

Defining and Characterizing Medical Wastes

Medical wastes include all infectious waste, hazardous (including low-level radioactive) wastes, and any other wastes that are generated from all types of health care institutions, including hospitals, clinics, doctor (including dental and veterinary) offices, and medical laboratories (42).¹ The main focus of concern has been on the portion of medical wastes that are defined as infectious, and how they are classified (e. g., as a solid, hazardous, or “special” waste) and regulated. These wastes are also the primary focus of this paper. The main sources of these wastes receiving attention are hospitals and other large facilities. Much of the information reported here will focus on these larger generators, but the proper disposal of other types of medical wastes and of wastes from all types of sources is also important.²

Amounts and Composition

The actual amount of medical waste generated in the United States today (or in the past) is not known; even estimating this figure is problematic, as the number of different reported estimates indicate. In 1987, the Environmental Protection Agency (EPA) reported the total generation rate of **hospital wastes at 5,900 tons/day** (83). This figure is based on the number of hospital beds estimated to exist (in 1985, the estimate was 1.3 million with a 69 percent occupancy rate) and a per bed per day generation rate of 13 pounds.

The per bed per day generation figure itself, however, is difficult to pinpoint. Recent independent estimates of hospital waste generation range between 16 to 23 pounds per bed per day (61). The

range reported by hospitals in various surveys of hospital waste generation is 8 to 45 pounds per bed per day.³ EPA expected the 13 pound per bed per day rate to remain constant, as it believes it did for the period from 1975 to 1985 (83). In 1980, however, one survey of North Carolina hospitals reported an average of approximately 10 pounds per bed per day of wastes. If this lower figure was typical in years past, then it would indicate that the amount of per bed generation of hospital wastes may have increased significantly within the last decade. Healthcare workers and administrators do indicate that the amount of disposable items used in hospitals and other medical facilities has increased dramatically in recent years, although data are not available to document this observation.

Few data are available on the composition of hospital waste, although it is characteristically heterogeneous in nature. The mix of materials includes, in addition to general refuse (e. g., office paper, food waste, non-infectious patient waste) and infectious waste (e. g., pathological wastes, human blood and blood products, contaminated sharps and anatomical wastes, isolation wastes), hazardous wastes (e.g., waste pharmaceuticals, cytotoxic agents used in chemotherapy, mercury or other heavy metals), and radioactive wastes.⁴

The composition of the medical wastestream is of concern given its effects on the incineration process. If incineration occurs on-site, it is likely that at least some of the hospital or facility's wastes are mixed (if wastes are shipped off-site, given the greater expense of treating infectious waste this

¹ See also ref. 39. It should be noted that extensive treatment of the current management of radioactive and other identified hazardous wastes in the medical wastestream is beyond the scope of this paper. It is recognized, however, that proper management of such wastes is important and a challenge for many medical waste generators, given the usually small quantities and high cost of adequate disposal of these wastes.

² The amount of medical wastes from such non-hospital sources is not known. Other sources of infectious wastes, such as sewage overflows, can also be a significant source of environmental contamination (e. g., impacting beaches and shellfish areas), but are beyond the scope of this paper.

³ Different methodologies to calculate per bed generation figures, may explain the wide variation in estimates. Also, of course, the actual hospital generation figures can vary greatly on a daily basis. Some surgical procedures generate much more waste (e. g., a heart transplant) than other routine operations (83). In addition, difficulties in segregating infectious and non-infectious wastes may lead to more mixed waste disposal that is treated as infectious.

⁴ It should be noted here that not all of these hazardous or toxic wastes are regulated by the Resource Conservation and Recovery Act (RCRA), and, in addition, many of the generators of these wastes may qualify for a small quantity generator exemption from RCRA requirements (e. g., this would include most hospitals under 200 beds). Nonetheless, if some of these wastes are incinerated on-site they could be a source of air emission concern (83).

way, it is likely that only infectious waste is sent for incineration).⁵ Particular components of the medical wastestream of special concern when this waste is incinerated include the relatively high plastic content of medical waste (to be discussed further below). About 20 percent of the hospital wastestream is estimated to be plastics (83), which is about three times the plastic portion of the municipal solid wastestream.⁶

In any case, reported generation figures do not include non-hospital medical wastes. In 1985, approximately 6,870 hospitals and an estimated 1,000 diagnostic and research laboratories existed, in addition to thousands of doctor offices and nursing homes (5).⁷ Although specific estimates are not available on the volume or composition of medical wastes from these sources, it is reasonable to expect that the *total* medical waste generation (both hospital and non-hospital) figure is somewhat higher.

