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DRAFT MANUAL FOR

INFECTIOUS WASTE MANAGEMENT

U.S. Environmental Protection Agency
Office of Solid Waste
Washington, D.C. 20460

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NOTICE

The mention of trade names of commercial products in this publication is for illustration purposes and does not constitute endorsement or recommendation for use by the U.S. EPA.

ABSTRACT

This manual discusses environmentally acceptable techniques for infectious waste management. Topics covered include a definition of infectious waste, and packaging, transportation, treatment, storage, and disposal practices. Recommendations are presented for methods of treating different types of infectious waste.

Described in detail are infectious waste treatment methods including steam sterilization, incineration, dry heat sterilization, gas/vapor sterilization, sterilization by irradiation, and chemical disinfection. Included in the discussion of each method is a description of the method, the process variables that affect the efficacy of the treatment, design parameters for standard operating procedures, and monitoring recommendations.

In addition, the manual provides citations of federal and state regulations as well as non-governmental guidelines that apply to infectious waste management. A list of state offices that may be contacted for further information is also included.

The information contained in this manual should be of value to those persons concerned with the management of infectious waste in hospitals, veterinary hospitals, medical laboratories, research laboratories, commercial diagnostic laboratories, animal experimentation units, pharmaceutical plants and laboratories, and other facilities which generate infectious waste. This document should also be of value as resource material for development of infectious waste standards by State and local regulatory agencies. EPA may update the manual as new information becomes available.

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FOREWORD

The Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended, requires EPA, among other things, to foster development of and evaluate methods for the management of solid waste which are environmentally sound and which maximize the utilization of valuable resources. In addition, the Act requires EPA to establish a "cradle-to-grave" management system for solid wastes which are identified as hazardous.

Congress defined hazardous waste generally to mean "a solid waste, or combination of solid wastes, which because of its quantity, concentration, or 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 substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed."

As a first step in fulfilling the Congressional mandate to establish a hazardous waste management system, EPA published proposed regulations in the Federal Register on December 18, 1978 (43 FR 58946-59028) which included a proposed definition and proposed treatment methods for infectious waste. EPA received approximately sixty comments during the ensuing 90-day public comment period which specifically addressed the infectious waste provisions of the proposed regulations.

In response to the comments on the proposed infectious waste regulations, EPA spent considerable resources refining the definition of infectious waste and analyzing acceptable alternative management techniques. On May 19, 1980 when EPA published the first phase of the hazardous waste regulations in the Federal Register (45 FR 33066-33588), the Agency stated in the preamble to Part 261 that the sections on infectious waste would be published when work on treatment, storage and disposal standards was completed. Although much Agency effort has been expended evaluating management methods for infectious waste, considerable effort will still be necessary to develop a regulatory package.

Because EPA has meanwhile received numerous requests for technical information and guidance on infectious waste management, the Agency wishes to appropriately respond. The Agency feels that publishing its findings to date on infectious waste in the form of a guidance manual would be useful to persons who have asked for this kind of information. It is EPA's belief that the recommendations contained in this document represent environmentally sound, technically achievable practices available for infectious waste management.

Publication of Agency recommendations in the manual thus serves several purposes. First, it gives EPA the opportunity to share accumulated information on infectious waste management with the numerous parties who have requested this information for use in planning infectious waste management systems. Second, it provides a source of technical information to State agencies that may be under legislative mandate to establish infectious waste regulations. Third, it serves as a potential focal point for information exchange for those persons interested in infectious waste management and treatment technology.

EPA wishes to point out that, for the most part, this manual addresses the management of a waste solely from the perspective of the problems posed by its infectious characteristics. Often an infectious waste poses additional hazards that should be assessed in making a decision for its proper management. EPA draws attention to this information gap and would appreciate comment on the appropriateness of expanding this manual in the future to address the management of wastes which exhibit other hazardous properties in addition to being infectious.

Because the public has not yet reviewed the information presented in this document as a whole, EPA is soliciting written comments on both the substance and the format of the manual. In response to these comments, EPA may publish a revised edition of the manual. For due consideration, written comments should be submitted to EPA no later than 6 months from the date that the availability of this document is announced in the Federal Register.

Comments should be sent to:

Docket Clerk
(Docket No. 3001/3004, Infectious Waste Management)
U.S. Environmental Protection Agency
Office of Solid Waste (WH-562)
401 M Street, S.W.
Washington, D.C. 20460

For further information, contact Claire Welty at (202) 755-9187.

Requests for copies of this document should be directed to Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, telephone (202) 783-3238.

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CHAPTER 1

INTRODUCTION

The purpose of this manual is to provide comprehensive guidance for proper management of infectious waste. Recommendations are based on techniques that are practical and effective, and that assure protection of human health and the environment. This document is written for use by all who seek specific information on infectious waste management including biological safety officers, environmental engineers, hospital infection control committees, laboratory supervisors, principle investigators, and others.

1.1 Scope of Manual

Fundamental to management decisions regarding infectious waste disposal is the proper identification of infectious waste based on the known or potential infectious characteristics of the waste. A waste management system can then be developed which addresses the following aspects:

- Handling infectious waste
- Storage (when necessary)
- Packaging for safe transport and effective treatment
- Transport both within the facility and off-site
- Selection of appropriate treatment and disposal methods
- Establishment of standard operating procedures for the selected treatment methods
- Monitoring of treatment methods
- Compliance with local, state and federal ordinances and regulations

These components of an appropriate system for managing infectious waste are described in this manual in detail. EPA realizes that an optimal system will vary from facility to facility because of the particular combination of operating variables that may be unique to each physical setting. This manual should provide assistance to a manager in meeting the challenge of developing an environmentally sound waste management system that adequately addresses the above listed elements.

The reader should note that it is EPA's intention to provide a guidance manual that can also be used as a resource document. There is valuable information in each section, and EPA recommends that this manual first be read in its entirety so that the reader will understand the principles behind the recommended approach to infectious waste management and will be familiar with the types of information that are available in the manual. Nevertheless, there will subsequently be times when users will choose to refer directly to a particular section. Therefore, each section was written so that it would be a complete and independent part of the manual. Background material is presented followed by a summary of recommendations for each aspect of infectious waste management and, for convenience, reference is made to other sections of the manual whenever relevant. The reader should expect some repetition when this publication is read through from beginning to end.

In the interest of promoting good management practices, this manual addresses a few problems related to waste management that do not pertain strictly to the infectious properties of a waste. For example, it is prudent as well as more convient to uniformly manage certain types of waste that are usually but not always infectious. For the most part, however, EPA is emphasizing how to manage wastes solely from the perspective of their infectious properties. EPA realizes that often other properties of an infectious waste -- such as toxicity, corrosivity, ignitability, or radioactivity -- may complicate and often affect the decision on how to manage the waste. This is particularly a problem in research laboratories. EPA therefore warns the reader that when an infectious waste is characterized by any additional hazard, the decision on how to manage the waste must take into account all of the various hazards present in the waste. The person responsible for waste management decisions must weigh the hazards carefully and give priority to the primary hazard that characterizes the waste.

Several federal regulations and guidelines pertain to hazardous properties of wastes other than infectiousness, and these must be taken into consideration. For example, the EPA hazardous waste regulations address the toxic, ignitable, corrosive and reactive properties of wastes (1); Nuclear Regulatory Commission guidelines address radioactive properties (2); and EPA guidelines written under the Toxic Substances Control Act address the total management of certain chemicals (3). Although EPA realizes that the problem of multiple hazards is a very real one to those who must make decisions pertaining to infectious waste management, a detailed discussion of the additional management considerations for wastes posing multiple hazards goes beyond the scope of the current version of this manual.

1.2 State Regulations Pertaining to Infectious Waste

For the most part, State regulation of infectious waste has been carried out by state health departments in the past. Since the passage of the federal solid and hazardous waste act -- the Resource Conservation and Recovery Act of 1976 -- many States have passed hazardous waste statutes that give the State authority to control the treatment, storage, and disposal of infectious waste. Only several States, however, have actually promulgated regulations controlling infectious waste under these statutes.

In the absence of infectious waste regulations under hazardous waste laws, some States control infectious waste under their solid waste laws through the permitting process for sanitary landfills. In addition, most States have general requirements for licensing of hospitals and nursing homes that pertain to infectious waste disposal. Requirements that are specific to hospitals and nursing homes, however, do not pertain to other sources of infectious waste in the State.

It should be noted that there is not unanimity of opinion among the States as to what constitutes safe disposal of infectious waste. The degree of concern regarding the dangers posed by infectious wastes ranges from none to extremely high, and State control of infectious waste that varies from none to the most stringent reflects this range of attitudes.

A complete list of States, statutory authorities and regulations pertaining to infectious waste management, summary of requirements, and responsible State agencies is given in Appendix A.

CHAPTER 2

INFECTIOUS WASTE CHARACTERIZATION

2.1 Introduction

The question of how to define infectious waste has been discussed for years without resolution satisfactory to all interested parties. Regulatory agencies, hospitals, and research laboratories, for example, all have different perspectives that influence their views of infectious waste. There is no general unanimity of opinion about which types of waste should be classified as infectious. Even the terminology that has been used for this type of waste is imprecise -- the terms infectious, pathological, biomedical, biohazardous, toxic, and medically hazardous have all been used at various times to describe similar material. The result has been a proliferation of definitions that are often confusing and sometimes even contradictory. Because the purpose of this manual is to discuss methods of infectious waste management, it is first essential to clarify what constitutes infectious waste.

Infectious or infective is defined as "capable of producing infection; pertaining to or characterized by the presence of pathogens" (4). A pathogen is "any disease-producing microorganism or material" (4). Etiologic agent is defined as "a viable microorganism or its toxin which causes, or may cause, human disease" (5). The related term "biohazard" -- which is defined as an "infectious agent presenting a risk or potential risk to the well-being of man, either directly through his infection or indirectly through disruption of his environment" (6) -- is commonly used, and the biological hazard symbol (see Figure 3-1) is used universally to denote the presence of etiologic agents.

From these definitions it would appear to be simple enough to define infectious waste as "waste that contains pathogens." However, infectiousness as a characteristic of some wastes is difficult to define and impossible to quantify. The difficulties in establishing the definition of infectious waste derive from the characteristics of pathogens, the nature of disease, and the factors that determine the induction of disease. These topics are discussed briefly in this chapter as they relate to the determination of which wastes should be classified as infectious because of their potential for causing illness in people or animals.

2.2 Pathogens

Pathogenic microorganisms include bacteria, fungi, viruses, viroids, rickettsiae, and protozoa. They cause a variety of diseases in many hosts in the animal and plant worlds. In addition to the natural strains of pathogens, there are now strains that are characterized by resistance to antibiotics; such resistant strains are often found in hospitals and other health-care facilities. Most pathogens cause a single disease whereas a few may induce different diseases depending on the route of transmission and the susceptibility of the host. Pathogens are diverse in their physiology and life cycle. Some microorganisms are obligate pathogens (i.e., they can survive only in specific hosts) while others are facultative pathogens (i.e., they can infect hosts to induce disease but they can also survive without a host when environmental conditions are suitable). Similarly, no generalizations can be made about the type of environmenal conditions that are necessary for pathogen survival. Some pathogens are obligate aerobes or anaerobes (i.e., they require aerobic or anaerobic conditions, respectively, for survival) whereas others are facultative aerobes or anaerobes (i.e., they flourish under one set of conditions but they are able to survive under the other). Because of the great natural diversity in environmental conditions, pathogens are ubiquitous in the environment.

Not all pathogens are microorganisms. Many parasites such as the nematodes (helminths) and trematodes (flukes) are higher forms of life. Other pathogenic agents are not viable, but they are produced by living organisms. Bacterial toxins and mycotoxins are examples of this last type of pathogenic agent, specific examples being the bacterial toxins that cause diphtheria and botulism and the mycotoxin aflatoxin that can cause cancer. Disease-causing materials that are neither living organisms (or parts thereof) nor produced by living organisms -- e.g., chemical carcinogens -- are not discussed in this guidance manual.

The pathogens of relevance to this document are those whose presence in various wastes renders the waste hazardous -- that is, a potential cause of disease. The pathogens of greatest concern are those that cause diseases that are severe, difficult to treat, and for which there are no effective and reliable immunizations. Theoretically, it would be useful to have a comprehensive list of all pathogens, especially one which ranks pathogens according to hazard. Different schemes for classifying pathogens have been developed by various experts and organizations. For example, some of these are based on the severity of the hazard that the pathogen presents to the public health (7,8) or to laboratory and

research workers (9-16). None of these classifications, however, is appropriate for use in defining infectious wastes because none takes into consideration all relevant factors such as the obligate nature of some pathogens, resistant strains, pathogen concentrations, the nature of the waste, and the conditions within the waste to which the pathogens are exposed. Nevertheless, as one example, Appendix A presents the list of etiologic agents that was published by the Centers for Disease Control for use in setting minimum packaging requirements for the interstate shipment of materials containing etiologic agents (17).

2.3 Diseases and Disease Induction

Diseases differ greatly in type and severity. Illness need not even be manifest as a disease; it can be subclinical and asymptomatic. Some of the difficulties in establishing a definition of infectious waste are related to the variabilities in disease and in the disease-causing process.

The principal factors that are necessary for the induction of disease include:

- the presence of a pathogen,
- the presence of a susceptible host,
- a route of exposure for transmission of the pathogen to the host,
- exposure to a virulent pathogen, and
- exposure to an infective dose.

These factors are discussed below in general terms as they relate to the definition of infectious waste.

The presence of a pathogen. The induction of disease by pathogens requires the presence of pathogens. Therefore, in order for a waste to be infectious, it must contain pathogens with sufficient virulence in adequate numbers to provide an infective dose. See Section 2.2 for a detailed discussion of pathogens. Pathogen virulence and infective dose are discussed below.

The presence of a susceptible host. Pathogens cause disease in a host, and therefore disease induction requires the presence of a susceptible host. In the general population, there is great variation in susceptibility to disease. Susceptibility depends on a variety of factors that include the person's state of health (or illness), age, general immune

state, and the degree of immunity to a particular pathogen that may have been conferred by previous exposure or immunization. The groups that are most susceptible are the very young, the very old, the chronically ill, and the immune-deficient (as the result of genetics, illness, or treatment).

A route of exposure for transmission of the pathogen to the host. In order for a pathogen to induce disease in a susceptible host, there must be a route of exposure that transmits the pathogen to the host. The principal routes of transmission that are relevant to infectious waste as a source of disease are ingestion, inhalation, and percutaneous transfer. Every exposure route is not necessarily conducive to disease induction; for example, some pathogens are pathogenic only in the respiratory system and they are rendered harmless or are killed in the digestive tract. Ingestion of pathogens can result from eating material that contains the pathogens (contaminated food products, for example). With most infectious wastes, however, it is more likely that ingestion would result from hand-to-mouth transfer of pathogens when hands are contaminated, for example, from handling the waste. Inhalation of pathogens associated with wastes results in the introduction into the respiratory system of air-borne pathogens associated with dust particles or in aerosolized or splattered liquids. Percutaneous transfer occurs when pathogens, present on the skin or in waste that is touched, penetrate the skin through cuts or abrasions, when cuts or puncture wounds are inflicted by sharps contaminated with pathogens, and when animal vectors transmit pathogens by contact with cuts or abrasions or by biting or stinging the host.

Exposure to a virulent pathogen. Pathogen virulence -- i.e., "the degree of pathogenicity of a microorganism as indicated by case fatality rates and/or its ability to invade the tissues of a host; by extension, the competence of any infectious agent to produce pathologic effects" (4) -- varies with the species as well as with the individual microorganism. The virulence depends on numerous factors including the strain of the pathogen, the environmental conditions to which it was subject, and the route of exposure.

Exposure to an infective dose. It is impossible to quantify infective dose -- i.e., "that amount of pathogenic microorganisms that will cause infection in susceptible subjects" (4) -- because the number of pathogens that are required in order to induce a disease varies greatly. The principal factors that determine infective dose are the nature of the pathogen (i.e., species, strain, and virulence), the susceptibility of the host, and the method of transmission.

2.4 Designation of Infectious Wastes

Any definition of infectious waste must take into consideration the factors that have been discussed in this chapter. For a waste to be infectious in the sense that it presents the hazard of causing disease, it must contain pathogens or biologically active material in sufficient concentration or quantity so that exposure to the waste could result in disease.

Testing of wastes for the presence of pathogens is certainly not advocated. The results of such culturing of the wastes would not be meaningful for identifying infectious waste. Negative cultures do not necessarily confirm that no pathogens are present because many microorganisms require very specific conditions for growth and there are some pathogens (e.g., those causing hepatitis) that cannot be cultured. The expense of providing all possible culture conditions and specific tests for every batch of waste, or even for some batches, is not warranted.

Therefore, the most rational approach to defining infectious waste is to designate as infectious those wastes that in all probability contain pathogenic agents that -- because of their type, concentration, and quantity -- may cause disease in persons exposed to the waste. In the interests of clarity and for ease of reference, EPA recommends that 13 types of waste be designated infectious wastes (see Section 2.5). This designation is based primarily on specific waste type rather than on the source of the waste. Therefore, a particular type of infectious waste may be generated by different industries and by more that one source within a facility (see Section 2.6).

2.5 Types of Infectious Waste

After consideration of the comments submitted in response to the proposed regulation on the listing of infectious wastes (18) and after numerous discussions with experts in the affected industries and in the biological safety field, EPA concluded that infectious wastes can be classified into 13 categories. Certain of these wastes (e.g., pathological wastes and sharps) are not necessarily always infectious, but they are included in the list because they should always be handled in accordance with management practices that minimize the hazards and address the special problems of these wastes.

EPA recommends that the following types of waste (as further defined in this section) be considered infectious waste and that they be managed in accordance with the recommendations of this manual:

- isolation wastes
- cultures and stocks of etiologic agents
- blood and blood products
- pathological wastes
- other wastes from surgery and autopsy
- contaminated laboratory wastes
- sharps
- dialysis unit wastes
- animal carcasses and body parts
- animal bedding and other wastes from animal rooms
- discarded biologicals
- contaminated food and other products
- contaminated equipment

2.5.1 Isolation Wastes

Isolation wastes are those that are generated by hospitalized patients who are isolated in separate rooms in order to protect others from their severe and communicable diseases (19). These wastes contain pathogens that are shed by the patients. It should be noted that the wastes from hospital patients who are placed in protective isolation (i.e., isolation imposed only in order to protect these patients from the diseases of others) are not infectious, and these wastes should be handled as part of the general non-infectious waste stream.

2.5.2 Cultures and Stocks of Etiologic Agents

All cultures and stocks of etiologic agents constitute infectious wastes with a particular hazard because the pathogenic organisms are present at high concentrations in these materials. Included in this category are cultures of specimens from medical and pathological laboratories, cultures and stocks of etiologic agents from research laboratories and pharmaceutical companies, and wastes from the production of biologicals and antibiotics by pharmaceutical companies (e.g., eggs used in the production of vaccines).

2.5.3 Blood and Blood Products

The principal hazard in blood and blood products (e.g., plasma, serum) is the possible presence of the hepatitis agent (20). Less common are the pathogens of other diseases (malaria, congenital rubella, disseminated neonatal Herpesvirus hominis, dengue, smallpox, Lassa fever, Marburg virus disease, yellow fever, and Colorado tick fever) in which the etiologic agent circulates in the blood. Hospitalized patients with these diseases are placed in isolation, and the Centers for Disease Control recommends that blood precautions be taken with these patients "to prevent acquisition of infection ... from contact with blood or items contaminated with blood" (19). Even though blood samples are often tested in the laboratory, it is impractical to test for the presence of all infectious agents. In addition, a negative hepatitis virus test, by current technology, only demonstrates that the viral concentration is below the limits of detection. Therefore, all waste blood and blood products should be managed as infectious waste regardless of test results. Hospital and medical laboratories, blood banks, dialysis centers, and pharmaceutical companies generate wastes in this infectious waste category.

2.5.4 Pathological Wastes

Pathological wastes consist of tissues, organs, body parts, blood, and body fluids that are removed during surgery and autopsy. Pathological wastes from patients with infectious diseases should be managed as infectious waste because of the probability that these wastes contain pathogens. However, it is prudent to handle all pathological wastes as infectious because of the possibility of unknown infection in the patient or corpse -- it has been reported that pathogens are consistently removed from the bodies of people who were certified as having died of causes other than infectious diseases (21). Furthermore, there are also other considerations (e.g., aesthetics) that affect practices in pathological waste disposal. The best and simplest procedure is to manage all pathological wastes uniformly. Pathological wastes are usually generated in hospitals in the operating rooms, pathological departments, autopsy departments, and laboratories.*

* Burial practices in this country (22) provide sufficient containment to prevent dispersal of viable pathogens into the environment. Because of the long period of time that would elapse before disintegration of both the outer container (or vault) and the casket, it is highly unlikely that pathogens from the cadaver would still be viable when dispersal would be possible.

2.5.5 Other Wastes from Surgery and Autopsy

The surgery or autopsy of septic ("dirty") cases or patients with infectious diseases generates waste that may be contaminated with pathogens from the patient, and these wastes should be managed as infectious waste. Wastes in this category include soiled dressings, sponges, drapes, casts, lavage tubes, drainage sets, underpads, and surgical gloves. The American Hospital Association recommends that all surgical dressings from patients should be regarded as contaminated whether or not clinical evidence of infection is present (23). Because of the possibility of unknown disease (see discussion of pathological wastes in Section 2.5.4), it would be prudent to manage as infectious all wastes from surgery and autopsy that have been in contact with patient tissues, blood, body fluids, secretions, and excretions.

2.5.6 Contaminated Laboratory Wastes

Contaminated laboratory waste refers to the wastes that were in contact with pathogens in any type of laboratory work -- e.g., in medical, pathological, pharmaceutical or other research, commercial, or industrial laboratories. The variety of wastes in this category includes culture dishes; devices used to transfer, inoculate, and mix cultures; and paper and cloth items that were in contact with specimens or cultures. Wastes from medical and pathological laboratories that are generated in the process of culturing patient specimens pose a special hazard because of the prevalence of resistant strains of microorganisms that have developed in hospitals and other institutions. Table 2-1 lists contaminated wastes that are frequently generated by medical laboratories (24). Contaminated wastes from the culturing and handling of pathogens in research, commercial, and industrial laboratories should also be managed as infectious waste because they are usually contaminated with etiologic agents from pure cultures, often at high concentrations.

In addition, there are the wastes that are generated in research and industrial applications of various biotechnologies (including recombinant DNA). For example, biotechnologies are utilized in vaccine production, fermentation biology, cell biology and virology, microbiology, and other aspects of applied biology and applied microbiology. At this time there is divergence of opinion among experts in the field about the extent and degree of the potential hazard posed by these wastes. Therefore, in the interests of safety, all biotechnological wastes -- that is, from research work as well as from commercial production -- should be managed as infectious waste.

TABLE 2-1

COMMON CONTAMINATED WASTES FROM MEDICAL LABORATORIES (24)

Culture dishes
Pipettes
Syringes and other sharps
Tissue culture bottles and flasks
Membrane filters in plastic dishes
Collection bottles, cups, and tubes from specimens of blood, urine, feces, saliva, exudates, or secretions
Micro-titer plates used for hemagglutination testing, complement fixation, or antibody titer
Slides and plates from immunodiffusion testing
Slides and cover slips from blood specimens or tissue or colony picking
Disposable rubber gloves, lab coats, and aprons
Swabs, capillary tubes, and spreaders used to take or transfer samples containing pathogens
Tubes, cards, tabs and assemblies used for diagnostic purposes to speciate enteric or other pathogens
Centrifuge tubes

Reprinted from Laboratory Management, 16(6): 37-44, 1978.

