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Biohazardous waste refers to wastes that are potentially infectious to humans, as well as wastes from animal or plant research that could be potentially infectious to these organisms, or could alter their genetic selection process. Research resulting in generation of biohazardous waste is typically conducted at large, research-based universities. The purpose of this study was to examine how 122 universities manage their biohazardous waste through a survey of environmental health and safety professionals responsible for waste management at these institutions.

Based on the data collected from this survey (82.6% response rate), university biohazardous waste policies are heavily influenced by state environmental regulations, the OSHA Bloodborne Pathogens Standard, and CDC/NIH biosafety guidelines. Biosafety or hazardous materials professionals are the individuals most likely to be responsible for program administration.

Contaminated wastes, both sharps and non-sharps, are almost exclusively treated as biohazardous waste by these institutions if they are a potential infection risk to humans. They are also likely to be treated as biohazardous waste if they are an infection risk for animals but less likely to be treated in this manner if they are a potential infection risk for plants.

Over 70% of the universities indicated that they are using a licensed medical waste hauler for some portion of their waste. Even so, 90% of universities use sterilization by autoclave for waste treatment, yet only 52% of those users indicated validation of the process using a biological indicator. Forty-two percent of respondents currently use incineration for waste treatment. Of those incinerators, roughly half (22 of 42) are HMIWI's. Ten of the twenty-two HMIWI's will continue to operate under EPA's revised regulations for these processes.

To assure compliance with institutional policies, most universities require segregation and packaging of waste, training for waste generators, and inspections of waste generating areas.

Biohazardous waste definition and management in large universities is variable, and is the likely result of the diversity of activities that contribute to waste generation as well as state-specific environmental requirements in addition to other regulatory and guideline issues that need to be addressed in a comprehensive management program.

Defining and Managing Biohazardous Waste in Research-Based Universities in the United States: A Survey of Environmental Health and Safety Professionals

by

Robin Lyn Mecklem

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I understand that my thesis will become part of the permanent collection of Oregon State University libraries. My signature below authorizes release of my thesis to any reader upon request.

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Robin Lyn Mecklem, Author

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Chapter 1

INTRODUCTION

Background

Biohazardous waste is a term for waste that poses a biological hazard to living organisms. It encompasses medical waste, that primarily refers to wastes that are potentially infectious to humans, as well as wastes from animal or plant research that could be potentially infectious to these organisms, or alter their natural genetic selection process. Research that results in generation of biohazardous waste is commonly conducted at large, research-based universities. Management of the biohazardous waste stream in this environment is a challenge to the health and safety professional who must consider multiple state and federal regulations, as well as understand the nature of research being conducted. Medical waste management guidelines alone do not meet the needs of these health and safety professionals. Studies regarding biohazardous waste management in this unique environment are warranted.

Improper management of biohazardous or potentially infectious waste came to light as a public health concern during the summer of 1988 when wash-ups of medical waste occurred along beaches of the Atlantic coast and Great Lakes. At that time, the U.S. Congress responded by enacting an interim standard and the Medical Waste Tracking Act (MWTA), a two-year demonstration program administered by the U. S. Environmental Protection Agency (EPA). The goals of the Act were to define medical waste, establish a tracking system in order to determine the size and origin of the waste stream in four states, and to define management practices.

The Act also required that the Agency for Toxic Substances and Disease Registry (ATSDR) conduct a comprehensive study of the role that medical waste may play in human infection and disease. The ATSDR released its report in 1990 and in short, concluded that the general public's health is not likely to be adversely affected by medical waste in the traditional health care setting. However, occupational health concerns do

exist for workers involved with handling medical waste. The ATSDR did note a number of limitations regarding the accuracy and availability of occupational exposure information collected for various high risk groups such as refuse workers, janitorial and laundry workers and laboratory workers. Another limitation was the lack of available information regarding waste generators-who they are and how much waste they generate (Turnberg, 1996).

The MWTA was part of a two-year interim standard that expired in 1991 and was not reauthorized by Congress (Turnberg, 1996). However, 43 states have adopted their own standards for dealing with this waste stream modeled after this standard (*Infectious Wastes News*, 1998). State regulations can be more, but not less, stringent than federal standards. This means that even though state programs may have been modeled after the federal standard, they can be more restrictive in their definition of medical waste (or whatever term they adopt to call the waste stream) and requirements for treatment and disposal.