Designating Infectious Waste

Determining which portion of medical waste is infectious goes to the heart of the definitional problems associated with medical waste management. There are two basic sources that hospital and other medical facilities may use in determining their working definition of infectious wastes: EPA guidelines and Centers for Disease Control (CDC) guidelines. These will be discussed below.

How infectious waste is defined can greatly affect the cost of waste management, and ultimately the choice of waste management disposal options for generators. For example, one 600-bed hospital found that it saved \$250,000 annually by changing its infectious waste designation from 13 categories to the 4 designated by the CDC (59). General cost figures for disposal are (approximately): \$0.01 to \$0.25/lb. for general refuse/non-infectious waste (usually landfilled); \$0.10 to \$0.25/lb. for incineration on-site (includes infectious wastes);⁸ and 0.30 to 1.00/lb. (although costs

may be higher in some areas) for commercial, off-site incineration (6, 10).

Most estimates are that 10 to 15 percent of all hospital wastes are infectious. The total range of estimates, however, is from 3 to 90 percent of a hospital's waste defined as infectious, depending on the definitions and procedures followed (10,83). According to Lawrence Doucet, a consultant on hospital waste management, about 3 to 5 percent of a hospital's total wastestream would be classified as infectious waste according to previous interpretations of CDC guidelines for infectious wastes, while approximately 10 percent would be classified that way according to the 1986 EPA guidelines (10).⁹

The recommendations issued by CDC in August 1987, however, have apparently been interpreted by some hospitals as classifying virtually all patient-contact waste as infectious (77). This can amount to 70 to 90 percent of total hospital waste. **The potential impact of such a trend on medical waste management could be to both increase the cost of disposal significantly and strain existing capacity for managing infectious wastes.** The CDC has issued a clarification of its definition, yet confusion at the generator level appears to remain over the proper classification and management of medical wastes (78).

Definitional Differences—EPA v. CDC

William Rutala, University of North Carolina School of Medicine (Director of the Statewide Infection Control Program), has noted that no tests exist to objectively identify infectious wastes, unlike the case with chemical or radiological wastes (60).¹⁰ This has led the CDC, EPA, States, and other agencies to identify and further define infectious waste by waste category based on waste characteristics.

EPA defines infectious waste as "waste capable of producing an infectious disease" (81). Coupled

⁵Actual data on the amount of waste incinerated on-site v. off-site, and whether waste is usually mixed or not, are not currently available.

⁶Estimates of the portion of plastics in hospital waste range as high as 30 percent.

⁷See also ref. 10.

⁸It should be noted that capital costs, depreciation, and other types of costs may not be included in these figures.

⁹Interestingly, a recently completed survey for the American Hospital Association reported that 80 percent of the hospitals are following CDC guidelines, while only 52 percent are complying with EPA guidelines (to be discussed further below) (61).

¹⁰See also ref. 70.

with the definition is the need to consider at least four factors necessary for the induction of disease:

1. presence of a pathogen of sufficient virulence,
2. dose,
3. portal of entry, and
4. resistance of the host.

Thus, the Agency notes that:

... for a 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 (81).

The CDC recommendations, issued in August 1987, and referred to as "universal precaution" procedures, are essentially that blood and body fluids from "all patients be considered potentially infected with HIV (human immunodeficiency virus) and/or other blood-borne pathogens and [that health care workers] adhere rigorously to infection-control precautions' (77). In June 1988, the CDC attempted to clarify several issues associated with apparent confusion over the application of their 1987 recommendations. As part of this effort, the CDC now limits the application of universal precautions to blood and other body fluids containing visible blood, to semen and vaginal secretions, and to other specified fluids (78). The CDC also notes

that the recommendations are intended to protect healthcare workers and do not address waste management practices or the definition of infectious wastes (78).