A special source of contaminated laboratory waste is the maximum containment facility. (Under accepted laboratory practices and the proposed biosafety guidelines prepared by the Centers for Disease Control and the National Institutes of Health (13), certain levels of containment should be instituted to protect the laboratory employees, the general public, and the environment from the etiologic agents that are used in these experiments. [In the United States, containment or biosafety levels are designated 1 through 4 or P1 through P4, with level 4 denoting the greatest degree of containment. The facilities that provide these levels of containment are known as the basic laboratory, containment facility, high containment facility, and maximum containment facility.] The specific biosafety level that is appropriate for a particular experiment depends on the type of etiologic agent involved, its concentration and quantity, and the types of laboratory procedures that are used.) Wastes from the maximum containment facility consist of laboratory wastes, laboratory wastewater, and effluents from showers and toilets. (Wastes from other levels of containment facilities can be classified in the various other categories of infectious wastes -- e.g., stocks and cultures of etiologic agents, sharps -- and should be managed in accordance with the recommendations for those types of waste.)

2.5.7. Sharps

Discarded sharps (e.g., hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) present the double hazard of inducing disease and inflicting injury. The disease potential is great if the sharp was used in the treatment of a patient with an infection or infectious disease; however, even with apparently healthy persons, there is always the possibility of unknown hepatitis. Other contaminated sharps are generated in the inoculation of people or animals. All sharps also pose the hazard of physical injury through cuts or puncture wounds. A typical injury rate from sharps is 15 per month for a 475-bed hospital with an average cost of $65 per injury (25). With good management practices, the hazards of disease and injury from sharps can be minimized. All waste sharps should be managed uniformly in accordance with the practices established for infectious sharps.

2.5.8 Dialysis Unit Wastes

This category of infectious wastes consists of wastes that were in contact with the blood of patients undergoing hemodialysis at hospitals or independent treatment centers. These wastes are classified as infectious because of the high rate of hepatitis among these patients (26,27). The

wastes in this category include disposable dialysis equipment such as tubing and filters and other wastes such as sheets, towels, gloves, aprons, and lab coats. Sharps from dialysis units should be managed in accordance with the practices for all sharps (see Sections 2.5.7 and 3.7.7).

2.5.9 Animal Carcasses and Body Parts

This infectious waste category includes the carcasses and body parts of all animals that were exposed to pathogens in research or were used in the production of biologicals or in the *in vivo* testing of pharmaceuticals as well as those that died of known or suspected infectious disease.*

2.5.10 Animal Bedding and Other Wastes from Animal Rooms

Animal bedding and other wastes that were in contact with diseased and laboratory research animals (as described in Section 2.5.9) or their secretions, excretions, carcasses, or body parts probably contain pathogens shed by these animals.* For this reason, these wastes are designated as infectious.

2.5.11 Discarded Biologicals

This infectious waste category is designated for waste biologicals (e.g., vaccines) produced by pharmaceutical companies for human or veterinary use. These products may be discarded because of a bad manufacturing lot (i.e., off-specification material that does not pass quality control or that is recalled), out-dating, or removal of the product from the market. Because of the possible presence of etiologic agents in these products, the discarded material constitutes infectious waste. It should be noted that wastes from the production of biologicals are included in other infectious waste categories such as stocks and cultures of etiologic agents (Section 2.5.2), sharps (Section 2.5.7), and animal carcasses (Section 2.5.9).

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* Another factor that should be taken into consideration is the prevalence of zoonotic diseases (i.e., diseases transmissible from animals to man) in animal colonies (see Table 2-2 and references 6 and 28). Nearly 200 zoonoses have been identified, and animals or animal tissues are probably involved in 30% to 40% of laboratory-acquired infections (28). Experts in the biosafety field recommend that it may be prudent to regard *all* laboratory animals -- those used in research of infectious diseases as well as apparently healthy laboratory research animals -- as infectious, and also to manage their carcasses, excretions, secretions and bedding as infectious waste.

TABLE 2-2

IMPORTANT ZOONOSES

Species	Disease	Frequency in U.S. Animal Colonies	Severity in Man
Chickens, turkeys, Japanese quail	ornithosis	++	+
	Newcastle disease	++	+
	equine encephalomyelitis	+	+
	salmonellosis	+	+
Mice, rats, hamsters, guinea pigs	lymphocytic choriomeningitis	+	+++
	encephalomyocarditis	+	++
	leptospirosis	+	++
Rabbits	tularemia	+	++
Opossum, skunk, fox	rabies	++	+++
	leptospirosis	+	++
Cats	toxoplasmosis	++	++
	cat scratch disease	+	+
	ringworm	++	+
Dogs	rabies	+	+++
	leptospirosis	+	++
	visceral larva migrans (*Toxocara canis*)	+++	+
Cattle, sheep, goats, pigs	louping ill	+	++
	Q-fever	+	+
	anthrax	+	+
	tuberculosis	+	++
	brucellosis	+	++
	listeriosis	+	+
	contagious ecthyma	+	+
	ringworm	++	+
	vesicular stomatitis	+	+
	cow pox	+	+
	erysipelas	++	++
	leptospirosis	+	+
Nonhuman primates	tuberculosis	++	++
	hepatitis	+	++
	Marburg viral disease	±	+++
	salmonellosis	++	+
	shigellosis	+++	++
	Herpes simiae infection (B virus)	++	+++
	malaria	+	++
	yaba and tanapox	+	+
	measles	++	+
	amebiasis	+	++
	SV 40	++	±
	rabies	±	+++

Courtesy of R.A. Griesemer and J.S. Manning, "Animal Facilities," in *Biohazards in Biological Research*, A. Hellman, M.N. Oxman, and R. Pollack, eds., Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, 1973.

\+ Low frequency or degree of severity.
++ Moderate frequency or degree of severity.
+++ High frequency or degree of severity.

2.5.12 Contaminated Food and Other Products

Food and other products that are being discarded because of contamination with etiologic agents are infectious wastes. Examples of wastes in this category are contaminated foods, food additives, cosmetics, and drugs. In addition, canned food that is recalled because of the danger of botulism resulting from the presence of the toxin of the Clostridium botulinum bacterium should be managed as infectious waste in order to prevent exposure to the toxin, dispersal of the toxin in the environment, and access to the contaminated food.

2.5.13 Contaminated Equipment

Equipment and equipment parts that are contaminated with etiologic agents and are to be discarded constitute a category of infectious waste. These wastes include equipment that was used in patient care, in medical laboratories, in research with etiological agents, and in the production and testing of various pharmaceuticals. Another example is the HEPA filter that is used in biological safety cabinets and in the ventilation systems of biological containment facilities -- if the filter is not decontaminated *in situ*, it should be handled as infectious waste.

2.6 Generators of Infectious Waste

Various industrial, institutional, and research facilities are sources of infectious waste. The largest generators of infectious waste are:

- the health care industry
- academic and industrial research laboratories
- the pharmaceutical industry
- veterinary facilities
- the food, drug, and cosmetic industries

This manual should provide guidance and be useful to these as well as to all other generators of infectious waste.

This section contains a brief discussion of each of these types of facilities as a source of infectious wastes. In addition, various regulations, guidelines, and standards that relate to infectious waste management in these facilities are cited. The deficiencies of these regulations are also noted; they constitute part of the rationale for the need for a manual

that provides guidance on good practices in infectious waste management.

The health care industry is a source of infectious waste because it provides care for sick people many of whom harbor and are shedding pathogens. Furthermore, as was mentioned above, hospitals are reservoirs of resistant strains of pathogens that often are the cause of nosocomial (hospital-acquired) infections.

The Department of Health and Human Services has established minimum requirements for construction and equipment of hospitals and medical facilities. These requirements apply to all such facilities undergoing construction or renovation that are receiving Federal funds. The sections on waste processing services require that general hospitals, long-term care facilities, and outpatient surgical facilities have an incinerator (or access to one) for destruction of pathological and infectious waste (29).

The Joint Commission on Accreditation of Hospitals has instituted a standard for sanitation in hospitals (30). This standard, however, is general and non-specific and does not deal adequately with the topic of infectious waste management. The mortuary industry is not specifically included (see the footnote to Section 2.5.4 on page 2-7).

Academic and industrial research laboratories that work with pathogens or animals or that use various biotechnologies are sources of infectious wastes. The proposed biosafety guidelines for microbiological and biomedical laboratories that were developed by the Centers for Disease Control and the National Institutes of Health included sections on waste management (13); however, these guidelines are being substantially revised and they have not yet been published in final form. The Guidelines for Research Involving Recombinant DNA Technology of the National Institutes of Health (41) are mandatory only for institutions that receive NIH funding for research projects that involve recombinant DNA molecules. Some state and local jurisdictions have extended or are considering extending these guidelines to all activities, academic as well as industrial, that involve use of recombinant DNA biotechnology. Two proposals for major revisions of the Guidelines were published recently (42,43). EPA recommends that the NIH guidelines for waste treatment in the Laboratory Safety Monograph (6) be followed by all who work with recombinant DNA molecules in research as well as in commercial activities. It should be noted that the Guidelines (41) are revised fairly frequently, and the Monograph (6) was updated in January 1979; those in the field should always maintain familiarity with the most recent version of each document.

The pharmaceutical industry generates infectious wastes in the process of producing pharmaceuticals such as biologicals (e.g., vaccines) and antibiotics. Infectious wastes are also generated during the testing of these and other products (e.g., antitumor drugs) for efficacy and safety by means of *in vitro* and *in vivo* studies. When biological products become out-dated and are discarded, infectious waste is generated. Infectious wastes are also generated in the processing of blood and blood components. The United States Food and Drug Administration regulations pertaining to wastes from the manufacture of pharmaceuticals and blood and blood components specify only that the wastes should be disposed of in a safe and sanitary manner (44,45). The United States Department of Agriculture regulations on production of biologicals are nonspecific about waste disposal (46). The United States Food and Drug Administration regulations for nonclinical laboratory studies do not address waste management (47).

Veterinary facilities, including the pet industry and animal supply houses, constitute a source of infectious waste that parallels the human health care industry. The United States Department of Agriculture has promulgated regulations that govern the treatment and disposal of diseased agricultural animals and contaminated animals in the food supply (31-40). However, there are no similar regulations for the pet care industry that pertain to the disposal of diseased animals.

The food, drug, and cosmetic industries generate infectious waste on occasion, but usually not routinely. Examples of such waste are specific lots of food additives, food products, drugs, and cosmetics that are disposed of because they are contaminated. There are no Food and Drug Administration regulations pertaining to methods of disposing of these wastes.

CHAPTER 3

INFECTIOUS WASTE MANAGEMENT

3.1 Introduction

Infectious wastes should be treated properly in order to eliminate the potential hazard that these wastes pose to human health and the environment. EPA recommends that each facility establish a plan for infectious waste management that will ensure proper treatment of the waste and provide for effective and efficient management practices prior to ultimate disposal of the treated waste. Such a plan should cover all aspects of infectious waste management from the time of generation when an infectious material becomes a waste, through treatment of the waste to render it non-infectious, to final disposal of the treated waste.

A waste management plan for an institution should be a comprehensive written plan that includes all aspects of management for different types of waste including infectious, radioactive, chemical, and general wastes as well as wastes with multiple hazards (e.g., infectious and radioactive, infectious and toxic, infectious and radioactive and carcinogenic). In addition, it is appropriate for each laboratory or department to have specific detailed, written instructions for the management of the types of waste that are generated in that unit. The waste management section would probably constitute one part of a general, more comprehensive document that also addresses other policies and procedures. Many such documents that include sections on the management of infectious waste have been prepared by various institutions and government agencies. A few examples pertaining to hospitals are Isolation Techniques for Use in Hospitals (19), Policies and Procedures for the Control of Infections: Cytopathology (48), and Isolation Technique (49). Similar documents that are relevant to research laboratories include Safety Manual for Biological Research Laboratories (50), Laboratory Safety Monograph (6), Biological Safety Instructions (51), Biological Safety Manual for Research Involving Oncogenic Viruses (52), and "Hot" Suite Operations: Standard Operating Procedure (53).

An infectious waste management plan should address the following topics:

- Segregation of the infectious waste stream. Directions for discard of infectious waste directly into separate, special, distinctive containers.

- Handling of the infectious waste. Designation of waste that is to be treated by the technical personnel;

instructions for removal of certain wastes from the room or laboratory by the housekeeping staff for treatment elsewhere (either within the facility or off-site); and special instructions for the housekeeping staff.

- Packaging and transport. Designation of containers to be used for holding the different types of infectious waste during collection and during movement within the facility or off-site for treatment.

- Treatment techniques. The type of treatment that is to be used for each type of infectious waste, and detailed procedures for each treatment process.

- Alternative arrangements. The alternatives to be used if treatment equipment is inoperable and the instructions for storage of wastes, if necessary, if they cannot be promptly treated.

- Disposal methods. Procedures for the disposal of the treated infectious wastes.

An infectious waste management plan cannot be effective unless it is fully implemented. The management plan should designate those persons (e.g., laboratory supervisor, operating room supervisor, principal investigator) who are responsible for implementation of the plan. These people should have the responsibility as well as the authority to make sure that the provisions of the management plan are being followed. In addition, someone should be delegated the responsibility for evaluating the relative hazards in wastes with mixed hazards and for deciding which is the major hazard so that the waste can be managed accordingly, i.e., first according to the greatest hazard followed by treatment for the other hazards as necessary.

Every facility that generates infectious waste should provide training for its employees in infectious waste management. Such education is important for all employees who generate or handle infectious wastes regardless of the employee's role (i.e., supervisor or supervised) or type of work (i.e., technical/scientific or housekeeping/maintenance). Training is necessary for new employees whose work will involve infectious wastes. Training is also necessary whenever a facility changes its infectious waste management practices so that employees will learn what new procedures they should follow and why. Occasional refresher courses for all personnel are also useful and important -- they remind personnel how infectious waste should be handled, and they can also be useful in promoting the infectious waste management plan.

3.2 Infectious Waste Management Options

The objective of infectious waste management is to provide protection to human health and the environment from the hazards of infectious waste by ensuring that the waste is handled properly from the moment of generation through treatment to final disposal of the treated waste. This protection can be assured only if the infectious waste is contained by proper packaging and the integrity of the packaging is maintained throughout. The integrity of the packaging cannot be ensured during landfilling or within a sanitary landfill, and, as a result, containment of the infectious waste might be disrupted with dispersal of pathogens into the environment. Therefore, infectious waste should be treated prior to disposal.

Within the bounds of this practice, there are certain areas in which alternative options are available for the management of infectious waste. These areas include: treatment site (i.e., within the facility, or even in the room where the waste is generated, or off-site); treatment technique or techniques for the different types of infectious waste; specific kinds of equipment for the different treatment techniques; alternative arrangements for waste treatment when treatment equipment is inoperative; and various waste handling practices.

The waste management plan should specify which options have been selected and which practices must be followed. The plan should be as specific as necessary to provide sufficient details. It should be detailed and unambiguous so that it will be evident which management options and practices are to be used in the facility as a whole and which pertain to the particular units or departments where the infectious waste is generated. Adherence to a carefully developed management plan is the only way to maintain full control of the infectious waste and thereby to succeed in protecting people and the environment from the hazards posed by untreated infectious waste.

3.2.1 Treatment of Infectious Waste

The purpose of treating infectious waste is to render it non-infectious by killing the pathogens that are present. Steam sterilization and incineration are the techniques most commonly used to treat infectious wastes. Infectious waste can also be sterilized by treatment with dry heat, radiation, or chemicals. Some sterilization techniques involve a combination of these agents; for example, both heat and radiation are applied during thermoradiation in order to effect sterilization of the waste. The different treatment techniques are discussed in detail in Chapter 4.

Many incinerators of different types have closed down in the last decade because of problems in meeting air quality regulations (especially the standard for particulate emissions). Operation of some pathological incinerators has also been affected by air pollution concerns. There are no regulations pertaining to the emission of viable microorganisms from pathological (or other) incinerators. Nevertheless, regulations and ordinances have restricted the operation of pathological incinerators in some localities because of air quality considerations. In addition, energy conservation policy has resulted in reduced use of some pathological incinerators because of fuel consumption, and some facilities no longer accept pathological and other infectious waste from other generators for incineration.

Incineration plays a unique role in the treatment of pathological waste, and it is also used to treat other infectious wastes. Therefore, it would be advantageous if developments in the state-of-the-art would make feasible continued wide use of incineration as a method for treating pathological and other types of infectious waste. Of course, every incinerator that is used to treat infectious waste must be operated properly in order to ensure effective treatment of the waste (see Section 4.5 for details).

After treatment, most infectious waste may be handled and disposed of as ordinary waste. Therefore, the treated waste may be combined with the general waste stream from the facility for final disposal. For some wastes, however, additional treatment might be necessary before disposal. At the time of disposal, needles and syringes should be non-usable and body parts should not be recognizable, but initial treatment may not have achieved these results (see Sections 3.7.7 and 3.7.4 on treatment of sharps and pathological wastes, respectively). For wastes with multiple hazards, further treatment might be needed to eliminate the other hazards.

It is important to be able to distinguish treated from untreated infectious waste in order to ensure that only treated waste enters the general waste stream. Some treatment methods alter the packaging -- e.g., incineration which burns the waste and its packaging and steam sterilization which crumples many plastic bags. If the treatment process does not produce obvious changes, some method of distinguishing the treated waste should be used immediately after treatment. Suitable procedures include removal or obliteration of biohazard symbols, placement of biohazard bags within paper or opaque plastic bags that mask the red or orange color, and compaction or grinding of the treated infectious waste.

The most common option for disposal is the burial of treated waste or residue from an incinerator in a sanitary landfill. Other, less common, disposal options are suitable for

specific types of treated infectious waste; these include the pouring of liquid wastes down the drain to the sewer system. Certain solid wastes (e.g., pathological) may be ground up and subsequently flushed to the sewer system, if this procedure is in accord with local sewage treatment regulations. Infectious wastes may be treated on-site at the generating facility if the necessary equipment is available. However, infectious wastes may be transported to an off-site treatment facility if on-site treatment is not possible because of an absence or malfunctioning of treatment equipment. For example, many hospitals that do not have pathological incinerators send their pathological wastes to another institution for incineration, or to a mortician for cremation or burial. Some hospitals send all their infectious wastes off-site for treatment at another hospital or at a central community treatment facility.

Off-site treatment of infectious waste is an acceptable alternative to treatment on-site at the facility where the infectious waste is generated, provided that appropriate precautions are taken in packaging and labeling the waste to be transported. In fact, provision for off-site treatment may be appropriate as an alternative arrangement when infectious waste is usually treated on-site. The infectious waste generator should ascertain that the infectious waste is being treated properly at the off-site treatment facility.

Recommendations

The following recommendations pertain to the treatment of infectious waste. For those recommendations that are of a general nature, reference is made to other sections of this manual for details and more specific recommendations.

1. Selection of treatment techniques and location (that is, on-site or off-site) as appropriate for each facility.

2. Arrangements at each facility for alternative methods of infectious waste management in the event that the designated method cannot be implemented (for example, because of equipment failure).

3. Treatment of infectious waste in accordance with the specific recommendations for each waste type (see Section 3.7) and also in accordance with the standard operating procedures developed for each treatment method (see Chapter 4).

4. Treatment of all the hazards in waste with multiple hazards, with priority of treatment assigned to the greatest hazard.

5. Ascertainment by the waste generator that the waste is treated properly, whether the treatment equipment is situated on-site or off-site.

6. Easy and apparent differentiation of treated from untreated infectious waste.

7. Management and disposal of treated infectious waste as non-infectious waste, including possible mixing with the general non-infectious waste stream.

3.2.2 Selection of Management Options

The selection of options for management of infectious waste at a generating facility depends on a number of factors including the nature of the infectious waste, quantity of infectious waste generated, equipment types and applicability, the availability of equipment for treatment on-site and off-site, physical constraints, regulatory constraints, and cost considerations. These factors are discussed in this section in order to provide an overview of the considerations that are involved in decision-making for infectious waste management.

The first factor that should be considered is the nature of the infectious waste that is being generated. Different types of infectious waste should be treated in different ways, as is apparent from the recommendations for treatment of each type of infectious waste that are presented in Section 3.7. Therefore, the types of waste that are generated will determine which treatment methods should be considered.

The quantity of each type of infectious waste that is generated at the facility is another important factor in the selection of management options. If a certain type of waste constitutes only a minor component of the infectious waste stream, its management should not be the focus of the decision-making process. The management options should be selected on the basis of the major components of the infectious waste stream. If a selected option is not suitable for treatment of all the wastes, then other options should be included in the infectious waste management plan as necessary. For example, if a facility generates only a small quantity of pathological waste and that is the only waste for which incineration is the preferred treatment method and there are difficulties in installing or operating a pathological incinerator, then it would be inappropriate to select on-site incineration as the practice for treatment of pathological wastes. It would be better to select a different treatment option (e.g., steam sterilization) that is suitable for most of the waste and to use another option (e.g., off-site incineration) for the pathological waste. Many facilities use a combination of treatment techniques or management options for the different components of the infectious waste stream -- e.g., steam

sterilization for laboratory cultures and other wastes and incineration for pathological waste.

The next factor that should be considered is the type of treatment equipment and its applicability. Different kinds of equipment are needed for the different treatment methods, and various models of each kind of equipment are manufactured that have different features (e.g., size, instrumentation, degree of automation). For example, there are pathological and rotary kiln incinerators, autoclaves and retorts for steam sterilization, etc. The factors pertaining to equipment that should be considered prior to purchase include:

- technical capability (Will it do the job?),
- applicability (Is it suitable for treating the types of infectious waste being generated?), and
- versatility (Is it suitable for treating more than one type of waste? If it will not be used full-time for infectious waste treatment, can it also be used for other purposes?).

Another important factor pertaining to the equipment that would affect the selection of infectious waste management options is the availability of the necessary equipment both on-site and off-site. A facility that generates infectious waste does not have to have all or even part of the treatment equipment situated on-site at the facility. All or part of the infectious waste stream may be transported off-site for treatment. The treatment equipment or incinerator may be situated at another institution or at a special treatment facility. The off-site treatment option may be especially advantageous to generators of small volumes of infectious waste because it would eliminate the need to purchase equipment that would not be fully utilized. Another option is a central treatment facility or incinerator that handles infectious waste from various generators in the area; it could be owned and operated by those whom it serves or it could be an independent operation.

If the purchase of treatment equipment is being considered, certain possible physical constraints should be evaluated. These include:

- space (Is there sufficient space within the building or on the facility grounds?),
- auxiliary equipment (Are the necessary steam or gas lines available and accessible?),
- structure (Will the structure support the additional

weight? Is new construction necessary? Would the ventilating, steam, gas, etc. systems be affected?), and

- traffic patterns (How will equipment location affect the traffic patterns of waste, supplies, and people at the facility?).

