RADIOACTIVE MEDICAL WASTE: TWO REGULATIONS, ONE WASTE, NO OUTLET?

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ABSTRACT

A portion of the wastes from biomedical institutions is contaminated with both radioactive and potentially infectious materials. In the past, as stated in 10 CFR 61, the pathogenic component had to be inactivated before the waste was disposed of as low-level radioactive waste (LLRW). With the passage of the federal Medical Waste Tracking Act of 1988, additional handling, treatment, packaging, and recordkeeping requirements may apply to the radioactive medical waste. Due to the broad descriptive definition of medical waste under the Act, most of the LLRW from biomedical institutions is now regulated and must be disposed of as both radioactive under 10 CFR 61 and medical under 40 CFR 259. While currently, the commercial LLRW disposal facilities are accepting radioactive medical waste, efforts must be made to ensure that disposal options for this waste remain open. Otherwise, LLRW generators may be faced with another "mixed waste".

INTRODUCTION

The term "medical waste", while gaining use as such, is not a synonym for infectious waste. According to the U.S. Environmental Protection Agency (EPA), for a waste to be considered infectious, the following five conditions must be met simultaneously:

- A pathogen must be present
- The pathogen must have sufficient virulence to cause infection
- The possible dose from the pathogen must be sufficient to cause infection
- There must be a portal of entry into the body for the pathogen
- The pathogen must be capable of overcoming the resistance of the host

Infectious wastes are typically certain microbiological materials, blood and blood products, pathological waste and used sharps (e.g., needles and syringes). In the research setting, these materials have traditionally been segregated and rendered non-infectious by the generators, not only to protect the workers but also to protect the research.

MEDICAL WASTE TRACKING ACT

The wash-ups of needles, syringes and other waste onto the beaches of the U.S. northeast in 1988, led to a public outcry for special handling of these wastes. The Congress responded, uncharacteristically quickly, and passed the Medical Waste Tracking Act of 1988. Under the authority of this Act, the Environmental Protection Agency (EPA) promulgated an interim final rule (40 CFR 259) on medical waste tracking and management on March 24, 1989. In June 1989, amended on August 24, 1989, the EPA established a Demonstration Program to evaluate the feasibility and impacts of these tracking regulations. Five states, New York, New Jersey, Connecticut, Rhode Island and Puerto Rico, are participating in the program. The evaluation of this program will continue until the end of 1991. In addition to the five participating states, seven others have passed their own medical waste tracking laws. Twenty-five states have medical waste laws regulating aspects of treatment and/or disposal and 13 more have proposed laws.

According to the EPA, "regulated medical wastes" include microbial cultures and stocks, pathological wastes, human blood and blood products, animal wastes, isolation wastes, and sharps (syringes, needles, scalpels). This definition varies from state to state and from locality to locality, and may be more inclusive in certain localities. The trend among these laws is to regulate materials based upon their suspected hazard, that is, if it looks as if it may be infectious or comes from areas where infectious materials are handled, then it must be regulated as such.

The U.S. generates 158 million tons of municipal waste annually. Of this, only 0.3% (500,000 tons) is considered medical waste. Hospitals represent the largest medical waste generators, responsible for 77% of the total. Other medical waste generators include physicians' and dentists' offices, clinical laboratories, manufacturing facilities, veterinary offices and clinics, biomedical research institutions, funeral homes, in-home medical care, other health care and residential care facilities and intravenous (IV) drug users.

Under the Act, essentially all the waste from biomedical institutions is now considered medical waste. This includes those components that are contaminated with radioactive material and must be handled as low-level radioactive waste (LLRW). LLRW is defined under 10 CFR 61 by its source, not by its characteristics. LLRW from biomedical institutions represents only 3.3% of the volume and 0.2% of the activity of all the LLRW generated in the U.S. yearly.

The U.S. Nuclear Regulatory Commission (NRC) in its Information Notice No. 89-85 recognizes that some radioactive wastes from medical, academic and industrial generators will be subject to two regulations: 40 CFR 259 for the medical component and 10 CFR 61 for the radioactive. The second regulation, 10 CFR 61, requires treatment of hazardous, biological, pathogenic, or infectious material to reduce potential hazards from the non-radioactive components to the maximum extent practical.