The issue of defining biohazardous waste becomes more cumbersome when other federal agencies and accreditation organizations are considered. For example, the Bloodborne Pathogens standard, codified at 29 CFR1910.1030, and administered under the Occupational Safety and Health Administration (OSHA) addresses biohazardous waste handling and disposal. Although OSHA's definitions and practices are likely to overlap with state regulations, they are not all inclusive. OSHA addressed this by deferring the employer "to the applicable territorial, state, or local medical waste disposal requirements within those jurisdictions, should they exist". Accreditation agencies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) also have requirements for defining and managing biohazardous waste, which are likely to overlap and possibly be more restrictive than state regulations (Turnberg, 1996).

The definition of biohazardous waste extends beyond wastes that are potentially infectious to humans. This is especially true for research involving the use of infectious agents and recombinant DNA. When research involves agents or genetically-modified organisms that could pose a threat to animals, plants or humans outside of the laboratory environment, the researcher must comply with biological waste treatment requirements outlined by United States Department of Agriculture (USDA) protocols and/or the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (NIH, 1999). These treatment requirements are based on the principles

of biological safety containment. In short, exotic or infectious agents, or items contaminated with these materials, must be rendered biologically-inactive prior to disposal so that they are not inadvertently released to the environment. Wastes generated in these research environments must therefore be handled in the same manner as wastes generated in the clinical environment (i.e. medical waste).

Problem Statement

Proper management of biohazardous waste is essential for all generators of this waste stream in order to comply with regulatory requirements and meet accreditation criteria. Additionally, proper biohazardous waste management is essential to ward off public relations issues (such as the 1988 beach washups) and assure the safety of all persons who may come in contact with this waste between the point of generation and final disposal. A waste management plan is a tool that can be used to address all of these needs.

Based on the recommendations of the Council of State Governments (1992), a biohazardous waste management plan must address:

- personnel responsibilities
- definition of biohazardous waste
- procedures for waste segregation, packaging, storage and transportation
- treatment methods and monitoring of these methods
- disposal methods and facilities to be used
- contingency planning and spill response
- staff training and safety
- monitoring of program effectiveness such as inspections and recordkeeping

Biohazardous waste management plans may be implemented and monitored efficiently and effectively in hospital and clinical environments where waste generation occurs in a centralized location. In addition, these environments may have staff who deal specifically with the treatment and disposal of the waste stream because it is highly visible and regulated in this setting. In the large, research-based university setting such a plan is not easily administered. Such universities are likely to have facilities located throughout a campus, as well as satellite locations off-campus. If a centralized collection,

treatment and disposal program is not in place, each generator is left with the responsibility of properly treating and disposing of their biohazardous waste. In order to assure that this occurs, a strong biohazardous waste training program must be implemented and reinforced through equipment validation, on-site inspections and audits of equipment and waste disposal records.

Based on personal experience as an environmental health and safety (EHS) professional in the academic environment, academic regulatory compliance remains to be a "hard sell" in the research environment. Many researchers were working in the lab prior to the enactment of regulations for the safe use and disposal of hazardous chemical or biological materials. They can be apprehensive about EHS personnel "telling them how they should run their labs". This mind set establishes a barrier for the reliance on principal investigators to assure that biohazardous waste is managed properly at the lab level.

Purpose of the Study and Research Questions

Environmental health and safety officers are often charged with the responsibility of assuring proper biohazardous waste disposal campus-wide. This is a tremendous challenge in an environment where several kinds of research may be generating biohazardous waste, depending on the nature of the specific project. For example, a plant used in one project may be thrown in the trash. The same kind of plant used in a recombinant DNA application may have to be treated as biohazardous waste to render it biologically-inactive. Clearly, the federal definition of medical waste, and the guidelines for developing a medical waste management plan (designed primarily for the health care setting) do not meet the needs of the large research-based university. The purpose of this study is to identify how such universities are addressing this issue through a survey of the EHS professionals involved with biohazardous waste management at these institutions. The guiding questions on which the survey and study was based are:

1. Which agency regulations or guidelines do large, research-based universities follow to define their biohazardous waste stream?
   - State
   - Federal funding agency (i.e. USDA, NIH)
   - Accreditation agency (i.e. JCAHO)

2. What are the most common methods of treatment and disposal for various categories of biohazardous waste produced by large, research-based universities?
   - What are the categories of waste?
   - On-site or off-site treatment?
   - Incineration use?
   - Use of autoclaves and other means of decontamination?