Various regulations at the federal, state, and local levels may also be relevant to the selection of infectious waste management options, and regulatory constraints should be assessed during the decision-making process. For example, air pollution regulations could have a direct effect on the use of incineration for the treatment of infectious waste: if the incinerator is subject to the regulations and the air quality standards are not met, operation of the incinerator might be prohibited. It should be noted that there are no air pollution regulations that apply specifically to infectious waste incineration and therefore no standards for emission of viable microorganisms. Conversely, compliance with air pollution regulations does not necessarily mean that the incineration process is properly treating the infectious waste. Since the goal of infectious waste management and therefore infectious waste treatment is to prevent dispersal of viable pathogens into the environment from the waste, the criterion that no viable spores be recovered from the stack gas or the ash should be met whenever infectious waste is treated by incineration. Water quality regulations should also be considered when a system for treating infectious wastewater is being selected and designed -- for example, regulations and standards pertaining to thermal discharges would be relevant to heat sterilization systems while other water quality regulations and standards would be relevant to chemical treatment systems.

It is important also to consider prevailing community attitudes in such matters as site selection for incinerators and other off-site treatment facilities. These include the official legal policies as evidenced by local laws, ordinances, and zoning restrictions as well as the unofficial public attitudes that can be expressed by changes in and adoption of legal positions. The various site alternatives should be evaluated with consideration of all relevant factors including for example type of equipment, the environs, and impacts on the locality (e.g., potential for odors, emissions and noise, effects of traffic).

In addition to matters of technical feasibility and legalities, cost considerations are very important in the selection of the infectious waste management options. For example, for new equipment, capital costs must be considered. For new as well as existing equipment there are operating and maintenance costs that should be planned for; these include:

- labor (Is the option labor intensive? What are the pay scales of the employees who would be operating the equipment?),

- supplies, parts (How often do they need replacement? Are they readily available? Are they expensive?), and

- energy (What are the energy requirements? If steam, for example, is needed, is it available in sufficient quantities? What are the forecasts for supply and cost of fuel?).

The cost effectiveness of each management option should be evaluated and then compared with that of each alternative. For example, the costs of on-site and off-site treatment should be compared.

Therefore, selection of the options for management of infectious wastes should be based on the following considerations:

1. The nature of the infectious waste stream -- that is, the types of infectious waste, the quantity of each, and appropriate treatment methods.

2. Evaluation of types and models of treatment equipment for technical capability, applicability, and versatility.

3. Alternative locations of treatment equipment (that is, on-site and off-site) as well as the option of using equipment jointly with other infectious waste generators.

4. Physical constraints (relevant factors include space, auxiliary equipment, structure, and traffic patterns).

5. All relevant regulations and standards at the federal, state, and local levels and the regulatory constraints that would affect the selection of infectious waste management options.

6. Costs -- that is, capital costs for equipment as well as operation and maintenance costs (including labor, supplies, parts, and energy).

3.3 Segregation of the Infectious Waste Stream

For proper infectious waste management, infectious waste should be separated from all other wastes. Such segregation of infectious waste is important for several reasons. First, the inclusion of all infectious waste in a separate waste

stream will ensure that all such waste will receive the necessary special handling and treatment. Second, there will be no need to screen or search the general waste stream for bags or packages of infectious waste. Third, such a separation system is cost effective, as was demonstrated at the University of Minnesota Hospitals (54). The cost of disposing of infectious waste is greater than the cost of disposing of general non-infectious waste, and, therefore, disposal costs are increased unnecessarily when general wastes are included in the infectious waste stream. A system that properly segregates infectious waste simultaneously prevents the inclusion of non-infectious waste in the infectious waste stream. As a result, with proper management, the incremental cost of infectious waste management will be expended only on those wastes that do require such special handling.

Infectious wastes should be separated from the general non-infectious wastes at the source, that is, at the point where the infectious material becomes a waste, because separation is best done by those who work with the infectious material and who are qualified to assess the hazards of the waste. It is important that the burden of deciding which waste is infectious should not be placed on individuals who are not qualified to make this decision, e.g., the housekeeping and maintenance staffs unless they recieve special instruction. The infectious and the general wastes should be discarded directly into distinctly different containers so that identification of the infectious waste will be readily apparent to everyone who subsequently handles the waste. Futhermore, if the infectious waste is segregated into a separate waste stream at the point of origin, handling will be minimized and therefore the possibility of exposure to pathogenic organisms during handling will also be minimized.

Provision should be made for the segregation of infectious wastes that have multiple hazards according to the types of hazards. These wastes should be combined with other infectious wastes only if (a) infectiousness is the major hazard, (b) treatment for infectiousness will simultaneously provide appropriate treatment for the other hazard or hazards, and (c) commingling of the wastes is suitable and convenient (e.g., it would generally not be advisable to mix radioactive and non-radioactive wastes because of the special protective containers and management required for radioactive materials). If wastes are mixed, management (e.g., labeling and treatment) should be in accordance with the hazards of the various components of the mixture.

All infectious waste containers should be clearly marked with the universal biological hazard symbol (Figure 3-1) which is used to indicate the actual or potential presence of a biohazard (6,17,55,56,57). Alternatively, since red and orange colors are traditionally used to identify biological hazards, plastic

FIGURE 3-1

THE BIOLOGICAL HAZARD SYMBOL

The symbol is fluorescent orange or orange-red. The background may be any color that provides sufficient contrast for the symbol to be clearly defined (6). For specifications of dimensions, see p. 114 of reference 6 (Laboratory Safety Monograph. A Supplement to the NIH Guidelines for Recombinant DNA Research. U.S. Department of Health and Human Services, National Institutes of Health, Office of Research Safety, National Cancer Institute, and the Special Committee of Safety and Health Experts. January 1979).

bags of these colors may be used for infectious waste. However, red and orange should never be used for non-infectious waste, and, therefore, general wastes should be collected in bags of other colors. (See Section 3.4 for recommended specifications for plastic bags.) One example of a good system for separating the infectious from the general wastes, with easy identification of the two waste streams, involves the use of rigid or semi-rigid plastic waste receptacles lined with plastic bags. All the receptacles for infectious waste are round with red or orange plastic bag liners. All the receptacles for general waste are rectangular with non-red liners. With this scheme, the infectious wastes are immediately identifiable by all concerned, that is, the lab personnel and the housekeeping staff as well as emergency response crews (e.g., firefighters and police) who may have to enter the room or laboratory. (Note: only noncombustible plastic or metal waste containers should be used in order to minimize the fire hazard (58).)

For wastes characterized by mixed hazards, the containers should be suitable for the type of waste and types of hazards. Each container should be clearly labeled to indicate the hazards involved. It may also be appropriate to tag these containers with specifications for the type or types of treatment the wastes should receive and the sequence of the treatment processes.

Every waste management plan should also include instructions for the handling of contaminated re-usable items. Re-usables are not part of the waste stream until they are discarded. Nevertheless, because they are generated in the same rooms and laboratories as are the disposable items, the management of re-usable items should also be addressed in a waste management plan. Separation of re-usable from disposable items is best accomplished at the source, that is, at the point of discard. This practice minimizes the need for subsequent handling and therefore is important from considerations of both safety and efficiency. Such separation is also essential because many plastic items are heat-labile and melt during steam sterilization; melted plastic fuses to glassware (for example) and cannot be removed, and therefore the affected items cannot be re-used. Re-usable items that are infectious should be placed after use directly into a separate container; items like syringes, needles, and pipettes should be placed horizontally into a pan of chemical disinfectant.

Recommendations

The following recommended practices pertain to segregation of the infectious waste stream. For details about containers and packaging, see Section 3.4.

1. Placement of the infectious wastes and the general non-infectious wastes into separate containers with further separation of the re-usable from the disposable items. Placement of infectious wastes with multiple hazards into separate containers as necessary for subsequent management and treatment.

2. Discard of infectious wastes directly into suitable containers at the point of origin.

3. Distinctive and clear marking of the containers for infectious waste. For example, use of red or orange plastic bags for infectious waste but never for general waste. Marking of boxes and bottles for infectious waste with the universal biohazard symbol (and with other symbols also as necessary to indicate the presence of other hazards).

4. Tying, sealing, or tight covering of containers of infectious waste when full or at the end of the shift.

3.4 Packaging of Infectious Waste

The purpose of properly packaging infectious waste is to provide containment of the waste so as to protect handlers of the waste as well as the public from injury and disease that might be caused by contact with the waste. Such containment is essential from the moment the waste is discarded until it has been treated. The type of packaging depends on the type of waste, whether it will be moved within the facility or transported off-site, and how it will be treated.

It is important to note that some packaging materials and packaging methods may be suitable for containing the waste, but they can interfere with the effectiveness of treatment. Therefore, the type of packaging that is selected should be appropriate for the intended method of treatment. For example, plastic containers can impede treatment when conduction of heat is an important factor in the treatment process (e.g., in the steam- and dry-heat-sterilization methods) because plastic is a poor conductor of heat. Packaging considerations that are specific for each type of treatment are discussed in detail in Chapter 4.

Plastic bags are frequently used to collect many types of infectious waste. However, numerous problems may be encountered when plastic bags are used to collect and to contain infectious waste. It is important to be aware of these potential problems because plastic bags are now in common usage. The problems relate primarily to the following factors:

- Preserving the integrity of the package,
- Handling before and during transport,
- Interference with the effectiveness of treatment, and
- Side effects of treatment.

These factors are discussed below.

Preserving the integrity of the package. The integrity of the package will be disrupted and pathogens could be dispersed in the environment if a plastic bag containing infectious waste is torn or otherwise opened before the waste is treated. Such disruption may result from separation at a seam, from puncturing or tearing by a sharp object either from within or outside the bag, or from rupturing caused by overfilling. These problems can be alleviated somewhat, but not eliminated completely, by measures such as: using only seamless, tear-resistant plastic bags; not placing sharp items or items with sharp corners in the bags; not filling a bag beyond its weight and volume capacity; and exercising special care during handling in order to keep the plastic bags from coming into contact with external sharp objects.

Handling during transport. Extra care must be exercised in order to prevent tearing whenever plastic bags containing infectious waste are handled and especially when they are moved. For example, mechanical devices should not be used to load onto a truck plastic bags that contain infectious waste because of the possibility that the bag will be torn in the process. Good practices for handling the plastic bags include: loading the bags by hand, transporting the loaded dumpster in order to minimize handling, and placing the plastic bags within rigid or semi-rigid containers before handling and transport.

Interference with the effectiveness of treatment. Plastic bags can interfere with the effectiveness of treatment by preventing sufficient exposure of the infectious waste to the treatment agent (e.g., heat or chemical). In steam sterilization, for example, plastic bags (sometimes even those designated as "autoclavable") can prevent proper treatment by trapping air within the bag or by otherwise impeding steam penetration, thereby preventing the waste from attaining the necessary treatment temperature (59, 60). Plastic is a poor conductor of heat, and therefore the use of plastic bags in both the steam and dry heat treatment methods will necessitate longer treatment times than if a good heat conductor such as metal is used to contain the waste. In

gas/vapor treatment, the plastic bag must be permeable to the chemical in order for the treatment to be effective. The effects of plastic bags and possible remedies to the problems created by their use are discussed in the sections in Chapter 4 on steam sterilization (Section 4.4), dry heat treatment (Section 4.6), and gas/vapor treatment (Section 4.7).

Side effects of treatment. In steam sterilization and dry heat treatment, the heat can melt heat-labile plastic and thereby disrupt the integrity of plastic bags. Melting or crumpling of the plastic can result in spillage of waste within the autoclave or oven. This would cause clean-up problems and could also clog the drain of the autoclave. (Selection of waste containers suitable for steam sterilization and dry heat treatment is discussed in Sections 4.4 and 4.6, respectively.) When infectious waste in plastic bags is incinerated, the chlorine content of the plastic can create problems. Two specific problems are the formation during the incineration process of corrosive hydrochloric acid and of highly reactive free radicals. The problems can be minimized to some extent by using only bags of non-chlorinated plastic -- e.g., not polyvinyl chloride -- to contain waste that will be treated by incineration; however, these problems cannot be eliminated if the chlorine content of the waste itself is high. (See Section 4.5 on incineration for details.)

Collection in plastic bags is suitable for most infectious wastes (the exceptions, sharps and liquids, are discussed below). For containment purposes, the plastic should be seamless, impervious, and tear resistant (e.g., a minimum thickness of 3.0 mils when single bags are used, 1.5 to 2.0 mils with double bagging). For aesthetics, the plastic should be opaque. The bags of infectious waste should be tied securely closed to contain the waste. However, a loose tie may be more appropriate when the waste will be steam sterilized; if the waste is to be transported within the facility or off-site before such treatment, the bag should be tied tightly or placed within a container that is covered with a tightly fitting lid. For identification purposes, the bags should be the distinctive red or orange color that signifies biohazardous material. As was mentioned above, the use of plastic bags may not be suitable when the infectious waste is transported to an off-site treatment facility (see also Section 3.6) and when certain treatment methods are used (see also Chapter 4).

An alternative to plastic bagging is the use of plastic, metal, or glass receptacles to contain infectious waste during movement within the facility or off-site, and also sometimes to contain it during treatment. These containers

may be used with plastic liners. If such liners are not used or if they are not sealed, the containers should be covered with secure lids during movement and storage. The lids may have to be opened or removed during the treatment process.

Sharps should receive special containment because they present a special hazard of physical injury in addition to their infectious hazard. They should be packaged in a way that eliminates the possibility of contact during subsequent handling, treatment, and disposal. After use, sharps should be placed directly into special containers. Needles should not be recapped because of the possibility of injury by self-inoculation (61). Furthermore, contaminated needles should not be broken or clipped unless the clipping device effectively contains aerosols and needle parts. Otherwise, the aerosol or splatter that is generated during clipping might contain pathogens that were present on the needles, and there is also the possibility of injury from needle parts that might become airborne (62). (See Section 3.7.7 for details on management of sharps after treatment.) Containers for sharps should be impervious, rigid, and puncture-proof (that is, capable of withstanding crushing and also punctures by sharps). Suitable materials for sharps containers include glass, metal, rigid plastic, wood, and heavy cardboard. Sharps containers should be sealed, and they should be marked with the universal biohazard symbol (6,17,55,56,57).

One management system for handling disposable sharps that has received some attention involves placement of used sharps directly into pans of disinfectant, followed by steam sterilization treatment and subsequent clipping of the treated needles and syringes. Although this type of treatment removes the infectious hazard, the hazard of physical injury from the sharps nonetheless remains. Because of the potential for physical injury, EPA therefore believes that it is not prudent to retrieve needles from a loaded pan, to handle them, and to clip them. The preferable management system for sharps is placement directly into a puncture-proof container so that subsequent handling (of the container) is without risk of physical injury from the sharps.

Liquid infectious wastes should be contained in bottles or flasks that are capped or tightly stoppered. The bottles and flasks should be marked with the universal biohazard symbol as should any boxes or containers into which they may be placed. Infectious wastewater may be contained and then treated in batches within a closed system (e.g., a tank); however, if the wastewater is directed to a continuous flow treatment process, no special containment other than the piping system is necessary.

3. Discard of sharps directly into impervious, rigid, puncture-proof containers. Placement of intact needles directly into collection containers -- that is, without recapping, clipping, or breaking (see text for exception).

4. Discard of liquid infectious waste in capped or tightly stoppered bottles and flasks.

5. Marking of all containers (except plastic bags -- see recommendation #1), as well as any container into which they may be placed, with the universal biohazard symbol (and with other labels, as necessary, to denote multiple hazards).

6. No compaction of infectious waste or packages of infectious waste prior to treatment.

7. Use of packaging materials that are appropriate for the type of treatment. (See Chapter 4 for a discussion of the packaging factors that are important to the effectiveness of the different treatment methods.)

8. Use of packaging materials that are strong enough to remain intact during whatever type of handling, storage, and transfer the packages may undergo.

3.5 Storage of Infectious Waste

Infectious waste should always be treated as soon as possible after generation, preferably the same day. However, this is not always possible -- for example, treatment equipment may be unavailable because of insufficient capacity or malfunction; there may be insufficient time to treat that day; or personnel may be unavailable because of employee absence, the time of day, or the day of the week. Some special situations may necessitate temporary storage of the infectious waste. For example, if an incinerator is operated on a 5-day-a-week schedule, the waste may have to be stored over the weekend. If treatment equipment is temporarily inoperable while undergoing maintenance or repair, waste may have to be stored while alternative arrangements for treatment are being made.

Four primary factors are important in infectious waste storage -- the integrity of the packaging, the storage temperature, the duration of storage, and the storage area.

Packaging of waste that must be stored temporarily prior to treatment should be carefully evaluated. Packaging serves to contain the waste. It is also an important factor in excluding rodents and vermin that may be animal vectors of disease.

Storage temperature is important for two reasons. One is biological -- most microorganisms grow rapidly at warm temperatures, especially when an organic substrate is present. The other is aesthetic -- decomposition begins rapidly at warm temperatures, and the odors can be very unpleasant. Temperature and time are interrelated -- that is, the colder the temperature, the longer the acceptable period of storage. However, as was noted above, storage times should be kept as short as possible. If infectious waste cannot be treated immediately, it should be stored no longer than one day at room temperature (18°-25°C, 64°-77°F) or three days in a refrigerator (1°-7°C, 34°-45°F) or 90 days in a freezer (at -10°C, 14°F or lower). These recommendations are for total storage time prior to treatment, regardless of whether the waste is stored at the generating facility or at a separate treatment facility. It is realized that in some situations (in many hospitals for example), infectious waste that is generated during the weekend must be held until Monday for treatment because of staffing practices. It is preferable that infectous waste be kept no longer than one day at room temperature; however, this may be impossible when refrigerator storage capacity is insufficient to contain the weekend accumulation of infectious waste. In these circumstances, it is especially important that the stored waste be properly contained (e.g., in containers with tightly fitting covers) and that it be kept in a secured storage area.

All unpreserved pathological wastes and animal carcasses should be placed immediately into a refrigerator or freezer where they should be kept until treatment.

The storage area should be located at the treatment site or as near to it as possible. The security of the storage area is also important. The area should have limited access -- that is, only by authorized personnel -- in order to restrict the entry of persons who have no knowledge of the hazards inherent in the stored infectious waste. The storage area should be kept free of rodents and vermin. The biohazard label should be posted on the door as well as on the waste containers, refrigerators, and freezers.

Recommendations

EPA makes the following recommendations concerning the storage of infectious waste:

1. Avoidance of storage of infectious waste by treatment of the waste as soon as possible, preferably the same day it is generated.

2. Minimization of storage time, with storage in refrigerator or freezer if storage time exceeds one day (see text for details).

as well as some research laboratories and pharmaceutical companies. After treatment, the liquid portion of the blood may be decanted into the drain while the remainder can be disposed of together with the general waste stream, or all the treated waste may be disposed of with the general waste stream.

Although it has been recommended that untreated excess blood from laboratory specimens and untreated bulk blood be poured down a drain (61), EPA regards this practice as imprudent because there is not sufficient evidence that this disposal procedure is safe. At present there is divergence of opinion about whether hepatitis is transmissible through inhaled aerosols. If it is, then the aerosols that are generated in pouring blood down a drain constitute a risk to the person who is disposing of the blood in this manner. In addition, large quantities of whole blood should not be discarded into the drain because coagulation of the blood could clog the plumbing. Other considerations about disposal of infectious wastes to the sewer system are discussed above in the introduction to Section 3.7.

Recommendations

EPA's recommendations for treatment and disposal of blood and blood products are as follows:

1. All blood and blood products: steam sterilization or incineration in accordance with the determined standard operating procedures.

2. Other wastes associated with blood and blood products: steam sterilization or incineration.

3. Treated blood, blood products, and associated wastes: disposal with the general non-infectious waste stream. Any liquid may be decanted into the drain to the sewer system.

3.7.4 Pathological Wastes

In addition to the biohazard of pathological waste, other considerations that affect the management of this type of waste are aesthetics and religious practices. From biohazard considerations, pathological waste should be treated by incineration or steam sterilization before disposal. For aesthetic reasons, recognizable body parts should not be disposed of in a landfill, and, consequently, most pathological wastes are incinerated. For religious reasons, some patients prefer that their body parts (for example, amputated limbs) be transferred to a mortician for burial in a cemetary or for cremation.

Some hospitals that do not have access to a pathological incinerator send their pathological wastes to morticians for treatment and disposal. Mortuary practices are generally adequate to eliminate or contain any biohazard in the waste. (See footnote on page 2-7.)

Alternatively, pathological waste may be treated by a two-step procedure that first sterilizes the waste and then renders it unrecognizable before disposal. Such treatment consists of steam sterilization followed by incineration or by grinding of the waste and flushing it to the sewer system in accordance with state and local regulations. Treatment of pathological waste by steam sterilization followed by grinding and flushing to the sewer system would be appropriate, for example, when burial is not requested and pathological incineration is not available.

Recommendations

EPA recommends the following alternatives for the treatment and disposal of all pathological wastes:

1. Incineration in a pathological incinerator in accordance with the standard operating procedures determined for this type of waste. The incinerator ash may be disposed of in a sanitary landfill.

2. Treatment by steam sterilization followed by incineration. The incinerator ash may be disposed of in a sanitary landfill.

3. Treatment by steam sterilization followed by grinding of the waste and flushing to the sewer system.

4. Handling by a mortician with burial in a cemetary or cremation.

3.7.5 Other Wastes from Surgery and Autopsy

Surgery and autopsy wastes from infectious and septic (that is, "dirty") cases should be treated by steam sterilization or incineration. This is the general practice in hospitals.

Recommendations

EPA recommends the following alternatives for the treatment and disposal of surgery and autopsy wastes from infectious and septic cases:

1. Steam sterilization in accordance with the determined standard operating procedures.

2. Incineration in accordance with the determined standard operating procedures.

3.7.6 Contaminated Laboratory Wastes

Contaminated wastes from laboratories at biosafety levels 1, 2, and 3 or levels P1, P2, and P3 should be treated by steam sterilization or incineration.

All wastes from laboratory work that requires maximum containment because of the type, virulence, or quantity of etiologic agent present (i.e., wastes from biosafety level 4 or P4 laboratories) should be sterilized prior to disposal. Solid and containerized liquid wastes should be steam sterilized before they are removed from the laboratory; this should be done in pass-through double-door steam sterilizers to ensure that all waste that leaves the laboratory has been sterilized. Liquid effluents from maximum containment facilities should also be treated. Laboratory wastewater should be sterilized by heat or radiation while effluents from the auxiliary facilities (for example, hand-washing sinks, toilets, and shower rooms) should be treated with heat, radiation, or chemicals.

Large scale laboratory work or commercial production can generate large quantities of liquid waste (e.g., from fermentation vessels). These wastes should be treated before disposal. The preferred treatment technique for this waste is steam sterilization. Alternatively, the liquid waste may be heat sterilized, either by continuous flow or batch treatment, or it may be treated with chemicals if the method is in accordance with procedures that have been demonstrated to be effective. When available, gamma-irradiation may be used to treat the wastewater.

Additional sources of information on the management of various laboratory wastes are available. These include the biosafety guidelines for microbiological and biomedical laboratories that are being developed by the Centers for Disease Control in conjunction with the National Institutes of Health (the original draft (13) is being substantially revised). Guidelines for certain aspects of biotechnology, specifically the use of recombinant DNA technology, appear in Guidelines for Research Involving Recombinant DNA Molecules of November 1980 (41) and the supplementary Laboratory Safety Monograph of January 1979 (6); these are revised occasionally so the reader should always consult the most recent edition.

Recommendations

EPA recommends the following alternatives for the treatment and disposal of contaminated laboratory wastes from laboratories at biosafety levels 1, 2, and 3 or levels P1, P2, and P3:

1. Steam sterilization in accordance with the standard operating procedures determined for this type of waste.

2. Incineration in accordance with the determined standard operating procedures.

EPA makes the following recommendations for the treatment of wastes from biosafety level 4 or P4 (i.e., maximum containment) laboratories:

1. All solid and containerized liquid wastes: steam sterilization in a pass-through double-door steam sterilizer before removal from the laboratory in accordance with the standard operating procedures determined for the particular type of waste.