The Medical Waste Tracking Act stipulates specific handling and treatment procedures for all stages of the medical waste disposal process. The requirements are divided into six categories (40 CFR 259 Subparts E-J):

- Pre-Transport Requirements
- Generator Standards
- On-Site Incinerators
- Transporter Requirements
- Treatment, Destruction and Disposal Facilities
- Rail Shipments of Medical Waste

The effect of these provisions is similar to the "cradle to grave" requirements that RCRA imposes on the disposal of hazardous chemical waste. The last three provisions will not be discussed since they do not directly apply to medical waste generators.

Pre-Transport Requirements: Before shipping regulated medical waste off-site, the generator must segregate the waste into three categories: sharps, fluids and other. The waste must be packaged in containers that are rigid, leak-resistant, impervious to moisture and have sufficient strength to prevent bursting or tearing during normal handling. All regulated medical waste must be labeled with the name and identification numbers of both the generator and the transporter. Untreated waste must have additional labeling indicating the nature of the hazard. If regulated medical waste is to be stored on-site, the storage area must have limited access and protect the waste from the elements.

Generator Standards: Generators are required to calculate the amount of regulated medical waste generated per calendar month. Any generator producing more than 50 pounds per month is subject to all the provisions of the Act. Those who generate less are exempt from certain provisions of the federal regulations, but may still be subject to state and/or local regulations. Generators who treat and destroy or dispose of regulated medical waste on-site are exempt from the tracking requirements. Treatment of medical waste is any process which reduces or eliminates the potential to cause disease, e.g. autoclaving, chemical inactivation. Destruction involves mutilating, shredding, pulverizing or subjecting the waste to any other physical process that results in material that is no longer recognizable as medical waste. Disposal can be accomplished by incineration, burial or sewer release. Any medical waste transported off-site for treatment, destruction and/or disposal, must be tracked using a manifest system similar to that already in place for hazardous chemical waste. This manifest allows for tracking the waste from the point of generation, through any EPA-permitted transporter and treatment facility to its ultimate disposal. Records must be maintained for at least three years.

On-site Incinerator Standards: Generators destroying medical waste using on-site incinerators must maintain a log of the amounts of regulated medical waste that is destroyed and must file a semi-annual report with the EPA providing this information.

LOW-LEVEL RADIOACTIVE WASTE

The NRC, under 10 CFR 61, authorizes only the following disposal options for LLRW:

- Transfer to an authorized recipient [10 CFR 20.301(a)]
- Special ruling [10 CFR 20.301(b) and 302]
- Release into sanitary sewerage system [10 CFR 20.301(c)]
- Release of air and liquid effluents (10 CFR Part 20.106)
- Disposal of specific wastes without regard to radioactivity (10 CFR 20.306)
- Incineration of specific wastes - recommended under 20.306

There are two courses of action for regulated medical waste which is also radioactive:

a) Waste that has been treated to reduce the biohazards and destroyed on-site is no longer considered "medical waste" and is exempt from the tracking requirements under 40 CFR 259. In the case of treated and destroyed radioactive medical waste, the materials would still have to be disposed of as LLRW according to 10 CFR 61. Generators must maintain records of all on-site treatment and destruction.

b) Any waste that has not been treated and destroyed is considered "regulated medical waste" and as such, must be disposed of according to both EPA and NRC regulations. At a minimum, this entails tracking the waste with a dual manifest - a medical waste manifest and a radioactive waste manifest. Currently, medical waste disposal facilities are refusing any waste contaminated with radioactivity, sometimes with attendant fines and suspensions (1). Disposal of any radioactive regulated medical waste must be at one of the commercial LLRW disposal facilities. Should these facilities ban the disposal of medical waste, as they banned

organic liquid "mixed waste", generators will be left holding this portion of their radioactive medical waste.