Both the CDC and EPA designate pathological waste, blood and blood products, contaminated sharps (e. g., scalpels, needles, blades), and microbiological wastes (e.g. cultures and stocks) as infectious. Some apparent disagreement exists between the designations of and suggested treatments for different components of infectious wastes identified by the CDC and EPA. (See table 1.) EPA has identified several additional optional categories, which include a category of isolation wastes, a category of contaminated animal carcasses, body parts, and bedding, and categories of surgery, autopsy and contaminated laboratory wastes (81). The apparent inconsistencies are remedied in part by the fact that EPA refers to the CDC guidelines on isolation precautions (74) and to the joint CDC/National Institutes of Health guidelines on animal carcasses waste management and other guidelines on laboratory wastes.¹¹

¹¹Although the CDC does not classify animal carcasses as infectious wastes, the CDC/National Institutes of Health guidelines, "Biosafety in Microbiological and Biomedical Laboratories (75)," recommend incineration of infected animal carcasses and decontamination (preferably by autoclaving) before disposal for all wastes from animal rooms of certain designated biosafety levels.

Table 1.—CDC/EPA Designations of Solid Wastes and Recommended Treatment/Disposal Methods

Source/type of solid waste	CDC ^a		EPA	
	Infectious waste	Disposal/treatment method	Infectious waste	Disposal/treatment method
Microbiological (e.g., stocks and cultures of infectious agents)	Yes	S,I	Yes	S,I,TI,C
Blood and blood products (i.e., liquid blood and blood products) ., . .	Yes	S,I,Sew	Yes	S,I,Sew,C
Communicable disease isolation	Yes/No	HP	Yes	S,I
Pathological (e.g., tissue, organs)	Yes	I	Yes	I,SW,CB
Sharps (e.g., needles)	Yes	S,I	Yes	S,I
Contaminated animal carcasses, body parts and bedding	No	—	Yes	I,SW
Contaminated laboratory wastes .,	No	—	Optional ^b	(not bedding) If considered IW, use S or I
Surgery and autopsy wastes	No	—	Optional	If considered IW, use S or I
Dialysis unit	No	—	Optional	If considered IW, use S or I
Contaminated equipment	No	—	Optional	If considered IW, use S or I

^aAbbreviations: CDC—Centers for Disease Control; EPA—Environmental protection Agency; I—Incineration; S—steam sterilization; TI—thermal inactivation; C—chemical disinfection for liquids only; Sew—sanitary sewer (EPA requires secondary treatment); HP—in accordance with hospital policy; SW—steam sterilization with incineration or grinding; CD—cremation or burial by mortician; IW—infectious waste.

^bOptional infectious waste: EPA states that the decision to handle these wastes as infectious should be made by a responsible, authorized person or committee at the individual facility.

SOURCE: W. Rutala, "Infectious Waste—A Growing Problem for Infection Control," *ASEPSIS: The Infection Control Forum* 9(4):2-6, 1987.

The major *apparent* disagreement is over the designation of communicable disease/isolation wastes. Although the CDC and EPA agree that there is no inconsistency in their designations of these wastes, confusion exists in the application of these guidelines. This may indicate a need for further clarification of these guidelines by the two agencies. EPA considers communicable disease wastes as infectious. CDC recommends that communicable disease waste be treated according to hospital policy (74). Nelson Slavik notes, in his report of the proceedings of the EPA Infectious Waste Management Meeting held in November 1987, that recent interpretations by hospitals and other generators of the CDC universal precaution guidelines, and the concern over potential exposure to AIDS, can result in any blood or body fluid and any item contaminated with them being designated as infectious waste.

Previously, only patient waste from those patients in isolation would be included in the EPA's infectious waste definition; interpretation of the CDC guideline, however, could include all patient contact wastes and wastes of EPA's optional category (e.g., surgical and autopsy wastes, dialysis waste, contact laboratory wastes) in the infectious waste definition (70). The CDC disputes this interpretation of its recommendations (77,78). The CDC issued a statement in June 1988 that,

Universal precautions are not intended to change waste management programs previously recommended by CDC for health-care settings (78).¹²

This attempt at clarification by CDC, however, in part contributes to the confusion. It is not clear why the CDC is suggesting that its universal precautions guidance applies only to worker precautions and not waste handling procedures.