2. Laboratory wastewater: heat sterilization (or gamma irradiation, if available) prior to discharge into the sewer system.

3. Effluents from auxiliary facilities: treatment with heat, radiation, or chemicals prior to discharge into the sewer system.

EPA recommends the following alternatives for the treatment of liquid wastes from large and commercial scale production:

1. Sterilization by steam or heat (or gamma irradiation, if available) in accordance with the determined standard operating procedures.

2. Alternatively, chemical treatment in accordance with procedures demonstrated to be effective.

3.7.7 Sharps

Sharps present the double hazard of disease transmission and physical injury. Therefore, the handling, treatment, and disposal of sharps should be governed by consideration of these two factors. As was mentioned above in the discussion of packaging (Section 3.4), sharps should be placed directly into rigid puncture-proof containers at the site of origin in order to avoid injury of subsequent handlers. Sharps should be treated before disposal in order to eliminate the disease

potential. Steam sterilization is the recommended treatment method; it is commonly used for treating sharps.

Many states have regulations that require the destruction of needles and syringes so that they cannot be re-used after discard. All needles and syringes should be rendered non-usable before disposal. This can be achieved by grinding or compaction after treatment. Alternatively, the sharps can be heated in an oven so that the syringes melt and the sharps are enclosed within the resultant block. Clipping of sterilized needles and syringes after treatment is not advisable; although treatment will have removed the infectious hazard, the sharps will still pose a hazard of physical injury during handling and possibly also during clipping.

Recommendations

EPA recommends the following procedures for the handling, treatment, and disposal of sharps:

1. Treatment by steam sterilization in accordance with the standard operating procedures determined for this type of waste.

2. Destruction of the treated sharps by grinding or compaction prior to disposal. Alternatively, heat treatment to melt the syringes into a block with the sharps.

3.7.8 Dialysis Unit Wastes

The principal biohazard of infectious wastes from dialysis units is the hepatitis agent. Therefore, these wastes should be treated before disposal by incineration or steam sterilization. This recommendation is consistent with the recommendations for treatment of the specific components of the infectious waste stream from dialysis units (e.g., blood, sharps, laboratory wastes).

Recommendations

EPA recommends the following alternatives for the treatment of infectious wastes from dialysis units:

1. Incineration in accordance with the standard operating procedures determined for these wastes.

2. Steam sterilization in accordance with the standard operating procedures determined for these wastes.

3.7.9 Animal Carcasses and Body Parts

Management of animal carcasses and body parts is similar to that of pathological wastes described above. There are two main considerations -- removal of the infectious agent and destruction of the carcass. Incineration is a treatment technique that accomplishes both goals simultaneously.

Because of the high pressure in a retort, steam sterilization in a retort followed by grinding up of the treated waste and flushing to the sewer system is another suitable method for treatment and disposal of this type of waste; however, long cycles (e.g., eight hours) are necessary, and it is important to validate the duration of treatment by testing. Steam sterilization in autoclaves has only limited use in treatment of animal carcasses because of size constraints and the long treatment times that are necessary in order to effect sterilization. For example, Barbeito and Gremillion (64) reported that eight hours of autoclaving was still not sufficient time to effect sterilization of guinea pig carcasses in a fiberboard container and that tight packing of the carcasses within the container prolonged the time required for sterilization. Nevertheless, autoclaving can be useful in two applications: to decontaminate the surface of a carcass before it is transported through a facility to an incinerator, and to treat small carcasses and body parts before they are ground up and flushed to the sewer.

Rendering is another treatment method that has traditionally been used to dispose of the carcasses of diseased animals. For example, under the U.S. Department of Agriculture regulations for the control and eradication of livestock and poultry diseases, rendering is acceptable treatment for the carcasses of cattle destroyed because of tuberculosis and swine destroyed because of hog cholera (32,36). Therefore, rendering in a rendering plant is an acceptable alternative for the treatment and disposal of animal carcasses and body parts that constitute one type of infectious waste.

Recommendations

EPA recommends the following alternatives for treatment and disposal of animal carcasses and body parts:

1. Incineration in accordance with the standard operating procedures for this type of waste. When more virulent etiologic agents are involved and the carcass must be transported through a facility to the incinerator: preliminary autoclaving of the carcass for one hour at operating temperature in order to decontaminate the surface of the carcass. After incineration, disposal of the residue in a sanitary landfill.

2. Steam sterilization in a retort, in accordance with

the standard operating procedures for this type of waste, followed by grinding up of the treated waste and flushing to the sewer system.

3. Autoclaving of small carcasses and small body parts in accordance with the standard operating procedures determined for this type of waste. The treated waste may be disposed of by grinding and flushing to the sewer system, or it may be incinerated and the residue disposed of in a sanitary landfill.

4. Rendering in a rendering plant.

3.7.10 Animal Bedding and Other Wastes from Animal Rooms

A number of treatment methods are suitable for sterilizing animal bedding and other wastes from animal rooms. (It should be noted that this section refers only to animal bedding and other animal wastes from diseased and laboratory research animals as defined in Sections 2.5.9 and 2.5.10.) These methods include incineration and treatment with gases or vapors, dry heat, or radiation. In addition, steam or chemical treatment may also be appropriate for some of these wastes. However, these last two methods are not recommended for the treatment of large quantities of animal bedding because animal bedding has certain characteristics that interfere with the effectiveness of the steam and chemical treatment processes.

Sterilization is accomplished with steam when the waste material, including that at the center of the load, is exposed to sterilizing temperatures for a minimum period of time (see Section 4.4 for a detailed discussion of steam sterilization). However, animal bedding is a poor conductor of heat (and a good insulating material), and, therefore, even after several hours of steam treatment, the center of a load of animal bedding will not have reached the required temperature if the layer of bedding is too deep or if it is contained in a plastic bag or a plastic container (see Table 3-3). The addition of water to animal bedding before steam treatment also impedes the heating of the waste load (Table 3-3). Therefore, testing and standardization of procedures are essential in order to ensure the sterilization of animal bedding.

The most efficient technique for steam sterilization is to treat the bedding in shallow layers within metal pans. It is recommended that animal bedding be steam sterilized directly in the collection pans (for which metal is the best material because of its high heat conductivity). This practice provides the advantage of sterilizing the bedding and the equipment simultaneously as well as minimizing handling of the waste

TABLE 3-3
TESTS OF EFFECTIVENESS OF STEAM TREATMENT OF ANIMAL BEDDING

Treatment Conditions[a]	Time for Center of Load to Reach Sterilizing Temperature[a]	Treatment Conditions[b]	Temperature of Bedding 2 Inches from Bottom[b]	
			At start	After 50 minutes
Bedding 1 inch deep in nested metal animal cages, 250°F	2 hours	Pelletized corn cob bedding 5 inches deep in 13-quart container:		
		Steel container	26°C	104°C
Bedding 3 inches deep in nested metal animal cages, 250°F	4 hours	Polypropylene container	24°C	77°C
		1000 ml of water added to steel container	29°C	76°C
32 gallons of moistened bedding in garbage cans, 250°F	>4 hours[c]	1000 ml of water added to polypropylene container	27°C	48°C

[a] Data from Barbeito and Gremillion (64).

[b] Data from Lauer (65).

[c] Time requirements vary with the type of microorganism, moisture content, density of load, and other physical parameters.

and worker exposure to pathogens in the aerosols that are generated when bedding is dumped or scraped from the collection pans (see below). After treatment, the sterilized bedding can be safely scraped into a container for disposal with the general waste stream.

Animal bedding is also difficult to treat effectively with chemicals (chemical treatment is discussed in detail in Section 4.9). Many chemical disinfectants react with the organic matter that is present in the waste, and therefore the chemical must be added in sufficient quantity to ensure that an excess remains for killing of the pathogens. Stirring is also necessary to ensure contact of the chemical with all the waste. Chemical treatment is an appropriate method for sterilizing animal bedding only when small quantities of bedding are to be treated and only after tests of the procedures have led to standardization of techniques.

Another important factor that should be considered in the process of selecting a technique for treating animal bedding is aerosol generation during bedding changes. Fecal material may contain more than one billion bacteria per gram (66), and the bacterial count in the room air often rises from a base level of less than 5 colony forming units (cfu) per cubic foot to 50-200 cfu per cubic foot during bedding changes (28). Handling of the waste and exposure to pathogens can be minimized: (a) by treating the bedding before it is scraped from the collection pans, (b) by using a vacuum system to collect the untreated bedding instead of dumping it, or (c) by confining scraping procedures to the interior of an operating biological safety cabinet that is specially designed for disposal of bedding (67).

Recommendations

EPA recommends the following practices for the treatment of animal bedding and other infectious wastes from diseased and laboratory research animals (as defined in Sections 2.5.9 and 2.5.10):

1. Incineration in accordance with the standard operating procedures determined for this waste.

2. Steam sterilization of animal bedding in the collection pans or cages in accordance with the standard operating procedures determined for the steam sterilization of this waste.

3. Alternatively, treatment with gases or vapors, dry heat, or gamma radiation in accordance with the standard operating procedures determined for the treatment of animal bedding.

4. Chemical disinfection of small quantities of animal bedding in accordance with the standard operating procedures determined for the chemical treatment of animal bedding.

3.7.11 Discarded Biologicals

Biologicals that are discarded should first be treated to destroy the biological activity of these products. Because biologicals are thermolabile (that is, sensitive to and unstable under heat), the three treatment methods that involve application of heat are suitable for treating this type of waste. Steam sterilization and incineration are commonly used to treat discarded biologicals. Incineration provides the additional advantage of destroying labels and often the packaging as well so that the products are no longer indentifiable. Treatment with dry heat is equally effective but usually more costly.

Biologicals are discarded in the original packaging which is usually glass vials with banded rubber stoppers. If the glass melts during incineration, problems with slagging might develop. It has also been reported that a layer of molten glass on top of the waste might insulate the waste material, thereby preventing proper incineration and complete combustion of the waste. Therefore, the tests that are run to determine the standard operating procedures for incineration of biologicals should also demonstrate which operating conditions will provide proper treatment to the waste while minimizing problems that could result from melting of the glass. For example, optimum conditions for incineration of biologicals may entail lower temperatures and longer residence times than are optimum for incineration of other infectious wastes.

Recommendations

EPA recommends the following alternatives for the treatment of discarded biologicals:

1. Steam sterilization in accordance with the standard operating procedures determined for this type of waste.

2. Incineration in accordance with the standard operating procedures determined for this type of waste.

3. Treatment with dry heat in accordance with the standard operating procedures determined for this type of waste.

3.7.12 Contaminated Food and Other Products

Products that are being discarded because of biological contamination should be treated before disposal. This will ensure the safety of the people who handle the waste as well as those who may come upon these items after they have been discarded. The contaminated materials may be in solid or liquid form in any of various types of packaging. Factors that affect selection of a suitable treatment method include the nature of the contamination (that is, type and concentration of etiologic agents present), the type of contaminated material, its volume, the type of packaging (e.g., boxes, bottles, cans), and the availability of treatment facilities. The types of treatment that are effective for most contaminated products are incineration, steam sterilization, and treatment with gases or vapor. For each type of contaminated material, the treatment method should first be tested to establish that it provides effective treatment. Incineration provides the additional advantage of destroying labels and often the packaging as well so that the products are no longer identifiable.

Food products that are found to be contaminated with the toxin of Clostridium botulinum are normally recalled by the manufacturer for destruction or reprocesssing. Because this toxin is one of the most potent poisons, an entire lot of processed food is recalled whenever the presence of toxin is demonstrated or suspected in any can in the lot and whenever processing conditions were such that toxin formation is possible. The special problems associated with the disposal of this type of waste derive from the possible presence of botulinal toxin in some of the cans; the difficulty in preventing pilferage of the food during storage, transport, treatment, and disposal; and the volume of waste which is frequently quite large although only a small portion may actually be hazardous. Therefore, effective management of this type of waste should minimize the risk to those who handle the waste and eliminate the possibility that contaminated food will be consumed, while providing an option for local disposal so that prolonged storage and transport are not necessary.

In order of preference, three management alternatives are recommended: (a) incineration in a rotary kiln; (b) treatment in a retort, steamer, or autoclave followed by destruction of the cans; and (c) crushing and burial of the cans in a sanitary landfill. The specifics for each alternative are discussed below in detail. Appropriate personal protection (e.g., gloves, protective clothing, face masks) should be used whenever there is a possibility of exposure to the toxin from leaky cans or aerosols because the toxin is hazardous by various routes of exposure, i.e., by ingestion, inhalation, and percutaneous transfer (68). Any spills or leakage should be cleaned up with an alkaline solution (e.g.,

0.1 M solution of sodium hydroxide) or with sodium hypochlorite to denature the toxin (68, 69).

When incinerated, the cases of contaminated food should be fed intact into the rotary kiln. This treatment simultaneously destroys the food. The ash may be disposed of in a sanitary landfill.

Alternatively, the cases of food should be treated in a retort or autoclave, or steamed a in steamer, with treatment of sufficient duration to destroy the toxin. Because bacterial spores might survive this treatment, the cans should be destroyed immediately after treatment to prevent pilferage and consumption. This can be accomplished by, for example, destruction in a hammermill or crushing with a bulldozer. After treatment and destruction of the cans, the waste may be disposed of in a sanitary landfill.

The final alternative, if permitted by the local jurisdiction, is disposal of untreated waste in a sanitary landfill in a manner that minimizes the risks of exposure during the disposal process and that ensures destruction of the toxin and the cans. Crushing the cans within a sanitary landfill releases the botulinal toxin into the soil where it will be destroyed by soil microorganisms while the landfill provides protection of the groundwater. At the same time, crushing ensures that the food cannot be pilfered and eaten. For this alternative, the following procedures should be followed:

- The food product should be disposed of immediately upon arrival at the landfill in order to minimize opportunities for pilferage;
- The intact cases of food should be placed in a single layer in trenches that are located away from other disposal operations;
- The cases should be covered with a one-foot layer of earth (to inhibit aerosol genertion) and should then be immediately compacted by a bulldozer in order to destroy the cans; several layers of cans may be compacted within a single trench;
- The crushed cans should be covered with a final two-foot layer of compacted earth;
- In accordance with FDA practice, an FDA representative, U.S. marshall, or local public health official should oversee the operation to ensure proper disposal and prevention of pilferage;

- The bulldozer operator and all others present at the disposal operation should use appropriate personal protection gear.

Recommendations

The following alternatives are recommended for the treatment of contaminated products:

1. Incineration in accordance with procedures demonstrated to be effective.

2. Steam sterilization in accordance with standard operating procedures for this type of waste.

3. Treatment with gases or vapors in accordance with procedures demonstrated to be effective.

For food products contaminated with botulinal toxin, the following three alternatives -- in order of preference -- are recommended:

1. Incineration in a rotary kiln in accordance with recommended procedures (see text for details).

2. Heat treatment in a retort, autoclave, or steamer in accordance with procedures demostrated to be effective (see text for details), followed by crushing of the cans.

3. Crushing of the cans within a sanitary landfill in accordance with the specific procedures detailed in the text.

3.7.13 Contaminated Equipment

Contaminated equipment, and parts thereof, that are being discarded should first be treated in a way that destroys all etiologic agents. Sterilization is preferable to decontamination to ensure protection of human health and the environment. Any treatment technique that results in sterilization is appropriate. The effects of treatment on the integrity and the functioning of the equipment need not be considered because they are immaterial with equipment that is being discarded. Treatment techniques that may be applicable are steam sterilization, incineration, irradiation, and treatment with heat, gases or vapors, and chemicals.

Selection of a treatment technique should be based on the nature of the contamination (that is, type and concentration

of etiologic agents present), availability of treatment equipment, feasibility, and cost considerations.

Recommendations

The following EPA recommendations pertain to the treatment of discarded contaminated equipment:

1. Treatment before disposal of contaminated equipment and parts that are being discarded.

2. Use of a treatment technique (steam sterilization, incineration, irradiation, or treatment with heat, gases or vapors, or chemicals) in accordance with operating procedures that are demonstrated to be effective.

CHAPTER 4

TECHNIQUES FOR TREATMENT OF INFECTIOUS WASTE

4.1 Introduction

The purpose of treating infectious waste is to change its biological character by any method, technique, or process so as to render the waste non-hazardous and safe for disposal. Three general types of treatment are suitable for treating infectious waste: heat treatment (i.e., the use of steam heat, incineration, or dry heat), chemical treatment (i.e., the use of chemicals in gaseous or liquid form), and irradiation. The techniques that are used most frequently to treat infectious waste are steam sterilization and incineration. However, each of the techniques has its advantages (and disadvantages) and is appropriate for treating different types of infectious waste (see Section 3.7).

In Sections 4.4 to 4.9, each of the following treatment techniques is discussed in detail:

- Steam sterilization
- Incineration
- Dry heat sterilization
- Gas/vapor sterilization
- Irradiation
- Chemical disinfection

The use of other treatment methods is discussed in Section 4.10. The reader is referred to the literature for more information on the principles of sterilization, waste sterilization, and the different treatment techniques. See, for example, references 6, 70, 71, 72, 73, 74, and 75.

The reader is reminded of the repetitious nature of this manual, particularly certain elements in each of the later sections of this chapter. Each section of this chapter is complete in all aspects pertaining to the particular treatment technique, even at the risk of repeating some discussions and recommendations. Also mentioned repeatedly in this chapter are the problems relative to particular treatment techniques that are encountered when plastic bags are used to contain infectious waste; this matter is discussed in detail and from a general perspective in Section 3.4.

4.2 General Approach to Treatment of Infectious Waste

The sterilization of supplies, instruments, equipment, and products has long been standard practice in health care, pharmaceutical, and many research facilities and institutions. Sterilization procedures have been standardized in terms of types of supplies, package size and density, type of package wrapping, loading volume and configuration, and processing variables. There has not been, however, a similar standardization of the procedures for terminal sterilization -- that is, sterilization of infectious waste before disposal.

There is concern in the biological safety field that persons may derive a false sense of security from using a particular treatment technique without considering the numerous variables that determine the effectiveness of that treatment. Various studies reinforce the validity of this concern; they have demonstrated that, for example, pathological incineration and autoclaving do not always accomplish sterilization (59, 60,71,76,77,78). Indeed, as a consequence of the recent EPA endeavors to develop regulations for infectious waste management, some institutions have undertaken experiments to ascertain whether the procedures that are now being used do indeed sterilize the infectious wastes. Some of the preliminary test data were surprising because they demonstrated that the established procedures do not always sterilize the waste.

Standardization of infectious waste treatment methods is necessary to ensure the effectiveness of the treatment in achieving terminal sterilization. The approach to terminal sterilization that is recommended by EPA is the concept of standard treatment loads with development (by consideration of the relevant variables in operating conditions and practices) of standard operating procedures that will be used to treat each standard load. This approach requires standardization of both waste loads and operating practices, and it therefore entails the following procedures:

1. Designation of standard loads,

2. Determination, by testing, of the operating conditions and practices required for each standard load to ensure sterilization of the waste,

3. Development of standard operating procedures, and

4. Establishment of a periodic monitoring program using biological indicators placed in the waste.

The designation of standard treatment loads is recommended because the characteristics of the load (in terms of variables such as type of waste, density, moisture content, packaging, size, and loading configuration) have significant impact on

the effectiveness of treatment. Therefore, the first step in developing standard operating procedures for each method of infectious waste treatment is to designate standard loads. Alternatively, a single worst-case load that is the most difficult to sterilize can be designated the standard load for each treatment technique. The alternative of a single worst-case standard load for a given treatment method may be preferred for simplicity of operations or when the composition of the infectious waste stream is so variable that the designation and use of different standard loads would be too cumbersome or even impossible. The alternative of using several standard loads involves different treatment cycles that are tailored to the requirements of these loads and, therefore, this alternative provides the advantage of savings in time, energy and/or materials relative to the treatment cycle for the worst-case load. Whichever alternative is selected, the various relevant factors should be carefully controlled and recorded. The significance of the specific variables in load characteristics that are relevant for each treatment technique is discussed below in Sections 4.4 to 4.9. Each standard load should be described in sufficient detail so that subsequently it will be possible to reconstitute it easily.

For each treatment technique there are a variety of possible operating conditions and practices (e.g., temperature, pressure, concentration, time, feed rate), and these should be standardized in terms of the standard treatment loads. Therefore, the second step in the procedure is to determine which operating conditions and practices must be instituted with each standard load to ensure that the waste is being properly treated. This determination should be made through a testing program in which standard loads are subjected to treatment while the operating variables are carefully controlled and recorded. Monitoring of the effectiveness of treatment (see below and Section 4.3) will provide data on the effectiveness of each set of conditions in treating the various standard loads.

The data obtained by testing should be used to establish standard operating procedures for infectious waste treatment by each treatment technique. These standard operating procedures should be developed in written form for each treatment method that is used at each treatment facility and should be posted near the treatment equipment. In addition, it is important that all individuals who will be treating infectious waste be educated in the standard operating procedures that have been developed and be trained to operate the equipment effectively.

Sterility of the waste is the only criterion that can be used to ensure destruction of pathogenic organisms. Therefore, sterilizing the waste should be the objective of every infectious waste treatment process. Monitoring the effectiveness of treatment is necessary in order to develop the standard operating procedures. Monitoring should also be done periodically thereafter to provide verification that the standard operating procedures are being implemented and that the equipment is functioning properly. The frequency of monitoring depends on the treatment technique (see Sections 4.4 to 4.9 for specifics). Monitoring is discussed in detail in Section 4.3.

4.3 Monitoring

The effectiveness of the treatment process in achieving sterilization can best be monitored by using biological indicators (71). Biological indicators are standardized products that are routinely used to demonstrate the adequacy of the sterilization process (74). They consist of preparations of specific microorganisms that are resistant to particular treatment methods. Bacterial spores are the microorganisms that are used as biological indicators for the sterilization process because they are much more resistant than other microorganisms (that is, vegetative bacterial cells, fungi, and viruses). Therefore, if bacterial spores are killed by a given treatment process, it is reasonable to assume that this indicates that all microorganisms were killed by that processing.

Spores of the various species of bacteria differ in their resistance to the different sterilization processes. Therefore, the more resistant species have been selected for use as biological indicators, and it is now standardized to use spores of a resistant strain of a particular bacterial species for testing each specific treatment process. In Table 4-1 are listed some biological indicators and the treatment processes for which they are suitable indicators as recommended by The United States Pharmacopeia (74,79).

There are many commercial preparations of biological indicators for verification of the sterilization process. These include spore strips (strips of filter paper holding specified numbers of spores) and ampules (which contain the spores in a culture medium). The specifications for biological indicators include suggested performance characteristics for resistance to the treatment process (79); that is, the spores should survive a specific time under the treatment conditions but be killed within a specified time limit (see Table 4-1). This resistance "window" minimizes the occurrence of false negative and false positive readings and thereby enhances the reliability of the biological indicators in demonstrating

TABLE 4-1

BIOLOGICAL INDICATORS FOR MONITORING
INFECTIOUS WASTE TREATMENT[a]

Biological Indicator	Treatment Process	Resistance Data	
		Survives	Killed
Spores of Bacillus stearothermophilus	steam sterilization	250°F 5 min.[b,c] 270°F 20 sec.[c]	250°F 15 min.[b], 270°F 2 min.[c]
Spores of Bacillus subtilis variety niger (globigii)	dry heat	250°F 30 min.[c]	300°F 60 min.[c]
	ethylene oxide	15 min.[b,d]	120 min.[b,d]
	incineration	e	e
	chemicals	e	e
Spores of Bacillus pumilus	ionizing radiation	e	e

[a] Data from The United States Pharmacopeia. pp. 1038-1039 of the 20th revision (1980) and pp. 710-711 of the 19th revision (1975). United States Pharmacopeial Convention, Inc., Rockville, Maryland.