WASTE SEGREGATION AND TREATMENT

A review of the types of radioactive medical waste generated at biomedical institutions and how it may be treated will highlight some of the impacts of and difficulties encountered in complying with the new medical waste regulations. Biomedical LLRW may be classified according to form (gaseous, liquid, scintillation vials and fluid, solid and animal) and half-life (short- or long-lived). The solid LLRW typically contains glass- and plasticware, papers, gloves, and disposable protective clothing and the liquid LLRW is primarily aqueous. Of all biomedical LLRW, the materials most likely to be classified as medical waste are the liquids, solids and animals. If the waste is contaminated with short-lived radionuclides (half-life less than 65 to 90 days, e.g. ^{32}P, ^{125}I, ^{35}S), the material can be held for decay of the radioactive component and the waste thereafter treated solely as medical waste. If the waste is contaminated with long-lived radionuclides (half-life greater than 65-90 days, e.g. ^{3}H, ^{14}C), effort should be made to treat and destroy it so that it will no longer be considered regulated medical waste. The potentially infectious component this waste should also be considered for deregulation under a de minimis or Below Regulatory Concern (BRC) exemption.

- Treatment methods for medical waste include:
- Incineration
- Chemical inactivation, e.g. hypochlorite solution
- Autoclaving
- Ethylene oxide gas
- Microwaves
- Irradiation
- Dry heat sterilization

Each of these methods must be evaluated in terms of its necessity, legality, effectiveness and the potential for radiation exposure and release of volatile components when used for treatment of radioactive materials. For example, in most localities with sanitary sewer systems, liquid medical waste can be discharged, even untreated, into the sewer. However, there are well-specified limits on the amount of types of radioactive materials that can be disposed of via the sewer [10 CFR 20.301(c)]. The by-products of the waste treatment must be considered as well. For example, in Illinois the ash from incineration of medical waste is regulated as hazardous waste.

Most liquid medical wastes can easily be treated with chemicals, such as hypochlorite, to render them non-pathogenic. In some cases, chemical treatment is not recommended because the reaction may liberate volatile radioactive components and pose an exposure hazard to the handler, e.g. ^{125}I liquids should not be treated with hypochlorite. Treated liquids can then be disposed of as radioactive, "non-regulated medical" waste.

Solid wastes containing short-lived radioisotopes may be held for decay. After the radioactivity has decayed to background levels, the waste is still considered regulated medical waste and must be disposed of as such or treated and destroyed and disposed of as trash. Solid wastes containing long-lived radioisotopes may be treated chemically or autoclaved and then shredded but would still have to be disposed of as radioactive waste. If the wastes are to be autoclaved, precautions must be taken not to contaminate the autoclave with volatilized radioisotopes. Unfortunately, incineration of these materials is currently prohibited. While the three commercial LLRW disposal facilities, none of which are located in the five states subject to the Demonstration Program, are still accepting this type of waste for burial, it remains to be seen if this practice will be allowed to continue. New York City and Rhode Island have passed laws specifically prohibiting landfilling of any medical waste.

Animal carcasses and tissues represent the major treatment and disposal problem. The only method for rendering animal wastes "non-regulated medical" waste is incineration. The NRC permits the incineration only of materials containing no more than 0.05 μCi/g (1.85 kBq/g) of ^{3}H and/or ^{14}C. Animal carcasses and tissues contaminated with short-lived radioisotopes could be held for decay to background levels in freezer rooms and then incinerated as non-radioactive waste. All other animal waste must be shipped for burial as radioactive regulated medical waste.

Complying with regulations governing the "medical" aspect of radioactive waste streams adds steps to an already complicated waste handling procedure. It also adds expense: more manhours in handling and paperwork, higher disposal costs for decayed radioactive waste which is still considered "regulated medical waste", capital and maintenance costs of equipment for on-site treatment and destruction, and finally increased liabilities. All of this to protect the public from the risk of infection from medical waste. But what are those risks?