EPA agrees with CDC that its recommendations are not in serious disagreement with EPA recommendations and that universal precautions are meant to protect healthcare workers and do not "attempt to define what is infectious waste" (87). Given the state of confusion at the generator level,

¹²According to the CDC, for example, blood, some body fluids, and sharps from an isolation room should be handled as if potentially infectious, but not *all* wastes from this type of room. CDC further states that, "While any item that has had contact with blood, exudates, or secretions may be potentially infectious, it is not *usually* considered practical or necessary to treat all such waste as infective" (78).

though, further clarification and perhaps *jointly issued guidance* on these definitional issues is desirable.

Currently, based on the proceedings of the EPA meeting of experts on infectious wastes held in November 1987, there appears to be agreement that:

Notwithstanding the risk perceptions and anxieties associated with the fear of contracting AIDS, those categories of infectious wastes that possess the greatest potential to transmit disease are contaminated sharps, human blood and blood products, pathological wastes (primarily body fluids), and laboratory wastes (70).

The position is that, given the consistent recognition of the potential hazards from these wastes, either due to known disease association or risk of accidental injection, their "prudent" handling and proper disposal are warranted (70). EPA did, however, solicit comments regarding the basis on which wastes should be defined as infectious and is currently reviewing its definition of infectious wastes. ¹³

Classifying Infectious Waste as Hazardous Waste

Additional confusion arises over the question of whether or not infectious wastes should be classified and regulated as Subtitle C, RCRA hazardous wastes. In 1978, EPA did include regulations for infectious wastes in its proposed hazardous waste regulations. The Agency never promulgated these, however, and has not classified any infectious wastes as hazardous wastes—even though the language of RCRA includes "infectious" as a characteristic to be considered in determining whether or not a waste is a hazardous waste. ¹⁴The statu-

¹³53 *Federal Register*, June 2, 1988. The EPA published a notice of data availability and request for comments on infectious wastes issues. Comments were due August 1, 1988 and the Agency received over 100 responses. EPA is now in the process of responding to and summarizing these comments as part of its consideration of possible regulatory action for medical wastes (86).

¹⁴RCRA (public Law 94-580), in Section 1004 (codified as 42 U.S.C. 6903(5)), includes the following definition:

(5) The term "hazardous waste" means a solid waste, or combination of solid wastes, which because of its quantity, concentration, physical, chemical, or infectious characteristics may—

(A) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or

(B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed [emphasis added].

tory language can be interpreted as requiring these wastes to be classified as hazardous and thus regulated under Subtitle C of RCRA.

EPA, based largely on its determination of a lack of evidence that infectious wastes “cause harm to human health and the environment” sufficient to justify Federal rulemaking (under Subtitle C, RCRA), has instead issued a manual of recommendations for the management of infectious wastes (81). It should be noted, however, that the statutory language refers not only to whether a waste will “cause harm, but also to whether it may *“pose a substantial present or potential hazard . . .”* (emphases added; RCRA, Section 1004).

Even so, 12 years after the passage of RCRA and 8 years after making the determination that insufficient evidence existed to justify Federal regulation, EPA has not undertaken or encouraged research to substantiate a lack of “a substantial present or potential hazard to human health or the environment when a waste with infectious characteristics is improperly managed (a criterion of RCRA, Section 1004(5) definition of hazardous waste). Alternatively, the Agency has not issued its assessment, based on existing epidemiologic information, of the degree of risk posed by infectious or other types of medical wastes.

To date, EPA’s actions have not been legally challenged. Congress may clarify the conditions under which medical wastes are to be regulated as part of the current RCRA reauthorization process. Currently, the Agency considers medical waste a solid waste subject to RCRA, Subtitle D regulation and is in the process of addressing the need for additional regulations to control infectious wastes. 15 EPA did include a space for infectious waste on the “Notification of Hazardous Waste Activity” form, which is used by hazardous waste generators to apply for EPA identification numbers, but no paragraph addressing infectious wastes actually exists in the regulations referenced on the form. ¹⁶

Interestingly, a manual published by the Joint Commission for the Accreditation of Hospitals (JCAH)¹⁷ designates infectious wastes and sharps

¹⁵40 CFR 240.101. (See refs. 73,86.)