[b] Suggested performance characteristics (79).

[c] Typical performance characteristics (80).

[d] At 600 mg ethylene oxide/liter, 130°F, and 60% relative humidity.

[e] Data not available.

the achievement of sterilization.

The commercial preparations of biological indicators also differ in the number of spores present in each unit (e.g., 10^8 versus 10^4). Use of preparations with more rather than fewer spores is preferable because it increases the reliability of the test. Furthermore, when the waste is especially hazardous (e.g., from biosafety level 4 and P4 laboratories), it may be advisable to use several different preparations of biological indicators in each waste load.

In using biological indicators, certain procedures should be followed. The indicators should be placed within the waste load, processed with the waste, and then retrieved at the end of the treatment cycle. They should then be incubated in an appropriate culture medium for the designated period of time. All commercial preparations of biological indicators specify the culture conditions that should be used -- that is, culture medium (if not supplied), incubation temperature, and incubation time. After incubation, the spores should be examined for signs of growth. Sterilization is indicated by the absence of viable spores.

The disadvantage that is inherent in the use of biological indicators for monitoring infectious waste treatment is the minimum 48-hour incubation period prior to determination of the presence or absence of viable spores. Such verification is standard practice in clinical laboratories, for example, and the use of a "device which indicates proper sterilization" or "an adequate recording thermometer" is required of those laboratories that receive Medicare funds (81). Nevertheless, it is obviously impractical for all treated infectious wastes to be retained until the results of monitoring can be ascertained, and EPA does not recommend that all treated wastes be held in storage routinely. Treated waste should be retained before disposal for verification of the effectiveness of the treatment process during standardization of loads and procedures for new wastes, new equipment, or new techniques.

There are other indicators that provide an instantaneous indication -- usually by a chemically induced color change -- of the achievement of some condition (e.g., attainment of a certain temperature or exposure to ethylene oxide gas). However, these indicators are not suitable for use in monitoring the sterilization process because each treatment technique involves a combination of factors and therefore no single factor is a valid criterion of the effectiveness of the process. For example, in the steam and dry heat treatment methods, the wastes must be exposed to a certain temperature for at least a minimum period of time in order to achieve sterilization. Therefore, any indicator that indicates only the attainment of a particular temperature is not suitable for monitoring the effectiveness of infectious waste treatment

when time is a factor that is equally as important as temperature. There are some indicators that do integrate time and temperature; however, these do not seem to be sufficiently standardized and reliable for use in monitoring sterilization (82,83). Similarly, the indication of mere exposure to ethylene oxide does not mean that the degree of that exposure has been sufficient (in terms of time and gas concentration) to achieve sterilization. Until other indicators have been standardized for use in monitoring the sterilization process, biological indicators should be used in all monitoring.

It is essential that the indicators be properly placed within the waste load so that they will indicate the effect of the treatment on the waste at the interior of the load. Ascertaining that the outside of a package of infectious waste has been sterilized provides no information about the effect of treatment on the waste inside the package. There are only a few exceptions to this including treatment of contaminated equipment (when placement of biological indicators on the surface may be appropriate) and treatment of food products contaminated with the toxin of Clostridium botulinum (because of the risk of exposure in opening the container (69)). Otherwise, for accurate monitoring, the biological indicators should be distributed throughout the waste load. It is also important that the indicators be placed within waste situated at those locations within the treatment chambers where treatment conditions are not optimum (for example, near the drain of a steam sterilizer) so that monitoring will provide accurate data on the worst-case conditions.

As was mentioned above, monitoring is essential in development of standard operating procedures for each treatment technique to verify that the treatment process is achieving sterilization. Monitoring also permits refinement of the standard operating procedures so that excess processing can be avoided while savings are realized in expenditures of time, energy, and/or materials. Subsequent periodic monitoring serves to verify sterilization, thereby verifying that proper procedures were used and that the equipment was functioning properly. Specific recommendations for monitoring the different treatment techniques (i.e., appropriate biological indicator and frequency of periodic monitoring) are included in the discussions of the treatment techniques (see Sections 4.4 to 4.9). The recommended monitoring frequencies are less frequent than those that are standard practice for the same processes when supplies are treated (84,85).

Recommendations

EPA makes the following recommendations for monitoring infectious waste treatment:

1. Monitoring of all treatment processes to establish standard operating procedures for treatment of standard loads of infectious wastes.

2. Subsequent periodic monitoring of the treatment processes, as recommended in Sections 4.4 to 4.9 for the different treatment techniques, in order to verify that the infectious waste is being sterilized.

3. Use of biological indicators to monitor the efficacy of infectious waste treatment. Placement of the biological indicators within and throughout the waste load and processing with the waste. Retrieval of the indicators, culturing in accordance with the manufacturer's instructions, and examination of the biological indicators after incubation. Sterilization is indicated by an absence of viable spores.

4.4 Steam Sterilization

The equipment that is used for steam sterilization is known as a steam sterilizer or autoclave. A pressure vessel called a "retort" has also been marketed recently for the steam sterilization of infectious waste. There are two general types of steam sterilizers -- the gravity displacement type, in which the displaced air flows out the drain through a steam-activated exhaust valve, and the pre-vacuum type, in which a vacuum is pulled to remove the air before steam is introduced into the chamber. With both types, as the air is replaced with pressurized steam, the temperature of the treatment chamber and of the waste load increases. When all the air is removed and replaced with steam, the saturated steam that is essential for accomplishing sterilization is present within the treatment chamber. For a detailed discussion of the theory and practice of steam sterilization, see reference 71.

The operating temperature of the steam sterilizer is related to the steam pressure. Most gravity displacement steam sterilizers operate at 121°C (250°F) with saturated steam at 17 to 18 psi within the chamber, although some units of this type operate at 132°C (270°F). Pre-vacuum steam sterilizers operate at 132°C (270°F) with saturated steam at 27 to 32 psi within the chamber. A typical retort operates at 132° to 135°C (270° to 275°F) with chamber pressure at 35 to 38 psi.

The criteria used to set minimum exposure times for steam sterilization are the kill times for Bacillus stearothermophilus spores exposed to wet heat, e.g., 15 minutes at 121°C (250°F) (79). Kill times at various temperatures are listed in Table 4-2 (86). In practice, exposure times are usually

TABLE 4-2

STEAM STERILIZATION[a]

Temperature		Spore Kill Time[b]
(°F)	(°C)	(minutes)
240	116	30
245	118	18
250	121	12
257	125	8
270	132	2
280	138	0.8

[a] Data from Table 1A in reference 86 (E. Hanel, Jr. Chemical Disinfection. In: Control of Biohazards in the Research Laboratory, Course Manual. The John Hopkins University, School of Hygiene and Public Health, Baltimore, Maryland. 1981).

[b] In steam sterilization, exposure time for treatment is usually at least double the kill time (71).

at least double the kill times in order to provide an adequate margin of safety (71). With steam sterilization of infectious wastes, it is essential to ensure that the entire waste load has been exposed to the necessary temperature for the required period of time. Heating of the containers and the waste usually lags behind the heating of the chamber (71,73).

There are reports that the commonly used (and even prolonged) treatment times are often not sufficient to sterilize wastes because the center of the waste load does not reach the sterilizing temperature (59,60,64,76,87,88). One method of ascertaining when the interior of a load has attained the proper temperature is to use thermocouples. However, thermocouples are not standard equipment for steam sterilizers. It is important, therefore, that the principles of steam sterilization be understood and be used in the development of standard operating procedures.

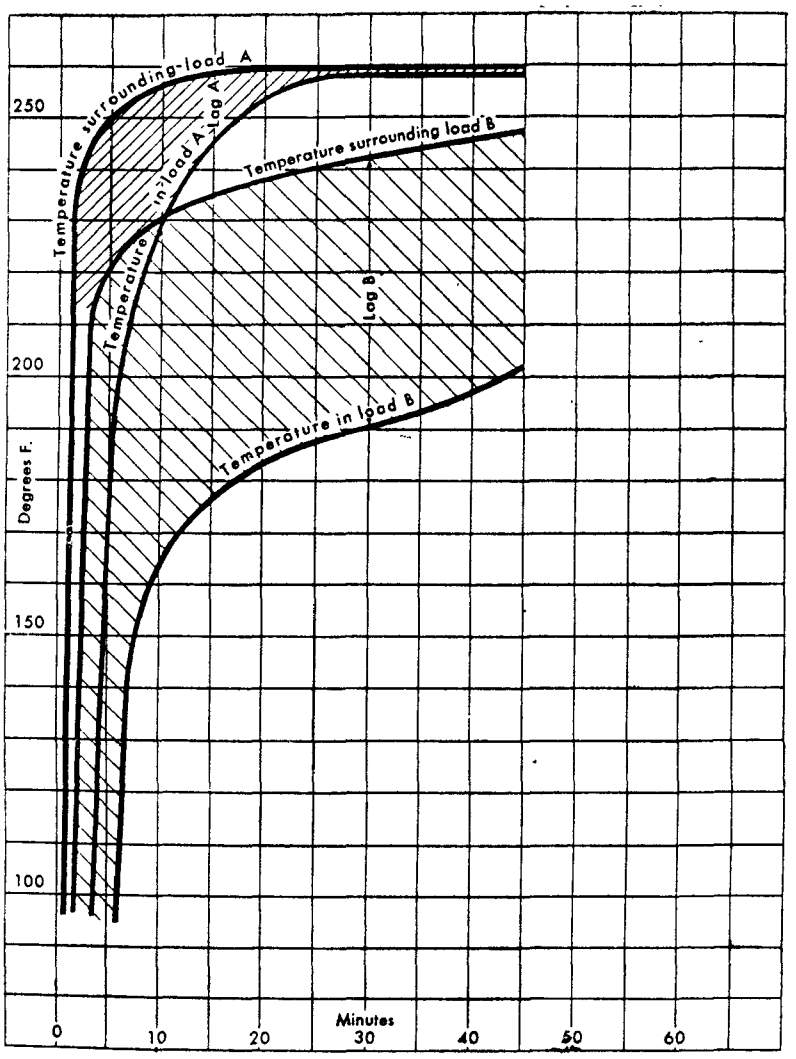
In steam sterilization, heating of the waste occurs by two mechanisms: steam penetration and conduction of heat. Steam is lighter than air, and therefore the air must be completely displaced in order for the steam to penetrate throughout the waste load. The presence of air within the sterilizer chamber can prevent effective sterilization by: (a) reducing the ultimate possible temperature of the steam, regardless of pressure; (b) causing variations in temperature throughout the chamber because air and steam do not mix readily; (c) prolonging the time needed to attain the maximum temperature; and (d) inhibiting steam penetration into porous materials (71). The temperature curves in Figure 4-1 illustrate the effects on load temperature of the presence of air in the sterilizer chamber.

Other problems can result from the use of plastic bags (which may exclude steam or trap air), plastic containers (which are poor conductors of heat), and deep containers (which may prevent displacement of air from the bottom). Therefore, packaging, containers, and loading considerations are of critical importance to the efficacy of the steam treatment process. The factors that should be considered in designating the standard loads for steam sterilization include the following:

- Type of waste
- Packaging materials
- Integrity of the package
- Type of containers
- Addition of water to bags or pans

FIGURE 4-1

TEMPERATURE CURVES FOR STEAM STERILIZATION WITH AND WITHOUT COMPLETE REMOVAL OF AIR (71)



Courtesy of American Sterilizer Company, Erie, Pa.

Run A: when air was completely discharged from the chamber, temperature in package rapidly approached that of surrounding steam. Run B: when only a small amount of air was discharged, temperature in package lagged about 50°F behind that of surrounding steam throughout the 45-minute exposure. Pressure was maintained at 20 pounds. Loads A and B were identical.

- Volume of the treatment load and its configuration in the treatment vessel

Type of Waste. For factors that are relevant to the steam sterilization of specific types of infectious waste, see the discussion of the recommended treatment techniques for the different waste types in Chapter 3. The type of waste (body tissue, paper, rubber, plastic, glass, liquid) is an important factor in steam sterilization because the density of the waste affects the degree of steam penetration. Waste type also determines the type of packaging and the containers that are used. If different types of waste are to be steam sterilized, the composition of the standard loads should be designated according to types of waste, either singly or in standardized combination that is based on the composition of the infectious waste stream. Testing of the steam sterilization process to develop standard operating procedures may indicate that changes in standard loads (e.g., to a single type of waste such as petri dishes or flasks of liquid) will provide greater efficiency in processing. Alternatively, a worst-case load can be designated the standard load, with all loads being processed in accordance with the standard operating procedures determined for this load that is most difficult to steam sterilize.

Packaging materials. The type of material that is used to package the infectious waste for steam sterilization can hinder the treatment process. For example, it may be difficult to achieve steam sterilization of waste contained in plastic bags, especially if the bags are sealed (see below). Plastic bags are convenient for collecting many types of infectious waste, but the disadvantages of plastic must be understood when loads and operating procedures for steam sterilization are standardized. Plastic bags are manufactured from different types and thicknesses of plastic. Heat-labile plastic crumples and melts during steam sterilization and therefore should not be used when waste will be steam sterilized unless the plastic bag is placed within a strong paper bag or another container. Minimum thicknesses are specified for plastic bags used to contain infectious waste (3.0 mils for single bags, 1.5 to 2.0 mils when double bagging is used), but this thickness might interfere with the effectiveness of treatment. Even some so-called "autoclavable" plastic bags do not permit the penetration of steam (59,60). Therefore, the type of packaging used to contain wastes that will be steam sterilized should be appropriate for steam sterilization in order to assure efficacy of the treatment process.

Integrity of package. The integrity of the package -- that is, whether the plastic bag or the box or the pan is closed or open during treatment -- affects the ability of the steam to penetrate the package. It has been reported that longer exposures are required to steam sterilize waste in closed packages. Karle's study (76), for example, demonstrated that sterilization of a load of petri dishes in a plastic bag was best achieved when the top of the bag was folded back to the level of the top of the waste. However, as Karle noted, because of the potential hazard, this procedure is not recommended if the bag contains infectious waste (89). Some procedures that have been recommended include tying the bag loosely (87) and puncturing the bag before it is treated (61). It is important to remember that open bags and pans of infectious material constitute a potential hazard for dispersal of pathogenic agents into the environment. Therefore, if the infectious waste is transported through the facility to a steam sterilizer, any bag that is open or not securely closed should be conveyed within a container that is covered with a tightly fitted lid. Bags and pans should be opened, if necessary, only within the steam sterilizer. Other methods to enhance displacement of air from the bag (e.g., adding water to the bag, placing the bag in a shallow metal pan -- see below) should also be evaluated during standardization of the waste loads for steam sterilization.

Type of containers. Plastic bags are often placed in rigid containers to prevent spilling. The use of metal containers is advantageous in steam sterilization because metal is a good conductor of heat which therefore decreases the time required for the waste to attain sterilizing temperature. By contrast, plastic containers are poor conductors of heat and even prolonged cycles may not be sufficient to bring the waste to sterilizing temperature. The waste can be sterilized directly in the metal containers, or other packages such as plastic bags and cartons can be placed in metal containers in the steam sterilizer. Rubbo and Gardner (73) and Litsky (87) reported that shallow pans allow more rapid steam penetration than deeper containers and buckets.

Addition of water. There are some reports that the addition of water to the bag or pan of waste can help to ensure sterilization and to decrease treatment time by providing for steam generation and air displacement within the bag or pan (see, for example, reference 73). Different amounts of water have been recommended ranging from 100 milliliters (61) to one liter (87). Rubbo and Gardner (73) reported that the addition of one liter of water to metal containers greatly accelerated air removal. However, there are other reports that the addition of

water to plastic bags does not ensure sterilization (60,88), and that the addition of water to animal bedding slows the heating of the waste (65). Therefore, the effect of adding water to the waste should be evaluated, and, if the addition of water to plastic bags and other containers is effective, this practice should be standardized.

Volume and configuration of the waste load. The volume of the waste can be an important factor in the efficacy of the steam sterilization process. It can be difficult to attain sterilizing temperatures in large loads; it may be more efficient to autoclave a given quantity of waste in two small loads rather than one large load (76). In addition, the configuration of the load within the sterilizer affects the penetration of the steam throughout the load -- the steam must be able to move freely to the bottom of the sterilizer. Laying a bag or container on its side can facilitate the removal of air and is appropriate if such placement will not result in spilling within the autoclave (87).

Therefore, loads of infectious waste for steam sterilization should be standardized with due consideration of the variables in the factors discussed above. The standard load should be described in writing. The detailed description should address the variables without ambiguity and should provide specifics about the type of waste, quantity, size of the package, how it is closed, use of other containers, whether water is added and if so how much and when, how many packages are treated per load, how they are arranged within the autoclave or retort, and all other relevant details. From such a description, it should be possible to reconstitute easily the standard waste loads for steam sterilization.

When the standard loads have been designated, tests should then be run to determine the necessary operating conditions for each standard load. The temperature is a function of the steam pressure, and the principal variable in operating conditions is the length of the cycle. The total length of the cycle includes the heating, processing, and cooling phases. It is important to remember that a minimum time at temperature is necessary to kill the pathogens, and during this time the waste must be at sterilizing temperature.

Determination of standard operating procedures for steam sterilization will provide the necessary information for setting the length of the cycle to ensure that all of the waste is exposed to the proper temperature for sufficient time. (For example, 30 minutes might suffice for one standard load, but processing times of 60 to 90 minutes, or even longer, might be necessary with other loads.) When the operating conditions required for the sterilization of each

standard load have been determined, the standard operating procedures should be developed in written form and posted near each steam sterilizer that is used to treat infectious waste.

It should be noted that improper operating techniques can result in the dispersal of etiologic agents into the environment through the drain and the exhaust vent of the steam sterilizer. For example, such dispersal can occur when infectious waste is handled roughly or spilled within the autoclave. It has been reported that, when high vacuum steam sterilizers are used, viable microorganisms from the waste might be released to the atmosphere with the vented steam; this is most likely to occur when aerosols can be generated during loading and evacuation (e.g., from liquid wastes or animal bedding) (90). The possibility of pathogen release can be minimized by installing appropriate filters in the drain and exhaust lines. Various types of filters are available (e.g., roughing, HEPA, and chemical filters), but selection, installation, and maintenance must be done with care. The safety of steam sterilization can also be enhanced by other design features such as provision for proper exhaust and heat dissipation (i.e, not in the breathing zone of operating personnel) and by careful placement of the unit (i.e., away from traffic).

Additional precautions should be taken when certain wastes are steam sterilized because of multiple hazards in the waste as well as hazards created by the treatment process. For example, volatile chemicals and those that might be volatilized during steam sterilization should be autoclaved only if there are chemical (i.e., hydrophobic) filters on line. Radionuclides should be steam sterilized only if properly packaged to ensure that radioactivity is not dispersed within the sterilizer and into the drain and exhaust lines.

All individuals who will be steam sterilizing infectious waste should be properly trained to operate the equipment effectively. They should be educated in the procedures that have been developed for making up the standard loads and for using standard operating procedures. It is these individuals who are ultimately responsible for implementing the procedures.

In addition, personnel should be educated in the proper techniques to use in order to minimize personal exposure to the various hazards they might encounter while steam sterilizing infectious waste. These techniques include (a) avoidance of aerosol formation during waste transport (e.g., by proper packaging and sealing); (b) minimization of aerosol formation during autoclave loading (e.g., by avoiding rough handling of the waste, by loosening caps of liquid containers and removing pan lids only after the waste has been placed within the autoclave); (c) prevention of spillage of waste

during autoclave loading; and (d) use of equipment for personal protection as necessary (e.g., laboratory coats, rubberized aprons, insulating gloves that are impervious to liquids, respirators as necessary).

All steam sterilizers should be routinely inspected and serviced. Routine maintenance should include daily checking of the strainer, weekly flushing of the chamber drain, and weekly checking of the controls and data signals. Manufacturers recommend preventive maintenance by certified personnel on a quarterly basis. Servicing should include calibration of the thermometer.

Operation of the steam sterilizer should be logged with a recording thermometer which registers on a recorder chart. This simple device records the temperature at the drain line. The log should be checked routinely to ascertain that a sufficiently high temperature was maintained for an adequate period of time during the cycle. Failure to attain or maintain operating temperature is an indication of mechanical failure.

Bacillus stearothermophilus is the appropriate biological indicator to use in monitoring steam sterilization because the spores are very resistant to steam heat. After standard operating procedures have been established, the steam sterilization process should be monitored periodically to verify that proper procedures are being followed and that the equipment is functioning properly. A schedule of about once every two weeks would be appropriate for monitoring the steam treatment of infectious waste; this is less frequent than the at-least-once-a-week monitoring with Bacillus stearothermophilus spores that is recommended for the steam sterilization of supplies (84,85). However, when the waste is from a biosafety level 4 or level P4 laboratory, each load should be monitored with biological indicators and the treated waste should be retained before disposal until sterilization has been verified.

4.5 Incineration

In incineration, the waste is combusted, producing gases and a non-combustible residue or ash. The product gases are vented to the atmosphere through the incinerator stack while the residue from incineration of infectious waste may be disposed of in a sanitary landfill. Incineration provides the advantage of greatly reducing the mass and volume of the waste -- often by more than 95 percent -- which, in turn, substantially reduces transport and disposal costs.

An incinerator that is used to treat infectious waste may be situated on-site at the facility where the infectious waste

is generated or at some off-site location. Any incinerator may be used to treat infectious waste if it properly incinerates the waste by killing the pathogens and destroying any biologically active material that may be present. Two types of incinerators (the pathological incinerator and the rotary kiln) and the concept of "total incineration" are addressed briefly below. The remainder of this section provides a detailed discussion of the technique of treating infectious waste by incineration.

Pathological incinerators have traditionally been used for the incineration of pathological waste as well as some other types of infectious waste. Most pathological incinerators are multi-chambered with relatively small capacity; they provide high combustion temperatures and can be operated intermittently. Because of their design and operating characteristics, pathological incinerators are appropriate for the incineration of infectious waste when they are operated properly (see below). The intermittent mode of operation is suitable for incineration of pathological and other types of infectious waste because these wastes are seldom generated in sufficiently large quantities by a single facility to provide enough feed for a continuous-feed incinerator. Most large hospitals and medical centers have pathological incinerators on the premises; pathological incinerators are often found in smaller hospitals also, as well as in large research facilities. Many research laboratories use pathological incinerators -- either their own or others to which they have access.

A rotary kiln is much larger than a pathological incinerator, and it is therefore usually found in an industrial setting. It provides a controlled environment which, coupled with its rotation, facilitates complete combustion of the waste. The rotary kiln is the traditional type of incinerator that is used to treat many types of hazardous waste. It is now also being used to treat infectious waste. For example, a rotary kiln is used by at least one pharmaceutical company to incinerate production wastes, including infectious waste. Rotary kilns are used in some commercial incineration operations to treat various hazardous wastes including infectious wastes.

