to blood and/or body fluids by workers in at least one medical waste disposal facility was percutaneous injury. Inappropriate packaging of needles was the leading cause of these injuries. Continuing education of generators of medical waste on proper disposal methods and better designed packaging may reduce the risk of percutaneous exposure to medical waste disposal facility employees.