3. What administrative controls are used to assure safe and proper handling, treatment and disposal of biohazardous waste?
   - Who is responsible for the biohazardous waste management program?
   - What are the requirements for the waste generators (waste tracking, training, equipment logs, etc.)?
   - What controls are used to assure compliance with policies (inspections, audits, equipment validation, etc.)?

4. Based on the data collected in #1 through #3, what recommendations can be made to develop an effective model biohazardous waste management plan for research-based universities?

Significance of the Study

This study is significant because management of the biohazardous waste stream in the large, research-based university environment has been virtually unexamined to date. The data generated from this study will provide university EHS professionals with valuable information regarding the definitions and management practices that are currently used by other large, research-based universities. It will also provide guidance to university EHS personnel who are in the process of developing medical waste disposal policies and biosafety programs.

Limitations of the Study

The results of this survey can only be applied to large, research-based university settings. Results will provide information regarding biohazardous waste management, but not management of other forms of hazardous waste.

Based on the data collected in this study, recommendations for effective program development will be presented. This information may serve as a guide for all universities that are in the process of developing biohazardous waste management programs.

Definitions

Biohazardous waste: waste that poses a biological hazard to living organisms. It encompasses medical waste, as well as wastes from animal or plant research that could be potentially infectious to these organisms, or alter their natural genetic selection process.

Incineration: a means of treating and destroying waste by introducing the waste into a combustion chamber where it is burned at temperatures between 1400° and 2000° F.

Infectious agent: a disease-causing organism that is sufficiently virulent so that if a susceptible host is exposed to it in adequate concentration and through a portal of entry, transmission of disease could result.

Medical waste: any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals; in research pertaining thereto; or in the production or testing of biologicals (EPA definition).

Other Potentially Infectious Materials (OPIM): human body fluids capable of transmitting a bloodborne pathogen (HIV, hepatitis B virus, hepatitis C virus). These fluids include human blood products, semen, vaginal secretions, fluids from the spine, lungs and joints, saliva in dental settings and breast milk (OSHA definition).

Pathological waste: tissues, organs, body parts and body fluids generated through surgical or autopsy procedures.

Recombinant DNA molecules: molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that replicate in a living cell, or molecules that result from the replication of those described formerly (NIH definition).

Sharps: an item that is sharp enough to penetrate the skin and is contaminated with potentially infectious material. Examples: needles, scalpels, glass pipettes, microscopy slides.

Sterilization by autoclave: a treatment method where waste is placed in a chamber and is treated for at least 45 minutes at a temperature of at least 121 C. This temperature is typically achieved through pressurization of the treatment chamber.

Abbreviations/Acronyms

AAALAC:	Association For Assessment and Accreditation of Laboratory Animal Care
APHIS:	Animal and Plant Health Inspection Service
ATSDR:	Agency for Toxic Substances and Disease Registry
BSO:	Biological Safety Officer
BL:	Biosafety Level
CAA:	Clean Air Act
CDC:	Centers for Disease Control
CFR:	Code of Federal Regulations
DNA:	Deoxyribonucleic acid
DOT:	Department of Transportation
EHS:	Environmental Health and Safety
EPA:	Environmental Protection Agency
HMIWI:	Hospital/medical/infectious waste incinerator
JCAHO:	Joint Commission on Accreditation of Healthcare Organizations
NIH:	National Institutes of Health
OPIM:	Other potentially infectious materials as defined by the OSHA Bloodborne Pathogens Standard

OSHA: Occupational Safety and Health Administration

USDA: United State Department of Agriculture

CHAPTER 2

LITERATURE REVIEW

This chapter will review the concepts behind biohazardous waste management practices and regulations and guidelines that must be considered in developing waste management procedures. Additionally, research studies and current events related to the research topic are presented.