In recent years there has been increased interest in total incineration with heat recovery -- that is, incineration of all the waste that is generated by a facility with utilization of the energy that is recovered from the combustion process. If total incineration is undertaken at a facility that generates infectious waste, the possibility of including the infectious waste in the feed to the incinerator should be evaluated carefully. There might be management problems because the infectious waste should be accorded special handling -- for example, the infectious waste should be kept as a separate waste stream that is not mixed with other wastes and it should be incinerated promptly. In addition,

the use of special techniques (e.g., in feeding) might be required to ensure proper combustion of the infectious waste so that it receives the treatment necessary for elimination of the biological hazard. In consideration of the management and operational difficulties that might be encountered if infectious wastes were included in a total incineration program, it might be preferable to treat infectious waste by some alternative method, especially if the quantity or heat value of the infectious waste stream is small relative to the total waste stream of the facility. The treated waste could then be included in the general waste stream and incinerated without special handling.

It is known that pathological incinerators that are properly designed, maintained, and operated are effective in killing the pathogens that are present in infectious waste. There has not yet been sufficient experience with total incineration-heat recovery systems to ascertain their suitability for proper incineration of infectious waste. Nevertheless, it must not be inferred that all pathological incinerators will, by definition, automatically provide appropriate treatment for infectious waste nor that incineration-heat recovery systems are not appropriate for infectious waste incineration. In theory, any incinerator -- including municipal and industrial incinerators -- could be used for infectious waste incineration. However, incinerators do not always sterilize the waste in the combustion process, and if the incinerator operating conditions are not correct, viable pathogenic organisms can be released to the environment in stack emissions, residue ash, or wastewater (64,77,78,91,92).

Regardless of the type of incinerator that is used, the infectious waste must be exposed to a sufficiently high temperature for an adequate period of time to ensure destruction of all pathogenic organisms. It would seem to be a simple matter to designate the minimum combustion temperatures and residence times that will ensure destruction of pathogenic organisms during incineration of infectious waste. However, studies by Barbeito and co-workers (64,77,91) demonstrate that these requirements vary with each individual incinerator unit. It would therefore be inappropriate to designate operational standards for the incineration of infectious waste. Consequently, EPA recommends that each incinerator that is used to combust infectious waste undergo a trial burn to determine the standard operating procedures for that unit which, when implemented for the incineration of infectious waste, will ensure the killing of pathogens and the destruction of biologically active material present in the waste.

Design features as well as operating procedures affect the incineration process, and variations in these factors determine if the etiologic agents in the waste are exposed for sufficient time to the temperature that is necessary for kill. In

pathological incinerators, the design features that affect combustion conditions include type of refractory lining, number and location of burners, stack height, designed linear velocities, and accuracy and reliability of temperature-recording devices (77). Certain design features will help ensure that the infectious waste is being properly incinerated. Mechanical devices such as a lockout device and a shut-down device can help ensure that the infectious waste is exposed to the appropriate combustion temperature. The lockout device prevents ignition of the primary chamber until the secondary chamber is at operating temperature while the shut-down device keeps the secondary chamber at operating temperature for a certain period of time after the primary chamber is shut off or until it cools to a certain temperature. Monitors that provide continuous information on combustion temperature, waste feed rate, fuel feed rate, and air feed rate are important, and indeed essential, for maintaining operations within the limits prescribed by the standard operating procedures. For additional details on incinerator design, see references 93 and 94.

In order to establish standard operating procedures, every incinerator that is used for incineration of infectious waste should be tested for its efficacy in destroying microorganisms. Data from these trial burns should then be used to standardize operating procedures for the incineration of infectious waste. The trial burn would also provide information on the relative efficiencies of effective alternatives. The standardization of procedures should include establishing the acceptable operating limits for the various parameters that affect incinerator operation. These parameters include:

- Variation in waste composition
- Waste feed rate
- Combustion temperature
- Air feed rate
- Fuel feed rate

Variations in waste composition. The composition of the feed affects the combustion conditions because the different types of waste differ in characteristics that are important in incineration (e.g., moisture content, heating value). Because it is unlikely that only one particular type of infectious waste will be incinerated at a facility, it is important to realize the effect of each type of waste or each mixture of different wastes on the combustion process and to determine which adjustments in other operating variables

must be made in order to maintain proper incinerating conditions. Data from the trial burn may also indicate which particular combination of waste provides the best feed for efficient incinerator operation. Another factor that should be considered is the plastic content of the waste, in particular the content of polyvinyl chloride and other chlorinated plastics. The combustion products of these plastics include hydrochloric acid which is corrosive to the incinerator and would have to be scrubbed from the stack gases if significant quantities are produced. Chlorine is also important in free radical formation which occurs under the elevated temperatures of incineration. Therefore, the content of chlorinated plastics in the waste load should be minimized when incineration is used to treat the waste. This reduction can be achieved by: (a) eliminating the use of chlorinated plastic items where infectious waste are generated, (b) substituting other types of plastic (e.g., polyethylene and polypropylene) for disposable items and trash bags, (c) using other types of containers to hold the infectious waste, and (d) treating infectious waste with a high chlorine content by methods other than incineration.

Waste feed rate. The rate at which waste is fed into the incinerator also affects the efficacy and efficiency of incinerator operations. However, it is important to avoid overcharging which often results in incomplete combustion and therefore in unsatisfactory treatment of the infectious waste. The optimum feed rate should be determined for each type of feed. It should be noted that infectious waste that is to be incinerated should be properly contained to prevent dispersal of pathogens into the environment during transport and before and during loading of the waste into the incinerator. Furthermore, in order to facilitate complete combustion, the waste should not be compacted before incineration.

Combustion temperature. The trial burn will provide information for determining the minimum temperature that must be maintained during combustion to ensure proper treatment of the infectious waste. The combustion temperature can be maintained, as necessary, by adjustments in the combustion air feed and in the amount of fuel. With pathological incinerators, in particular, it is essential that operating temperatures be attained before charging of the waste or ignition of the primary chamber in order to achieve complete combustion of the waste and kill of the pathogens.

Air feed rate and fuel feed rate. The air and fuel feed rates should be adjusted to maintain the combustion temperature at the necessary level. Adjustments will be

needed as the composition of the feed and the waste feed rate vary.

The standard operating procedures that are developed should specify the acceptable operating limits for these parameters to ensure that no viable bacterial spores are recoverable from the stack emissions. The following practices should also be included in the standard operating procedures:

- Operating limits for charging, temperature, air flow, and fuel feed should be carefully observed while waste is being fed and combusted.

- The incinerator and associated equipment should be inspected to detect leaks and to check the operability of shut-down controls.

- The incinerator should be airtight, or it should be operated under negative pressure to prevent fugitive emissions from the combustion zone.

In addition, the following practices should be included in the standard operating procedures for batch-fed (e.g., pathological) incinerators:

- Infectious waste should not be fed during start-up and shut-down in order to ensure that the waste is incinerated at the proper combustion temperture.

- The primary chamber should not be ignited until the secondary chamber is heated to operating temperature.

- Waste should not be fed until the previous batch has completely burned out in order to prevent surges up the stack of incomplete combustion products including, possibly, viable microorganisms.

The standard operating procedures should be compiled in written form and posted near the incinerator so that they will be available at the incinerator at all times.

It is important to realize that even the best incinerator design and standard operating procedures will be valueless if the incinerator is not operated properly. The individuals who will be operating the incinerator should receive training in how to operate the incinerator effectively. They should be educated in proper procedures and in the importance of following the standard operating procedures that were developed during the testing program.

At present, pathological incinerators (i.e., those that burn only pathological waste) are not subject to the federal regulations promulgated under either the Clean Air Act (CAA)

(because of their small capacities) or the Resource Conservation and Recovery Act (RCRA) (because regulations for infectious wastes have not been issued). However, other types of incinerators that are used to incinerate infectious waste could be subject to CAA or RCRA regulations (95,96) because of their size or because they incinerate hazardous wastes. Some states and localities have applied emission standards, in particular standards for particulate emissions, to all incinerators (including pathological) within their jurisdictions.

A rule-of-thumb that is often used in incinerator operations is that operation is satisfactory if there is no visible opaque plume emanating from the stack. Although this criterion may be satisfactory regarding particulate emissions, it is neither valid nor relevant for emissions of microorganisms, and only specific testing can ascertain that no viable pathogens from the waste are being emitted from the stack.

In the trial burns that are used to establish the standard operating procedures for the incineration of infectious waste, spores of Bacillus subtilis variety niger (globigii) should be added to the waste. The stack gas should then be sampled for viable spores by the use of sampling trains (77) or midget impingers (92). The number of spores added to the waste (i.e., the spike) and the sampling time (volume) should be adjusted to ensure a theoretical challenge of at least 1×10^6 spores in the collected sample (in other words, at least 1×10^6 spores would be present in the sample if no spores were destroyed by the incineration process). Monitoring should be repeated whenever substantial repairs are made on the incinerator (i.e., work other than routine maintenance).

4.6 Dry Heat Sterilization

Dry heat treatment (that is, the application of heat without the addition of steam) is another method that is suitable for sterilizing infectious wastes (see references 71 and 97). Heat treatment is often used to sterilize liquid wastes in closed systems. It is also appropriate for other types of infectious waste including contaminated equipment. Although the sterilization of solid wastes in an oven is technically suitable, this treatment technique has the disadvantages of being costly and time-consuming. Nevertheless, this method is included among the alternative treatment options because it is often used to treat liquid infectious wastes and it may be the method of choice for treatment of solid wastes at some facilities.

The cycles used for dry heat treatment are longer or at higher temperatures than those used in steam sterilization because the heat is transmitted through the waste load only by conduction (i.e., without permeation of pressurized steam).

Furthermore, higher temperatures are necessary for protein coagulation (the principal factor in the killing of microorganisms) when less water is present (71).

Two methods are used in the heat sterilization of wastewater -- the batch and the continuous treatment processes. In the batch process, wastewater may be collected in a holding tank which is subsequently heated to, and maintained at, the treatment temperature. Alternatively, in the continuous sterilization process, the wastewater is heated to the treatment temperature and is then passed through heat retention tubing so that it is maintained at the required temperature for a sufficient period of time. Heat exchangers are often incorporated into the system beyond the heat retention tubing in order to recapture heat -- that is used to preheat the incoming wastewater -- and simultaneously to cool the treated effluent prior to its discharge. In both the batch and the continuous treatment processes, steam jackets are usually used to heat the wastewater.

Standard operating procedures should be developed to ensure that infectious wastewater is being sterilized by the heat treatment process. For batch treatment, the following variables are important in developing the standard operating procedures:

- Load volume
- Temperature
- Duration of treatment
- Mixing requirements

For the continuous treatment process, the important variables in operating procedures are:

- Temperature
- Exposure time (a function of the flow rate through the heat retention tubing)

Ovens and hot air sterilizers are used for the heat treatment of infectious solid wastes. The principal factors that are important in designating the standard loads for dry heat treatment of solid wastes are:

- Type of waste
- Load volume
- Packaging materials and containers

- Loading configuration

Type of waste. The type or types of waste that constitute the waste load should be standardized because the heat conductivity of each kind of waste is different. The heat conductivity affects the time that is needed for the waste load to reach the sterilizing temperature.

Load volume. Load volume is an important variable that should be standardized for each oven that is used for infectious waste treatment. Overloading makes sterilization difficult if not impossible to achieve even when standard operating procedures are followed.

Packaging materials and containers. The type of packaging materials and containers (that is, plastic or metal) affects the sterilization process because of the difference in heat conductivity of the different materials. (This topic is discussed in detail under steam sterilization, Section 4.4.)

Loading configuration. For an effective and efficient sterilization process, the configuration of the load should permit free circulation of the heated air throughout the chamber.

The variables that are important in developing the standard operating procedures for heat treatment of standard loads of solid wastes include:

- Treatment temperature
- Length of cycle

Obviously, differences in the composition of the standard load and the operating temperature affect the required operating conditions. Therefore, standard operating procedures should be determined for each standard load to ensure reproducibility and effectiveness of the sterilization cycle.

Spore kill times for dry heat sterilization at different temperatures are listed in Table 4-3. A typical cycle for dry heat sterilization is treatment at 160° to 170°C (320° to 338°F) for two to four hours. The appropriate biological indicator for monitoring the effectiveness of dry heat treatment is spores of Bacillus subtilis variety niger (globigii). Monitoring of the dry heat process for the treatment of infectious waste should be conducted periodically; a monitoring schedule of once every three months would be appropriate. (For the sterilization of supplies by dry heat treatment, monitoring frequencies of at least weekly (30) and at least once a month (85) have been recommended for monitoring with Bacillus subtilis spores.)

TABLE 4-3

DRY HEAT STERILIZATION[a]

Temperature		Spore Kill Time[b]
(°C)	(°F)	(hours)
121	250	6
140	285	3
150	300	2.5
160	320	2
170	340	1
180	356	0.5

[a] Data from reference 86, Table 1A. (E. Hanel, Jr. Chemical Disinfection. In: Control of Biohazards in the Research Laboratory, Course Manual. The John Hopkins University, School of Hygiene and Public Health, Baltimore, Maryland. 1981).

[b] In heat sterilization, exposure time for treatment is usually at least double the kill time (71).

4.7 Gas/Vapor Sterilization

In the gas/vapor treatment method, the sterilizing agent is a gaseous or vaporized chemical. Four chemicals, primarily, have been used for this purpose in the past -- ethylene oxide, formaldehyde, peracetic acid, and beta-propyl acetone -- but the latter two are rarely used today. All four chemicals are toxic, and ethylene oxide, formaldehyde, and beta-propiolactone are listed as chemicals having substantial evidence of carcinogenicity (98). Therefore, caution should be exercised when these compounds are used, and personnel protection is essential (see p. 4-27 for details). When use of this treatment method is considered, the relative hazards should be weighed -- that is, does the hazard of treatment exceed the hazard of the waste? Nevertheless, gas/vapor sterilization is included in this manual as an alternative treatment option because it is sometimes the method of choice for treating certain infectious wastes.

Ethylene oxide gas is usually used for the sterilization of supplies, especially those that are thermolabile, i.e., unstable to heat. Obviously, however, the effects of heat would not be a consideration in selecting the method for treating waste materials. Furthermore, ethylene oxide sterilization is usually more expensive than, for example, steam sterilization. Therefore, ethylene oxide may not be used frequently to sterilize infectious wastes. (See references 99, 100, and 101 for details on ethylene oxide sterilization).

Formaldehyde gas is used for sterilizing contaminated and infectious wastes (see references 102 and 103). Common uses of formaldehyde are for sterilization of contaminated equipment, ventilation systems, and spaces (i.e., rooms and buildings).

In the gas/vapor treatment method, the wastes must be exposed to a sufficiently high concentration of the gas/vapor for an adequate period of time in order to accomplish sterilization. Therefore, both loading considerations and operating conditions are important in ensuring proper treatment.

The factors that should be considered in designating the standard loads for gas/vapor sterilization of infectious wastes are those that affect the diffusion and permeation of the gas/vapor into and throughout the waste load. These factors include the following:

- Type of waste
- Packaging materials
- Load volume
- Loading configuration

Type of waste. The type of waste that is subject to this treatment is an important element in standardizing the waste load because of the different porosities of different types of infectious waste. The density of the waste also affects the rate at which the gas diffuses through the material.

Packaging materials. The materials that are used to package the waste must be permeable to the sterilizing gas. Of the plastic materials, for example, polyamide, polyethylene, and polypropylene are suitable for use with ethylene oxide whereas polyvinyl chloride and nylon are not (104).

Load volume. With gas sterilization as with the other treatment processes, overloading causes problems. Of special concern is the ratio of load volume to chamber size.

Loading configuration. The waste should be loaded within the treatment chamber so that there is maximum exposure of the waste to the gas and so that the gas can diffuse freely thoughout the chamber and the waste.

The operating variables that are important in determining the effectiveness of treatment include:

- Type of chemical
- Concentration of the gas/vapor
- Relative humidity
- Temperature
- Length of the cycle

Typical operating conditions for gas sterilization using ethylene oxide and formaldehyde are listed in Table 4-4. Other important data on the applications, effectiveness, and characteristics of these two compounds are also included in the table.

It is important to note that, because of the toxicity of these chemicals, care must be taken to avoid exposure of personnel during the treatment process. Furthermore, with both ethylene oxide and formaldehyde, there is the potential for worker exposure after the treatment process because of "degassing" from the waste, even after the bulk gas has been eliminated. (Because ethylene oxide is absorbed by rubber and plastic and formaldehyde frequently polymerizes to form a residue, these chemicals continue to be released from the waste for a while after treatment.) The gas should be properly vented at the end of the treatment cycle, and the treated

TABLE 4-4

SUMMARY OF DISINFECTANTS USED IN GAS STERILIZATION

	Gas	
	Ethylene Oxide	Formaldehyde
Inactivates:		
Vegetative bacteria	+	+
Lipoviruses	+	+
Nonlipid viruses	+	+
Bacterial spores	+	+
Treatment Requirements		
Gas concentration	8-23 g/ft^3	0.3 g^a/ft^3
Temperature, °C	37	>23
Relative humidity, %	30	>60
Contact time, minutes		
Lipovirus	60	60
Broad spectrum	60	60
Characteristics		
Corrosive	-	-
Flammable	+[b]	+[c]
Explosion potential	+[b]	+[c]
Inactivated by organic matter	-	-
Skin irritant	+	+
Eye irritant	+	+
Respiratory irritant	+	+
Toxic	+	+
Applicability		
Waste liquids	-	-
Books, papers	+	-
Dirty glassware	-	-
Equipment, surface decontamination	-	-
Equipment, penetrating decontamination	+	+
Ventilation systems	-	+
Large area decontamination	-	+

Source: U.S. Department of Health and Human Services, National Institutes of Health. Laboratory Safety Monograph. A Supplement to the NIH Guidelines for Recombinant DNA Research. pp. 104-105. NIH, Office of Research Safety, National Cancer Institute, and the Special Committee of Safety and Health Experts, Bethesda, Maryland. January 1979.

\+ Yes.
\- No.
[a] Paraformaldehyde.
[b] Neither flammable nor explosive in 90% CO_2 or fluorinate hydrocarbon, the usual use form.
[c] At concentrations of 7% to 73% by volume in air; solid exposure to open flame.

material should be well aerated before it is handled for disposal. All personnel should use protective equipment as necessary -- i.e., respirators, gloves, aprons, etc. For details on practices for the safe use of ethylene oxide, see reference 101.

The biological indicator that is suitable for use in monitoring the effectiveness of gas/vapor sterilization is spores of Bacillus subtilis variety niger (globigii). In order to monitor the effect of the fumigation process, the spores should be placed within and throughout the waste load. Monitoring of the treatment process should be conducted on a periodic basis. A monitoring schedule of once in every two weeks would be appropriate for treatment of waste; this is less frequent than the schedule (at least once a week) recommended for monitoring the gas sterilization of supplies (84,85).

4.8 Sterilization by Irradiation

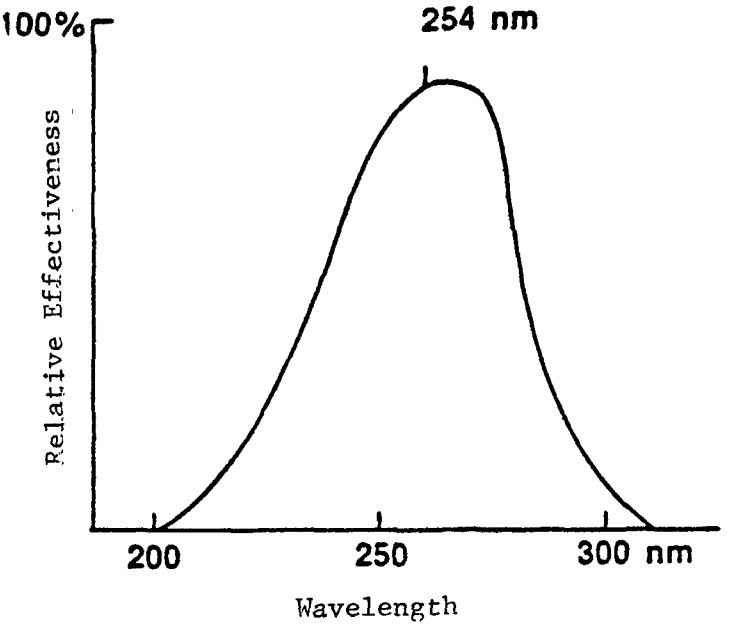
Irradiation is an effective method of sterilizing materials (105,106). At present, the use of radiation as a sterilant is generally limited in the United States; it is more widely used for this purpose in Europe and Canada. The lag in commercial use in the United States may be attributable to policies of the Food and Drug Administration, i.e., irradiated foods are not approved for consumption in this country and irradiated drugs must first be granted approval as "new drugs." In other countries, extensive experience in the use of irradiation to sterilize products (e.g., medical supplies) and to preserve foods probably provided impetus for development of other applications including treatment of wastes (e.g., municipal wastewater and sewage sludge). The ultraviolet ray, gamma ray, and accelerated electron types of radiation are suitable for use in waste treatment.

Ultraviolet radiation is generated by a special lamp which emits 95 percent of the radiant energy at the 254-nanometer wavelength (86); this is near the peak germicidal wavelength (Figure 4-2). Ultraviolet rays cannot penetrate surfaces and therefore ultraviolet irradiation is useful in sterilizing only those surfaces that are exposed directly to the rays. Consequently, ultraviolet irradiation is of limited use in sterilizing infectious waste. One application found in many containment laboratories is the pass-through ultraviolet box for sterilizing sheets of paper. The ultraviolet bulb should be kept free of dust because dust diminishes its output, and the output should be checked routinely. It is important to protect the eyes and to avoid prolonged exposure to ultraviolet radiation.

Gamma radiation for sterilization purposes is usually derived from the radioisotope cobalt-60 which is produced in nuclear reactors. Gamma rays penetrate to a depth of several meters and therefore can be used to irradiate packages. Another

FIGURE 4-2

BACTERICIDAL EFFECTIVENESS OF ULTRAVIOLET RADIATION



Source: E. Hanel, Jr. Chemical Disinfection (illustration 1E). In: Control of Biohazards in the Research Laboratory, Course Manual. The John Hopkins University, School of Hygiene and Public Health, Baltimore, Maryland. 1981.

advantage of gamma rays is the small requirement for electricity in the irradiation process. Many experts think that gamma radiation has potential as a replacement for the heat treatment of wastes, especially in cold climates, primarily because of the high cost of fossil fuels needed to generate electricity and steam. Furthermore, because heat is not involved, the treated waste (treated wastewater, for example) does not have to be cooled before it is disposed of or discharged. Gamma radiation devices require sheilding of the source during storage as well as during use. The type of shielding that is appropriate is determined by source strength and facility design (see reference 105 for information on sterilization device shielding). In a typical treatment facility, the source is stored in a pool of water and is raised into the air for exposure of the waste. Packages are conveyed mechanically through a maze to the source for exposure. When wastewater is treated, it may be channeled through a sluice for continuous treatment or accumulated in a tank for batch treatment. Provision should be made for replenishment of the source as it decays in order to maintain the gamma radiation at required levels.

Electron accelerators are used to generate electron beams. Electrons penetrate to a depth of a few centimeters, and they can be used to treat some packages as well as wastewater. The principal disadvantages of this type of treatment are the requirements for a high electrical energy source and for shielding during the treatment process (shielding during nonuse is not needed because the radiation can be turned off). Because of the high energy requirements, electron beam irradiators are economically feasible only when inexpensive sources of electrical energy are available.