RISKS FROM RADIOACTIVE MEDICAL WASTE

According to the Agency for Toxic Substances and Disease Registry (ATSDR) report to Congress (2), the public is unlikely to come into contact or be adversely affected by medical waste generated in traditional settings, e.g. hospitals. Outside of the health care setting, hepatitis B virus (HBV) and human immunodeficiency virus (HIV) infections from medical waste are unlikely to occur. Studies indicate that medical waste contains neither more nor dif-

ferent types of microbiological agents than residential waste and that pathogens tend to absorb tightly to organic matter. Despite the fact that HBV is the most prevalent occupationally-acquired disease among health care workers, a two-year study done in the 1970s on New York City Sanitation workers failed to reveal a single case of hepatitis B infection due to needlestick injuries on the job (3). Even for those involved in the health care field, an estimated maximum of only <0.003% to 0.01% of all HIV infections result from contact with medical waste sharps. A maximum estimate of 0.05 to 0.1% of all HBV infections result from occupational contact with medical waste sharps (4,5). Contact with non-sharp waste is even less likely to produce infection because of the lack of a means of entry into the body. In fact, to date, only one infection has been tied to contact with medical waste - a bacterial infection in a housekeeper possibly resulting from a needlestick. This is not to say that the handling of medical waste is hazard-free. As with any waste handling, physical hazards are present and injuries, e.g. cuts, punctures, back injuries, do and have occurred.

What are the risks from the radioactive component of medical waste? The amounts of radioactivity in LLRW is orders of magnitude lower than the types of waste the public typically thinks of when "radioactive waste" is mentioned, i.e., spent fuel and high level waste. LLRW from biomedical institutes represents only 0.2% of the activity of all commercial LLRW and is overwhelmingly Class A waste containing low activity, low-energy radionuclides. The radioactivity in the animal carcasses and solid wastes that must now be handled as medical waste presents such a low potential dose to the public as to be indiscernible from the natural background radiation. In fact, compared to the annual dose from natural sources [an average of 363 mrem/year (3.64 mSv/year)], the only recorded exposure from all commercial LLRW [< 1 mrem/year (0.01 mSv/year)] is trivial (6).

It is this trivial dose (1 mrem/year) that has been proposed as the basis for deregulation of radioactive waste as Below Regulatory Concern (BRC). Most radioactive medical waste falls easily into the conditions defined for BRC consideration. In fact, a petition filed with the NRC for solid radioactive medical waste contaminated with ^{3}H and ^{14}C has shown that incineration of this waste as BRC would result in worst-case potential exposures well below the 1 mrem/year limit (7).

Solid medical wastes and animal carcasses containing long-lived radioisotopes may become this nation's new "mixed waste", subject to two sets of regulations which demand different disposal methods. Based on the NRC's and EPA's inability to establish legal outlets for mixed radioactive, organic chemical waste, it is improbable that these agencies would quickly resolve a similar situation involving radioactive medical waste.

KEEPING DISPOSAL OPTIONS OPEN

In order to avoid these possibilities, action must be taken now to keep the disposal options for radioactive medical waste open. The minimal approach would be to maintain the status quo - that is, continue to allow the landfilling of medical LLRW at the commercial LLRW sites. While the three operating commercial sites are currently accepting these wastes, they may decide to exclude the radioactive medical waste from their facilities due to the added paperwork, costs and liabilities generated by this relatively small volume of waste. Even if they continue to accept this waste, as 1996 approaches and new LLRW disposal facilities begin operation, this issue will have to be addressed in any sited state that has banned landfill of medical waste.

A large portion of the LLRW from biomedical institutions, due to its low activity, could and should be exempted from regulation as radioactive waste. This could be done by broadening the existing *de minimis* exemption to include other radioisotopes and forms and by granting BRC exemptions. Exempted radioactive materials could then be treated and disposed of as medical waste.

By designating either the NRC or the EPA as the lead agency, a single set of standards for the treatment and disposal of radioactive medical waste could be developed. These standards could and should address both properties, radioactive and infectious, but would minimize recordkeeping and tracking. As a minimum, the NRC and the EPA should agree upon a single manifest for these materials.

While the ATSDR report is an important first step in the evaluation of the federal Medical Waste Tracking Act, further impact studies should be done. Specifically, a cost-risk-benefit analysis should be performed which considers the health risks, if any, from medical waste in light of the real risk of reduced biomedical research and health care. Ideally, the stringency and amount of regulation, and consequently the cost of disposal, should reflect the low levels of hazard associated with this type of waste instead of reenforcing the public's misconception that LLRW or medical waste is a threat to their health.

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