¹⁶EPA Form 8700-12, revised November 1985, referencing 40 CFR 261.34.

¹⁷Recently, JCAH changed its name to the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO).

as hazardous wastes, along with chemical, chemotherapeutic, and radioactive wastes. The manual outlines methods for handling each type of waste, and the JCAH requires that a system to handle all such hazardous wastes exist and be in compliance with Federal, State, and local regulations (34). 18 In addition, the National Committee for Clinical Laboratory Standards (NCCLS) in its proposed guideline for clinical laboratory hazardous waste includes infectious waste (i. e., waste with “infectious characteristics, following the RCRA, Section 1004 definition) in its definition of hazardous waste (49,50). **From a generator perspective, greater consistency on the classification of infectious and other medical wastes would help eliminate some of the current confusion over the proper treatment of these wastes.**

A policy debate continues over how best to classify infectious wastes, and other medical wastes, as well. Some observers, noting the likely increase in cost as more wastes become designated as infectious, expect even more costly disposal if in addition these wastes must be handled as hazardous. Further, concerns over the difficulty of siting hazardous waste facilities are noted. Others maintain that hospital disposal costs are likely to increase due to increased regulation in general and focus instead on the most reliable waste disposal options. Arguments over the difficulty of siting hazardous waste are countered by those who point out that any type of waste facility is difficult to site (although successful siting of facilities does occur when public participation and other measures are included in the site selection process). In addition, hospitals may continue to treat wastes on-site (if, for example, they have the space to upgrade or construct facilities).

Classifying infectious wastes as hazardous is seen as desirable by some in order to prosecute illegal dumping as a felony, to bring in force a manifest system for infectious wastes which would track the off-site movement of these medical wastes (21,22), and in general to ensure greater comprehensive management of infectious wastes. ¹⁹These purposes

¹⁸As Rutala (60) points out, since there are no Federal regulations, hospitals must comply with State and local regulations; if these do not exist, then hospitals should comply with either CDC or EPA guidelines.

¹⁹New York State recently passed legislation which both provides for penalties of up to 4 years in prison and fines of up to \$50,000 for illegal disposal of medical wastes (previously the penalties were up

could be accomplished without classifying infectious wastes as hazardous wastes (some of these issues will be discussed further below). Yet, proponents for regulating infectious wastes as a hazardous waste argue that to do so is likely to be the most expeditious approach to the problem (rather than risk delay and confusion created by developing another system). Furthermore, it is not clear how much flexibility the EPA has under RCRA to address infectious waste as a waste type other than hazardous.²⁰ Again, this issue could be clarified as part of the current reauthorization effort in Congress.

Uncertainties for State Regulators

These definitional and classification problems have created considerable uncertainties for State

to 15 days in jail and up to \$2,500 in fines) and establishes a manifest system to track medical wastes. Several bills pending in Congress also would classify illegal dumping of medical wastes as a felony and specify penalties. The Senate passed legislation to establish a model manifest program for several States in the Northeast; similar legislation is pending in the House (see ch. 5).

²⁰See 42 U.S.C. 6903(5) and 6921.

regulators. Approximately 10 States have definitions of infectious waste which include the four common CDC and EPA infectious wastes in their definitions (i. e., pathological wastes, microbiological wastes, blood and blood products, and contaminated sharps).²¹ As noted above, most States designate infectious wastes as special wastes, and the trend is for other States to do the same. Previously, infectious wastes were classified by States as hazardous wastes because of the aforementioned RCRA definition. In fact, States must have a program no less stringent than the Federal Government's. Since the EPA has not regulated infectious wastes as hazardous, the trend seems to be for the States not to do so, too.²² States apparently find the delisting of a hazardous waste after it has been treated to be a particularly cumbersome and difficult aspect of regulating infectious wastes as hazardous wastes (4).

²¹53 *Federal Register*, June 2, 1988.

²²Although some States and localities have moved beyond whatever a "baseline" Federal definition of infectious wastes might be, such a consistent definition might facilitate the development of other Federal regulations of infectious wastes.