Special factors must be taken into consideration to ensure that the wastes are exposed to sufficient radiation to achieve sterilization. The factors that are important in designating standard waste loads for sterilization by irradiation are:

- Type of waste
- Load volume
- Waste configuration

Type of waste. The type of waste is an important factor because the degree of contamination determines the dose that is needed to sterilize the waste. Waste loads can be standardized on the basis of presumed approximate degree of contamination (testing is not recommended), or a worst-case standard load can be established.

Load volume and configuration. Load volume as a function of the configuration of the waste is another important factor in standardizing the waste loads. The three

types of radiation (i.e., ultraviolet light, gamma ray, and electron beam) differ in penetrating capability (see discussion above), and configuration of the waste load or depth of the wastewater should be established and standardized accordingly.

The factors that are important in developing the standard operating procedures for each standard load include:

- Type of radiation
- Efficiency and power of source
- Exposure time

Dosimetry (i.e., measurement of the radiation dose) is often part of the irradiation process. It is especially important with gamma radiation because the power of the source diminishes as the cobalt-60 decays. Exposure time can be varied to assure an adequate dose of radiation by altering the speed of the conveyor moving packages around the radiation source or the velocity of the wastewater flowing past the irradiation zone.

Spores of Bacillus pumilus are the appropriate biological indicator to use in determining whether the irradiation has sterilized the waste. Periodic monitoring should be conducted once every two weeks.

4.9 Chemical Disinfection

Various chemicals are frequently used for disinfection of hospital supplies, equipment, and surfaces. (Chemical disinfection is discussed in references 6, 75, 86, 107, and 108.) These chemicals are usually of the following types and substances: acids, alkalies, aldehydes, alcohols, amines, halogens, heavy metal salts, ketones, quaternary ammonium compounds, phenolic compounds, and hydrogen peroxide.

Chemical treatment must be considered a disinfecting rather than a sterilizing process. Because of the type of action, the many factors that affect treatment results, and the difficulties in establishing proper standard operating procedures, there are too many variables for chemical treatment to be relied upon exclusively for effective treatment of most infectious wastes. Therefore, judgment should be exercised, and chemical treatment of infectious waste is an option that should be reserved for certain wastes and special circumstances.

The factors that should be considered in designating standard waste loads for chemical treatment include:

- Type of waste
- Volume of waste

Type of waste. Not all types of waste can be effectively treated with chemicals. The porosity and absorbency of the waste are factors that should be considered. For example, wastes such as glassware, plasticware, and some liquids could be chemically treated (at least initially) whereas this treatment technique would be ineffective with bulk wastes and porous or absorbent materials.

Volume of waste. The volume of the waste affects the practicality of using chemical treatment. For example, procedural difficulties would be encountered if large waste loads were treated chemically by hand (i.e., in a non-mechanical system) because of problems in handling (e.g., containing, mixing) the large volume of waste and chemical.

In the development of the standard operating procedures for each standard load, the following factors are important to ensure sufficient exposure of the wastes to the action of the chemicals:

- The type of contaminating microorganism
- The degree of contamination
- The amount of proteinaceous material present in the waste
- The type of chemical
- The concentration and quantity of chemical
- The contact time
- Other relevant factors

Type of contaminating microorganism. Chemicals are not equally effective against the different types of microorganisms. See Tables 4-5 and 4-6 for a guide.

Degree of contamination. The degree of contamination affects the time required for disinfection, the amount of chemical required, and other variables. For example, the greater the degree of contamination, the longer the contact time needed for effective treatment.

Amounts of proteinaceous material present. Proteinaceous material or "organic dirt" (e.g., blood, plasma, feces, tissue) absorbs and inactivates some chemical disinfec-

TABLE 4-5

ACTIVITY LEVELS OF
SELECTED CLASSES OF LIQUID DISINFECTANTS (107)

Class	Use-Concentrations	Activity Level[a]
Glutaraldehyde, aqueous	2%	high
Formaldehyde + alcohol*	8% + 70%	high
Formaldehyde, aqueous*	3 to 8%	high to intermediate
Iodine + alcohol	0.5% + 70%	intermediate
Alcohols	70 to 90%	intermediate
Chlorine compounds	500 to 5000 ppm[b]	intermediate
Phenolic compounds	1 to 3%[c]	intermediate
Iodine, aqueous	1%	intermediate
Iodophors	75 to 150 ppm[d]	intermediate to low
Quaternary ammonium compounds	1:750 to 1:500[e]	low
Hexachlorophene	1%	low
Mercurial compounds**	1:1000 to 1:500[e]	low

Courtesy of American Sterilizer Company, Erie, Pa.

a Degree of disinfecting activity.

b Available chlorine.

c Dilution of concentrate containing 5% to 10% phenolics.

d Available iodine.

e In appropriate diluent.

* See Section 4.7 for discussion of formaldehyde toxicity and necessary precautions for personnel protection.

** Should not be released into the environment and therefore no longer used.

TABLE 4-6

SUMMARY OF PRACTICAL DISINFECTANTS

	Quaternary Ammonium Compounds	Phenolic Compounds	Chlorine Compounds	Iodophor	Ethyl Alcohol	Isopropyl Alcohol	Formaldehyde	Glutar-aldehyde
Inactivates								
Vegetative bacteria	+	+	+	+	+	+	+	+
Lipoviruses	+	+	+	+	+	+	+	+
Nonlipid viruses	-	a	+	+	a	a	+	+
Bacterial spores	-	-	+	+	-	-	+	+
Treatment Requirements								
Use dilution	0.1-2.0%	1.0-5.0%	500 ppm[b]	25-1600 ppm[b]	70-85%	70-85%	0.2-8.0%	2%
Contact time, minutes								
Lipovirus	10	10	10	10	10	10	10	10
Broad spectrum	NE	NE	30	30	NE	NE	30	30
Important Characteristics								
Effective shelf life >1 week[c]	+	+	-	+	+	+	+	+
Corrosive	-	+	+	+	-	-	-	-
Flammable	-	-	-	-	+	+	-	-
Explosion potential	-	-	-	-	-	-	-	-
Inactivated by organic matter	+	-	+	+	-	-	-	-
Skin irritant	+	+	+	+	-	-	+	+
Eye irritant	+	+	+	+	+	+	+	+
Respiratory irritant	-	-	+	-	-	-	-	-
Toxic[d]	+	+	+	+	+	+	+	+
Applicability								
Waste liquids	-	-	+	-	-	-	-	-
Dirty glassware	+	+	+	+	+	+	+	+
Equipment, surface decontamination	+	+	+	+	+	+	+	+

TABLE 4-6 (concluded)

SUMMARY OF PRACTICAL DISINFECTANTS

	Quaternary Ammonium Compounds	Phenolic Compounds	Chlorine Compounds	Iodophor	Ethyl Alcohol	Isopropyl Alcohol	Formaldehyde	Glutar-aldehyde
Proprietary Products[e]	A-33 CDQ End-Bac Hi-Tor Mikro-Quat	Hil-Phene Matar Mikro-Bac O-Syl	Chloramine T Clorox Purex	Hy-Sine Ioprep Mikroklene Wescodyne			Sterac	Cidex

Source: Adapted from Laboratory Safety Monograph. A Supplement to the NIH Guidelines for Recombinant DNA Research. pp. 104-105. National Institutes of Health, Office of Research Safety, National Cancer Institute, and the Special Committee of Safety and Health Experts, Bethesda, Maryland. January 1979.

\+ Yes.

\- No.

NE Not effective.

[a] Variable results depending on virus.

[b] Available halogen.

[c] Protected form light and air.

[d] By skin or mouth or both. Refer to manufacturer's literature or Merck Index.

[e] Space limitations preclude listing all products available. Individual listings (or omissions) do not imply endorsement (or rejection) of any product by the National Institutes of Health or the U.S Environmental Protection Agency.

tants (71). Halogens, for example, combine readily with proteins. Therefore, when proteinaceous material is present in the waste, the halogens must be added in sufficient quantity to provide the excess needed to react with the micoorganisms and thereby disinfect the waste. Official methods have been published for determining, for example, available chlorine germicidal equivalent concentration (75).

Type of chemical. Different chemicals have different modes of action and levels of activity (Table 4-5). Therefore, they are effective for different uses (Table 4-6). It is important to understand the mode of action (e.g., reaction with the cell wall, protein, DNA, or RNA) in order to select the appropriate chemical.

Concentration and quantity of chemical. Most of the chemicals have a range of concentrations that are suitable for use for disinfection (Table 4-5). In the development of standard operating procedures, it is important to ascertain the concentration and quantity of chemical that are best used for the disinfection of each standard waste load.

Contact time. It is essential that contact time be sufficient to allow for action of the chemicals on the microorganisms. For example, as was noted above, the time required for disinfection is proportional to the degree of contamination.

Other relevant factors. Other factors that should be considered in establishing standard operating procedures for chemical disinfection include temperature, pH, mixing requirements, and aggregation of microorganisms.

If the waste loads are consistently similar, waste loads as well as the operating procedures for treating them can be standardized. However, if there is variability in the waste loads so that they cannot be standardized, each load should be monitored for effectiveness of treatment. Bacillus subtilis variety niger (globigii) spores are the appropriate biological indicator to use in demonstrating the efficacy of the standard operating procedures developed for each standard waste load (75). The Bacillus subtilis spores should be used for subsequent monitoring of the standardized treatment process on a weekly basis. However, if the waste consists of pure cultures, it would be appropriate to assay each waste load for the target organism after treatment.

4.10 Other Methods

Any other method of treating infectious waste should be demonstrated as effective in sterilizing the waste before it is used routinely. Efficacy of the method should be demonstrated

by the use of appropriate biological indicators. As with all the other treatment methods, standard waste loads should be designated (with reference to the relevant variables) and standard operating procedures should be developed (with reference to the relevant variables) for each such standard load. Monitoring should be conducted on a periodic basis using appropriate biological indicators.

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APPENDIX A

STATE REGULATIONS PERTAINING TO INFECTIOUS WASTE MANAGEMENT*

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Alabama	1975 Code of Alabama, Section 22-21-20. Alabama State Board of Health Rules and Regulations for Nursing Homes and Hospitals.	All infectious waste generated by nursing homes and hospitals must be incinerated on site.	Bureau of Licensure and Certification State Health Department Room 564 State Office Building Montgomery, Alabama 36130-1701 (205) 832-3250
	No regulations.	Policy is to recommend treatment of infectious waste prior to disposal.	Division of Solid Waste Management Department of Public Services Union Bank Building, Room 1212 Montgomery, Alabama 36130 (205) 834-1303
Alaska	Laws of Alaska, Title 44, Chapter 46; Title 46, Chapter 3. Alaska Administrative Code, Title 18 -- 18 AAC 60.040 Solid Waste Regulations.	All infectious waste generated by medical and veterinary facilities must be incinerated prior to final disposal. The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Air and Solid Waste Management Department of Environmental Conservation Pouch O Juneau, Alaska 99811 (907) 465-2666

* Data from telephone survey includes the 50 States and the District of Columbia.

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State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Arizona	Arizona Revised Statutes, Title 36, Article 2, General Hospitals. Regulation R9-10-220, Environmental Services, Subsection E.	All infectious waste must be either (1) autoclaved and disposed of in an approved sanitary landfill, or (2) incinerated in an approved incinerator. Variances are given for disposal of untreated waste when there is insufficient treatment capacity.	Bureau of Health Care Institution Licensure Arizona Department of Health Services 1740 West Adams Street Phoenix, Arizona 85007 (602) 255-1115
Arkansas	Act 414 of 1961, as amended by Act 444 of 1965 and Act 454 of 1965. Rules and Regulations for Hospitals and Related Institutions in Arkansas.	All infectious waste generated by hospitals and related institutions must be incinerated or disposed of by other approved methods.	Department of Health 4815 W. Markham Street Little Rock, Arkansas 72201 (501) 661-2201
	Arkansas Hazardous Waste Management Act of 1979 (Act 406 of 1979).	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Solid Waste Management Division Department of Pollution Control and Ecology P.O. Box 9683 8001 National Drive Little Rock, Arkansas 72205 (501) 562-7444

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State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
California	California Health and Safety Code Chapter 6.5, Article 2, Section 25117. California Administrative Code, Title 22, Division 4, Chapter 30: Minimum Standards for Management of Hazardous and Extremely Hazardous Waste; Infectious Waste Regulations.	The state has proposed to regulate infectious waste as a hazardous waste (April 1982).	California Department of Health Services Hazardous Materials Management Section 714/744 P Street Sacramento, California 95814 (916) 324-1798
Colorado	Colorado Revised Statutes, 1973, as amended; Title 25, Article 15, Parts 1, 2, and 3: Hazardous Waste Management Act.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Waste Management Division Colorado Department of Health 4210 E. 11th Avenue Denver, Colorado 80220 (303) 320-8333 Ext. 4364

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State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Connecticut	Connecticut General Statutes of 1979, Public Act 79-605. Hazardous Waste Management Regulations 25-54cc(c)-1 to (c)-5.	Infectious waste is regulated as a hazardous waste.	Hazardous Waste Management Section Department of Environmental Protection State Office Building 165 Capitol Avenue Hartford, Connecticut 06115 (203) 566-4869 or 566-5712
Delaware	Delaware Code, Title 7, Chapter 60: Solid Waste Act. Delaware Solid Waste Disposal Regulations, August 1974.	Infectious waste disposal is approved on a case-by-case basis. None has been allowed to go to landfills untreated since the approval process was initiated.	Solid Waste Management Section Department of Natural Resources and Environmental Control Edward Tatnall Building P.O. Box 1401 Dover, Delaware 19901 (302) 736-4781

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State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Idaho	Idaho Code, Title 39, Chapter 1. Idaho Solid Waste Management Regulations, Title 1, Chapter 6.	All solid waste must be managed to prevent health hazards, public nuisances, and pollution of the environment during treatment, storage and disposal. Policy is to recommend that infectious waste be double bagged prior to disposal.	Hazardous Materials Bureau Department of Health and Welfare State House Boise, Idaho 83720 (208) 334-4107
Illinois	Illinois Environmental Protection Act, Public Act 76-2429, July 1970, Section 21, Part h. State of Illinois Pollution Control Board Regulations, Final Rule R80-19.	All infectious hospital waste must be rendered innocuous before disposal (as of January 1, 1982).	Division of Land and Noise Pollution Control Environmental Protection Agency 2200 Churchill Road, Room A104 Springfield, Illinois 62706 (217) 782-6762

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State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Indiana	Indiana Code, Title 13, Article 7, Environmental Management Act; 1980 PL 103, Chapter 8.5.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Division of Land Pollution State Board of Health 1330 West Michigan Street, Rm.A304 Indianapolis, Indiana 46206 (317) 633-0176
	Refuse Disposal Act; recodified as Indiana Solid Waste Disposal Law IC-36-9-30. Rule 330 IAC 4.	Written approval must be obtained before disposal of infectious waste in a sanitary landfill. Infectious waste must be auto-claved before disposal.	
Iowa	Iowa Code 1977, Title XVII, Chapter 455B.78, Division IV, as amended. Iowa Department of Environmental Quality Rules, Title IV, Solid Waste Disposal, Chapter 28.	Land disposal of infectious waste is prohibited unless a special waste authorization is granted that requires autoclaving or formalin treatment before land disposal.	Air and Land Quality Division Department of Environmental Quality Henry A. Wallace Building 900 East Grand Street, 3rd Floor Des Moines, Iowa 50319 (515) 281-8692

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
District of Columbia	District of Columbia Hazardous Waste Management Act of 1977, D.C. Law 2-64.	The District has statutory regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Department of Environmental Services 5000 Overlook Avenue, S.W. Washington, D.C. 20032 (202) 767-8414
Florida	Florida Resource Recovery and Management Act (Florida Statutes Annotated, Title 27, Public Health, Chapter 403, Part IV, Enacted by the Laws of 1974, Chapter 342, as amended). Florida Resource Recovery and Management Regulations: Rules of the Department of Environmental Regulation, Chapter 17-7.04.	Infectious waste must be incinerated or treated by an approved treatment method before being placed in a landfill.	Solid Waste Management Program Department of Environmental Regulation Twin Towers Office Building, Room 421 2600 Blair Stone Road Tallahassee, Florida 32301 (904) 488-0300 and Department of Health and Rehabilitative Services 1317 Winewood Blvd. Tallahassee, Florida 32301 (904) 488-2905

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State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Georgia	Code of Georgia, Annotated, Title 43, Chapter 43-16: Solid Waste Management Act of 1972, as amended. Georgia Department of Natural Resources Rules and Regulations for Solid Waste Management, Chapter 391-3-4, 1972, as amended through 1974.	Infectious waste is considered a special waste. Policy is to require incineration or autoclaving before land disposal.	Land Protection Branch Environmental Protection Division Department of Natural Resources Room 822 270 Washington Street, S.W. Atlanta, Georgia 30334 (404) 656-2833
Hawaii	Hawaii Environmental Laws and Regulations, Vol. I, Title 19, Chapter 342, Part V, as amended by Chapter 230, Laws of 1974. Hawaii Environmental Laws and Regulations, Volume II, Chapter 46: Solid Waste Management Control, Effective July 30, 1974.	All infectious waste must be treated or otherwise rendered safe before disposal. Double bagging is considered a means of rendering an untreated waste safe.	Environmental Health Division Department of Health P.O. Box 3378 Honolulu, Hawaii 96801 (808) 548-6410

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Kansas	Kansas Statutes Annotated, Chapter 65, Article 34, as amended. Kansas Administrative Regulations, Title 28: Public Health, Article 29, Regulation 28, Effective May 1, 1979.	Infectious waste must be incinerated, treated before land disposal, or ground to the sewer. Untreated infectious waste may be sent to a hazardous waste land disposal facility.	Solid Waste Management Section Department of Health and Environment Forbes Field, Building 321 Topeka, Kansas 66620 (913) 862-9360, Ext. 309
Kentucky	Kentucky Revised Statutes, 224.005(227)(a).	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Division of Waste Management Department of Natural Resources and Environmental Protection 18 Reilly Road Frankfort, Kentucky 40601 (502) 564-6716
	Certificate of Need and Licensure Law, as revised, (originally effective January 1,1973). 902 Kentucky Administrative Regulations, 20:009, Hospital Facility Regulation.	Hospitals must have an incinerator capable of destroying infectious waste.	Division for Licensing and Regulation Department of Human Resources 275 E. Main Street Frankfort, Kentucky 40601 (502) 564-7960

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State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Louisiana	Louisiana Revised Statutes, Act 449, 30: 1133, Environmental Affairs Act.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Hazardous Waste Division Department of Natural Resources P.O. Box 44066 Baton Rouge, Louisiana 70804 (504) 342-1227
Maine	Title 38 of Maine Revised Statutes Annotated.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Bureau of Oil and Hazardous Waste Materials Department of Environmental Protection State House -- Station 17 Augusta, Maine 04333 (203) 289-2251
Maryland	Maryland Code, Article 41, Section 387-404.	Permits for infectious waste disposal are handled on a case-by-case basis.	Waste Management Administration Department of Health and Mental Hygiene 201 West Preston Street, Room 212 Baltimore, Maryland 21201 (301) 383-5740

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Massachusetts	Massachusetts General Laws, Chapter 111, Subsections 3 and 51-56, and Chapter 111D. 105 CMR 130.354, Hazardous Infectious Waste Disposal Regulations; and 105 CMR 180.275, Regulation for Disposal of Infectious Materials from Independent Laboratories.	Infectious waste must be incinerated or treated before disposal.	Massachusetts Department of Public Health 80 Boyleston Street Boston, Massachusetts 02116 (617) 727-6452
	Massachusetts Hazardous Waste Management Act, Chapter 704 of Acts of 1979.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Department of Environmental Quality Engineering Division of Hazardous Waste 600 Washington St., Room 320 Boston, Massachusetts 02111 (617) 727-0774 or 727-2658
Michigan	Michigan Compiled Laws, Chapter 299, Enacted by Public Acts of 1979, Act 64, Effective January 1, 1980. Michigan Administrative Code, R299.6201(d).	Infectious waste is regulated as a hazardous waste.	Office of Hazardous Waste Management Michigan Department of Natural Resources P.O. Box 30038 Lansing, Michigan 48909 (517) 373-2730

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Minnesota	Minnesota Statutes Annotated, Vol. 9, Chapter 115A, Enacted by Laws of 1980, as amended. Minnesota Code of Agency Rules, Title 6, Part 4, as amended SW1-12 and SW6-2viii.	Land disposal of infectious waste is prohibited.	Division of Solid and Hazardous Waste Minnesota Pollution Control Agency 1935 West County Road B-2 Roseville, Minnesota 55113 (612) 297-2705
Mississippi	No laws or regulations pertaining to infectious waste management.		Division of Solid/Hazardous Waste Management Bureau of Pollution Control Department of Natural Resources P.O. Box 10385 Jackson, Mississippi 39209 (601) 961-5171
Missouri	Missouri Hospital Licensing Law, Chapter 197 of Missouri Revised Statutes. Rules and Regulations for Hospitals.	Infectious waste generated by hospitals must be either incinerated or autoclaved before being sent to a landfill permitted to accept the waste.	Missouri Division of Health Bureau of Hospital Licensing P.O. Box 570 Jefferson City, Missouri 65102 (314) 751-2713

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Missouri	Missouri Hazardous Waste Management Law, Chapter 260 of Revised Statutes of Missouri, 1980, as amended.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Waste Management Program Department of Natural Resources P.O. Box 1368 Jefferson City, Missouri 65102 (314) 751-3241
	Missouri Solid Waste Management Law, Chapter 260.200 of Revised Statutes of Missouri, 1975. Missouri Solid Waste Management Rules and Regulations, 10CSR80, Chapters 1-5.	Infectious waste may be disposed of in any permitted solid waste landfill.	
Montana	Montana Solid Waste Management Act of 1976. Administrative Rules of Montana, Title 16, Chapter 14, Subchapter 5, Solid Waste Management/Refuse Disposal.	Policy is to recommend treatment of infectious waste before land disposal.	Solid Waste Management Bureau Department of Health and Environmental Sciences Cogswell Building, Room A201 Helena, Montana 59601 (406) 449-2821
	Montana Hazardous Waste Act of 1981.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Nebraska	Nebraska Environmental Protection Act, Section 81-1501 through 81-1540.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Water and Waste Management Division Department of Environmental Control State House Station P.O. Box 94877 Lincoln, Nebraska 68509 (402) 471-2186
Nevada	Nevada Revised Statutes, Chapter 444, Hazardous Waste Disposal and Solid Waste Disposal. Regulations Governing Solid Waste Management, Effective 1977.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations. *Infectious* waste generated by hospitals may be placed in a land disposal facility only under approval of the Department.	Division of Environmental Protection Department of Conservation and Natural Resources Capital Complex Carson City, Nevada 89710 (702) 885-4670

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
New Hampshire	New Hampshire Revised Statutes Annotated 151, 1979. Health Facilities Rules and Regulations.	Infectious waste generated by health care facilities must be incinerated.	Bureau of Health Facilities Administration Division of Public Health Department of Health and Welfare Hazen Drive Concord, New Hampshire 03301 (603) 271-4592
New Jersey	New Jersey Statutes Annotated, Title 13: Conservation and Development, Chapter 1E and Chapter 13A. New Jersey Administrative Code, Title 7, Chapter 26, as amended.	Policy is to require incineration of infectious waste.	Solid Waste Administration Division of Environmental Quality P.O. Box CN027 Trenton, New Jersey 08625 (609) 292-9877
	New Jersey Health Care Facilities Planning Act. New Jersey Administrative Code 8:43-B-3.6.	All infectious waste generated by hospitals must be treated before land disposal.	New Jersey Department of Health CN 360 Trenton, New Jersey 08625 (609) 292-7834

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
New Mexico	New Mexico Statutes, Title 74, Environmental Improvement, Article 4, as amended through 1981.	No specific regulations on infectious waste. Incineration or sterilization of infectious waste followed by land disposal is recommended.	Solid and Hazardous Waste Management Programs Health and Environment Department P.O. Box 968, Crown Building Santa Fe, New Mexico 87503 (505) 827-5271
New York	Environmental Conservation Law, Article 27. Title 6 NCRR Part 364, Collection and Transport of Industrial, Commercial, and Certain Other Wastes.	Anyone transporting a hospital waste off-site (including infectious waste) must have a waste transporter's permit.	Division of Solid Waste Department of Environmental Conservation 50 Wolf Road, Room 415 Albany, New York 12233 (518) 457-3254
North Carolina	North Carolina Solid and and Hazardous Waste Act, as revised, 1981. North Carolina Solid Waste Management Rules, Section .0505.	Infectious waste must not be placed in a landfill without approval. Policy is to recommend treatment of infectious waste before land disposal.	Solid and Hazardous Waste Management Branch Division of Health Services Department of Human Resources P.O. Box 2091 Raleigh, North Carolina 27602 (919) 733-2178

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
North Dakota	No governing statute or regulation.	Policy is to require autoclaving or incineration of all infectious waste generated by hospitals and nursing homes. No untreated infectious waste may be disposed of in a landfill. Every hospital and nursing home must have access to a double-chambered, approved incinerator in order to be licensed.	Division of Health Facilities Department of Health State Capitol Building Bismarck, North Dakota 58505 (701) 224-2352
Ohio	Ohio Revised Code, Title 37, Chapter 34, as amended. Ohio Administrative Code, Regulations 3245-27 and 3745-37, Effective July 29, 1976	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Division of Hazardous Materials Ohio Environmental Protection Agency 361 East Broad Street Columbus, Ohio 43215 (614) 466-7220

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Oklahoma	Oklahoma Statutes, Title 63, 1981, Section 1-2001 et seq., Oklahoma Controlled Industrial Waste Disposal Act.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Industrial and Solid Waste Service Department of Health P.O. Box 53551 1000 N.E. 10th Street, Room 803 Oklahoma City, Oklahoma 73152 (405) 271-5338
Oregon	Oregon Revised Statutes, Chapter 459, as amended. Oregon Administrative Rules, Chapter 340, Division 61.	Land disposal of infectious waste is controlled through the permitting process for land disposal facilities.	Solid Waste Management Division Department of Environmental Quality P.O. Box 1760 Portland, Oregon 97207 (503) 229-6266
Pennsylvania	Pennsylvania Statutes, 62 PS 901-1059, Public Welfare Code. Pennsylvania Code, Title 28, Chapter 147.74, Pennsylvania State Health Department Regulations; Disposal of Bacterial and Pathological Wastes That Are Generated in Hospitals and Medical Care Facilities.	Infectious waste must be decontaminated before leaving hospitals and medical care facilities.	Bureau of Solid Waste Management Department of Environmental Resources Fulton Building 8th Floor P.O. Box 2063 Harrisburg, Pennsylvania 17120 (717) 787-7381

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Rhode Island	Rhode Island Hazardous Waste Management Act of 1978. Hazardous Waste Rules and Regulations Effective December 20, 1979.	Infectious waste is regulated as a hazardous waste.	Solid Waste Management Program Department of Environmental Management 204 Cannon Building 75 Davis Street Providence, Rhode Island 02908 (401) 277-2797
South Carolina	Code of Laws of South Carolina, 1976, Sections 44-56-10 through 44-56-140, Hazardous Waste.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations. The state recommends that infectious hospital waste be incinerated or otherwise treated before land disposal.	Bureau of Solid and Hazardous Waste South Carolina Department of Health and Environmental Control J. Marion Simms Building 2600 Bull Street Columbia, South Carolina 29201 (803) 758-5681

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
South Dakota	South Dakota Codified Laws, Chapter 34A-6-2, Solid Waste Disposal Act.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Air Quality and Solid Waste Programs Department Water and Natural Resources Joe Foss Building Pierre, South Dakota 57501 (605) 773-3329
	South Dakota Codified Laws, Chapter 34-1-17, 34-12-13, 34-12-16, and 34-12-19. Rules Promulgated by the South Dakota Health Department Pertaining to Medical Facilities, Article 44:04.	Certain infectious wastes must be incinerated or autoclaved before land disposal.	South Dakota Department of Health Joe Foss Building Pierre, South Dakota 57501 (605) 773-3361
Tennessee	Tennessee Hazardous Waste Management Act of 1977, as amended.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Division of Solid Waste Management Tenessee Department of Public Health Terra Building, Suite 700 150 9th Avenue North Nashville, Tennessee 37203 (615) 741-3424
	Tennessee Code Annotated, 53-1301 to 53-1317. Minimum Standards and Regulations for Hospitals, 1974.	All infectious waste generated by hospitals must be autoclaved or incinerated.	Hospital Licensing Board 283 Plus Park Nashville, Tennessee 37210 (615) 741-6379

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Texas	Revised Civil Statutes of the State of Texas Annotated, Article 4477-7, Texas Solid Waste Disposal Act; and Article 4477-1, Texas Sanitation and Health Protection Law, as amended. Texas Department of Health, Municipal Solid Waste Management Regulations, Effective November 19, 1980; as amended.	Infectious waste is regulated as a special waste. Untreated waste may be double bagged and disposed of in a Type I municipal landfill.	Bureau of Solid Waste Management Texas Department of Health 1100 West 49th Street, T-602 Austin, Texas 78756 (512) 458-7271
Utah	Utah Code Annotated, Title 26, Chapter 14, Utah Solid and Hazardous Waste Act, Effective June, 1981.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Bureau of Solid and Hazardous Waste Department of Health P.O. Box 2500 150 West North Temple Salt Lake City, Utah 84110 (801) 533-4145

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Vermont	Vermont Statutes Annotated, Title 10, Chapter 159. Hazardous Waste Management Regulations, Effective July 18,1980.	Infectious waste is regulated as a hazardous waste.	Air and Solid Waste Programs Agency of Environmental Conservation State Office Building Montpelier, Vermont 05602 (802) 828-3395
Virginia	Code of Virginia, Title 32.1, Chapter 6, Article 3. Virginia Regulations Governing Disposal of Solid Waste, April, 1971.	Waste generators must have special permission to dispose of non-municipal waste. Rules do not preclude land disposal of untreated infectious waste.	Division of Solid and Hazardous Waste Management Department of Health 109 Governor Street Richmond, Virginia 23219 (804) 786-5271

APPENDIX A (Continued)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Washington	Revised Code of Washington, Hazardous Waste Disposal Chapter 70.105.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Hazardous Waste Section Department of Ecology Mail Stop PV-11 Olympia, Washington 98504 (206) 459-6000
	Revised Code of Washington, Hospital Licensing and Regulation Statute, Chapter 70.41. Washington Administrative Code, 248-18-170, Hospital Rules and Regulations.	Infectious waste generated by hospitals must be incinerated or disposed of by other approved methods. Approved methods include autoclaving, retorting, or double bagging before land disposal.	Department of Social and Health Services Licensing and Development Section of the Health Services Division BSHS Mail Stop LM-13 Olympia, Washington 98504 (206) 753-3764
West Virginia	Code of West Virginia, Chapter 20, Article 5E, Effective July 7, 1981. Proposed Infectious Waste Regulations (Estimated to be effective no later than spring of 1983).	Infectious waste will be regulated as a hazardous waste.	State Health Department 1800 Washington Street East Charleston, West Virginia 25305 (304) 348-2411

APPENDIX A (Concluded)

State	Statutory Authority and Regulation Citation	Summary of Requirements	State Agency
Wisconsin	*Wisconsin Statutes* Annotated, Chapter 144, as amended. Chapter NR 180.	The state has statutory authority to regulate infectious waste as a hazardous waste but has not yet promulgated regulations.	Bureau of Solid Waste Management Department of Natural Resources P.O. Box 7921 Madison, Wisconsin 53707 (608) 266-3084
	Chapter NR 181, and guidance manual "Handling and Disposal of Pathological Waste."	Untreated infectious waste must be disposed of in a hazardous waste landfill. Infectious waste which has been autoclaved or chemically treated may be disposed of in a sanitary landfill.	
Wyoming	No regulations pertaining to infectious waste management.		Solid Waste Management Program State of Wyoming Department of Environmental Quality Equality State Bank Building 401 West 19th St., Room 3011 Cheyenne, Wyoming 82002 (307) 777-7752 Department of Health and Social Services Division of Health and Medical Services 4th Floor Hathaway Bldg. Cheyenne, Wyoming 82002 (307) 777-7121

APPENDIX B

ETIOLOGIC AGENTS

Bacterial Agents

Acinetobacter calcoaceticus
Actinobacillus -- all species
Actinomycetaceae -- all members
Aeromonas hydrophila
Arachnia propionica
Arizona hinshawii -- all serotypes
Bacillus anthracis
Bacteroides spp.
Bartonella -- all species
Bordetella -- all species
Borrelia recurrentis, B. vincentii
Brucella -- all species
Campylobacter (Vibrio) foetus, C. (Vibrio) jejuni
Chlamydia psittaci, C. trachomatis
Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani
Corynebacterium diphtheriae, C. equi, C. haemolyticum, C. pseudotuberculosis, C. pyogenes, C. renale
Edwarsiella tarda
Erysipelothrix insidiosa
Escherichia coli, all enteropathogenic serotypes
Francisella (Pasteurella) tularensis
Haemophilus ducreyi, H. influenzae
Klebsiella -- all species and all serotypes
Legionella -- all species and all Legionella-like organisms
Leptospira interrogans -- all serovars
Listeria -- all species
Mimae polymorpha
Moraxella -- all species
Mycobacterium -- all species
Mycoplasma -- all species
Neisseria gonorrhoeae, N. meningitidis
Nocardia asteroides
Pasteurella -- all species
Plesiomonas shigelloides
Proteus -- all species
Pseudomonas mallei
Pseudomonas pseudomallei
Salmonella -- all species and all serotypes
Shigella -- all species and all serotypes
Sphaerophorus necrophorus
Staphylococcus aureus
Streptobacillus moniliformis
Streptococcus pneumoniae
Streptococcus pyogenes
Treponema carateum, T. pallidum, and T. pertenue
Vibrio cholerae, V. parahaemolyticus
Yersinia (Pasteurella) pestis, Y. enterocolitica

Fungal Agents

Blastomyces dermatitidis
Coccidioides immitis
Cryptococcus neoformans
Histoplasma capsulatum
Paracoccidioides brasiliensis

Viral and Rickettsial Agents

Adenoviruses -- human -- all types
Arboviruses -- all types
Coxiella burnetii
Coxsackie A and B viruses -- all types
Creutzfeldt-Jacob agent
Cytomegaloviruses
Dengue viruses -- all types
Ebola virus
Echoviruses -- all types
Encephalomyocarditis virus
Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses
Hepatitis associated materials (hepatitis A, hepatitis B, hepatitis nonA-nonB)
Herpesvirus -- all members
Infectious bronchitis-like virus
Influenza viruses -- all types
Kuru agent
Lassa virus
Lymphocytic choriomeningitis virus
Marburg virus
Measles virus
Mumps virus
Parainfluenza viruses -- all types
Polioviruses -- all types
Poxviruses -- all members
Rabies virus -- all strains
Reoviruses -- all types
Respiratory syncytial virus
Rhinoviruses -- all types
Rickettsia -- all species
Rochalimaea quintana
Rotaviruses -- all types
Rubella virus
Simian virus 40
Tick-borne encephalitis virus complex, including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses
Vaccinia virus
Varicella virus
Variola major and Variola minor viruses
Vesicular stomatis viruses -- all types
White pox viruses
Yellow fever virus

Source: U.S. Department of Health and Human Services. *Code of Federal Regulations*, 42 CFR 72.3. U.S. Government Printing Office, Washington, D.C., 1980.

☆U.S. GOVERNMENT PRINTING OFFICE: 1982-361-082/325

3. Immediate refrigeration or freezing of unpreserved pathological wastes and animal carcasses with removal from storage just before treatment.

4. Proper packaging to ensure containment of the waste and exclusion of rodents and vermin.

5. Limited access to storage areas.

6. Posting of biohazard signs on doors, waste containers, refrigerators, and freezers.

3.6 Transport of Infectious Waste within the Facility and Off-Site

Many infectious wastes can be treated where they are generated -- that is, there may be a steam sterilizer in the room or access to a steam sterilizer or an incinerator directly from the room -- and therefore no transport is necessary. Often though, infectious waste must be moved through the facility to the treatment equipment, or to a storage area, or to the loading dock for transport to an off-site treatment facility. The factors that should be considered in determining the transport conditions are those that affect the safety and health of facility employees, patients (if it is a hospital), visitors, waste handlers, and the general community.

The most important factor is the integrity of the packaging to ensure containment of the waste. Packaging was discussed in detail in Section 3.4; therefore, it is sufficient to restate here that single plastic bags are not adequate when the waste must be transported. For movement within the facility, the waste should be double-bagged or the bagged waste should be placed within a rigid or semi-rigid container, and all containers should be securely closed or sealed.

Carts are suitable for moving the packaged infectious waste within the facility. The carts should be washable or otherwise cleanable, and they should be cleaned and disinfected frequently. They should be used only for moving infectious waste. The time and route of waste transport within a facility should be selected so that few people are encountered while the waste is being moved.

For transport off-site, special packaging may be necessary in order to ensure containment of the waste. In addition, each package of infectious waste should be labeled with the universal biohazard symbol in accordance with the Department of Transportation specifications (57). Other appropriate hazard symbols should be used as well if the waste has multiple hazards.

Mechanical devices should not be used to transfer or load the packages of infectious waste if such use will result in tearing of the packaging. The packaged infectious waste should not be compacted before or during transport because the compacting process would disrupt the packaging and therefore the containment of the waste. It is important to prevent scattering and spillage of the waste during its transport off-site; therefore, the waste should be transported in closed and leak-proof dumpsters or trucks.

Recommendations

The following recommendations are made to ensure the safe transport of infectious waste within the facility as well as during its transport off-site for treatment.

1. Proper packaging to ensure containment of the waste.

2. Selection of time and route of transport so that exposure to the waste is minimum.

3. Use of special carts for moving infectious waste -- that is, they should not be used for other purposes. Frequent cleaning and disinfection of the carts.

4. Handling, transfer, and loading of packages of infectious waste in a manner that does not destroy the integrity of the packaging.

5. No compaction of packaged infectious waste prior to or during transport.

6. Transport of infectious waste off-site only in closed and leak-proof dumpsters or trucks.

3.7 Recommended Treatment Methods for the Different Types of Infectious Waste

The purpose of treating infectious waste is to eliminate any hazard that the waste may present because of the presence of pathogens. Therefore, to be effective, treatment must remove the disease-causing potential by killing the pathogens that are present in the waste. Various methods are now used to treat infectious wastes.

Each type of infectious waste is not necessarily amenable to treatment by each treatment method. The treatment techniques that are recommended are those that: (a) are known to be

effective for treating each type of infectious waste and (b) are generally in common use. The recommended treatment alternatives for each type of waste are equally appropriate if proper procedures are followed to ensure the effectiveness of treatment. (Treatment techniques and procedures are discussed in detail in Chapter 4). Table 3-2 summarizes the recommended treatment techniques that are most appropriate for the different types of infectious waste. These recommendations are based on the efficacy and feasiblity of treatment; other factors such as time and energy requirements and expense were not taken into consideration in formulating the recommendations (they are discussed in Chapter 4). The omission from the table of a treatment technique for a particular type of waste does not mean that that method should never be used for treating that type of infectious waste because the ultimate criterion of suitability is effectiveness. Therefore, any treatment technique may be used to treat any type of waste if the method provides effective treatment.

Before discussing the recommended treatment techniques for the different types of infectious waste, however, it is important to consider the possibility and advisability of discharging untreated infectious wastes into the sewer system. This procedure is advocated by some who maintain that the wastewater treatment plant is the best system for treating biological organic wastes. There are, however, certain drawbacks to this approach. Aerosols are created when waste is poured or ground up and flushed into a drain; if the waste is infectious, these aerosols might contain pathogens and unnecessary exposures might result. In addition, plumbers could be exposed to pathogens that might be present in the plumbing as the result of introducing the untreated infectious waste into the drains. Another factor is the type of treatment the wastewater receives. Secondary biological treatment is needed to ensure killing of pathogens, but not every wastewater treatment facility provides secondary treatment. Furthermore, with the combined sanitary-storm sewer system that is common in many municipalities, some wastewater is often discharged untreated during periods of heavy rain, and this practice could result in discharge of the untreated infectious waste. In consideration of these factors, EPA does not endorse the introduction of untreated infectious wastes into the sewer system unless it is known that the wastewater will receive secondary treatment, proper precautions are taken during disposal, and such disposal is allowed by the local governments. Disposal to the sewer system (by the pouring of liquids or the grinding up and flushing of solids) is appropriate for treated infectious wastes and is therefore recommended only after the waste has been treated and only if the waste is compatible with the wastewater treatment plant (e.g., it does not contain heavy metals or toxic substances).

After infectious waste has been treated, the waste may be

TABLE 3-2

RECOMMENDED TECHNIQUES FOR TREATMENT OF INFECTIOUS WASTES[a]

Type of Infectious Waste[b]	Recommended Treatment Technique					
	Steam Sterilization	Incineration	Gas or Vapor Sterilization	Dry Heat Sterilization	Chemical Disinfection	Other
Isolation wastes	X	X				
Cultures and stocks of etiologic agents	X					
Blood and blood products	X	X				
Pathological wastes	c	X				d
Other wastes from surgery and autospy	X	X				
Contaminated laboratory wastes:						
- Wastes from laboratories at biosafety levels 1, 2, and 3 or levels P1, P2, and P3[e]	X	X				
- Wastes from biosafety level 4 or P4 laboratories:						
Laboratories wastes, solid and liquid	X					
Laboratory wastewater				f		g
Other effluents[h]				f	X	g
- Liquid wastes from commercial scale production	X			f	X	g

TABLE 3-2 (continued)
RECOMMENDED TECHNIQUES FOR TREATMENT OF INFECTIOUS WASTES[a]

Type of Infectious Waste[b]	Recommended Treatment Technique					
	Steam Sterilization	Incineration	Gas or Vapor Sterilization	Dry Heat Sterilization	Chemical Disinfection	Other
Sharps	i					
Dialysis unit wastes	X	X				
Animal carcasses and body parts	c	X				j
Animal bedding and other wastes from animal rooms	k	X	k	X	k	
Discarded biologicals	X	X		X		
Contaminated food and other products	X	X	l			
Contaminated equipment	X	X	X	X	X	

[a] The recommended treatment techniques are those that are most appropriate and, generally, in common use; nevertheless, any treatment technique may be used to treat any type of infectious waste if it provides effective treatment.

[b] See Chapter 2 for definitions of infectious waste types.

[c] Steam treatment should be followed by incineration of the treated waste or by grinding with subsequent flushing to the sewer system in accordance with state and local regulations.

[d] Cremation or burial by mortician.

[e] Specimens of urine and feces that have not been cultured may be flushed to a sewer system.

[f] The heat for dry heat treatment may be derived from steam (e.g., in a steam jacket or through a heat exchanger).

[g] Irradiation.

[h] "Other effluents" refers to wastewater from shower, toilet, and hand-washing facilities.

[i] After treatment, sharps should be rendered non-usable by grinding, compaction, or baking with heat-labile plastics (e.g., syringes).

[j] Rendering.

[k] Steam and chemical treatment of large quantities of animal bedding may be difficult to accomplish effectively (see discussion in Section 3.7.10 below).

[l] Appropriate for non-dense materials such as powders.

disposed of as ordinary non-infectious waste with the general waste stream. Liquids may be decanted and poured down the drain to the sewer system. Wastes may be disposed of in a sanitary landfill or may be incinerated, for example, in an institutional or municipal incinerator. Incinerator ash may be disposed of in a sanitary landfill. It is important to note, however, that if the waste is otherwise hazardous (for example, a hazardous waste as listed in Title 40, Part 261 of the Code of Federal Regulations or a radioactive waste), it should be further treated prior to disposal, or it should receive other special handling in accordance with the requirements of applicable Federal, State, and local laws or the acceptable practices for the management of such wastes.

3.7.1 Isolation Wastes

Isolation wastes (as defined in Chapter 2) contain pathogens that were shed by patients whose diseases are sufficiently severe and contagious to warrant the imposition of isolation. Therefore, the waste from these patients should be sterilized before disposal in order to protect the general population from the pathogens that are present in the waste. Steam sterilization and incineraton are the two treatment methods that are recommended for isolation wastes. The equipment that is needed for these two processes -- steam sterilizers and pathological incinerators -- is available at most hospitals. When proper procedures are followed for steam sterilization and incineration, these techniques provide appropriate treatment of isolation wastes.

Recommendations

EPA recommends the following alternatives for the treatment of isolation wastes:

1. Steam sterilization in accordance with the standard operating procedures determined for this type of waste.

2. Incineration in accordance with determined standard operating procedures.

3.7.2 Cultures and Stocks of Etiologic Agents

Cultures and stocks of etiologic agents constitute infectious waste of particular hazard because the pathogenic organisms are present at high concentrations. Therefore, these wastes should be sterilized (63). A single treatment method -- steam sterilization -- is recommended for this type of infectious waste because it is the simplest and most effective treatment method. Steam sterilization of these wastes should

not be difficult to perform because autoclaves are present in most laboratories that culture infectious agents.

It could be argued that chemical decontamination can provide suitable treatment if the chemical that is used is known to be effective against the target organism. However, many experts in the biological safety field share the opinion that this type of waste must be sterilized and that chemical decontamination does not ensure sterilization. For example, chemical treatment may only inactivate rather than kill the pathogens. Furthermore, steam sterilization is simpler than chemical treatment and also easier to execute effectively because there are fewer process variables and interfering factors (see discussions of steam sterilization and chemical treatment in Sections 4.4 and 4.9, respectively).

Recommendations

EPA makes the following recommendations for the treatment and disposal of cultures and stocks of etiologic agents:

1. Steam sterilization of cultures and stocks of etiologic agents in accordance with the standard operating procedures determined for this type of waste.

2. Management of the treated waste with the general non-infectious waste stream for incineration or for disposal in a sanitary landfill (liquid treated waste may be poured down the drain to the sewer system).

3.7.3 Blood and Blood Products

The principal hazard of blood and blood products arises from the possible presence of the hepatitis agent, and it is general practice in clinical laboratories to handle every blood specimen as though it were positive for hepatitis and to take appropriate precautions. Other blood-borne etiologic agents may be present in blood, but they are less common. Because it is impractical to test all blood for the presence of each possible etiologic agent, it is prudent to manage all blood and blood products as potentially hazardous. It is logical to extend this practice to the wastes associated with blood specimens -- for example, the excess amounts of blood and the containers, needles, and syringes -- and to handle them as though they were contaminated. Therefore, all blood and blood products and all wastes that were in contact with blood should be treated before disposal. Two treatment methods are recommended: steam sterilization and incineration. Equipment for both these processes is generally available in or to facilities that generate this type of infectious waste -- that is, blood banks, clinical laboratories, and hospitals