General Biohazardous Waste Management Practices

Biohazardous waste management practices begin at the point of waste generation. These wastes must be segregated from other wastes and packaged in a manner that limits further personnel contact with the contaminated material. For example, sharps are deposited in a labeled, puncture-resistant, closable container to eliminate any further puncture hazard presented by such items. Solid, non-sharps wastes are stored in sturdy, labeled or color-coded bags that are resistant to leaks and punctures. While these bags are in use, they are typically stored in sturdy, leakproof, labeled trash containers with lids to reduce personnel exposure risk. These segregation and handling practices are outlined consistently in several regulations and guidance documents including the *EPA Guide for Infectious Waste Management* (1986) and OSHA's Bloodborne Pathogens standard as a means of protecting personnel who may encounter the waste.

Treatment of biohazardous waste may be performed on-site or sent off-site through a waste hauler or centralized waste management program. On-site treatment requires additional handling of wastes and therefore more opportunities for exposure. Treatment methods may include incineration, autoclaving, sewer discharge and alternative treatment technologies such as microwave or chemical disinfection.

Incineration is ideal for treatment of pathological wastes and anatomical parts, and is an effective means of reducing waste volume (AWMA Medical Waste Committee, 1994). However, this treatment option has fallen out of favor in recent years due to the costs associated with more stringent air emission requirements and public health concerns regarding dioxins and other pollutants released through this process.

Sterilization by autoclave is an effective means of decontaminating biohazardous waste under the appropriate operating conditions. This method may be used for nonsharp solid wastes such as contaminated plasticware and gloves. Autoclaving is an accessible means of on-site treatment in most lab environments. However, the method requires a long cycle time (usually in excess of 45 minutes), surveillance of equipment operating parameters, and is restrictive to relatively small quantities of waste in order to effectively decontaminate the load (Turnberg, 1996). Once decontaminated, waste may be landfilled as nonhazardous waste in some states (*Infectious Wastes News*, 1998). The question of effective decontamination is an issue that needs to be addressed through performance testing. Autoclave tape is commonly added to articles to be treated to verify that the required temperature has been achieved during the cycle. Chemical indicator strips may be used for the same purpose. However, these methods are generally only reliable as temperature indicators. A biological indicator, *Bacillus stearothermophilus*, is the recommended method for verifying that the autoclave is operating effectively for biohazardous waste treatment (Council of State Governments, 1992). In this test method, a heat-tolerant microorganism (*B. stearothermophilus*) is exposed to the autoclave treatment conditions and is then incubated to determine if the organism was deactivated to an acceptable level.

Incineration and autoclave sterilization are the two most commonly used techniques for treating biohazardous waste (Cross, 1990). Sewer discharge may be used as a disposal technique but is limited to primarily human blood and body fluids. Chemical disinfection of wastes may also be used. On a small scale, this process may be carried out at the point of generation and involves treating the waste liquid or materials with a disinfectant such as bleach solution in order to inactivate the biological contaminants of

these materials prior to disposal. On a large scale, this process could involve a stand-alone treatment unit specifically designed to treat hundreds of pounds of waste in a short period of time. Chemical disinfection on this scale is an example of an alternative treatment technology, meaning large-scale treatment process without using incineration.

Alternative treatment technologies are growing in popularity. Many alternative treatment system manufacturers claim that these emerging technologies are an effective means for treating virtually all forms of biohazardous waste and can significantly reduce the final volume of the waste. At this time, such technologies are primarily used by large hospitals and waste haulers because the expense of such units is cost-prohibitive for most waste generators as a form of on-site treatment (Turnberg, 1996).

Regulations and Guidelines

Federal Environmental Regulations

Federal environmental regulation of biohazardous waste began after the Resource Conservation and Recovery Act (RCRA) of 1976 went into effect. This Act defined hazardous wastes and specified requirements for the handling and disposal of such wastes. Subtitle C of the Act required the EPA to develop and promulgate regulations for the identification of characteristics of hazardous waste. Infectiousness was, at that time, included as a waste criterion. However, when final hazardous waste rules were published in 1980, EPA had omitted the previously proposed infectious waste standards (Turnberg, 1996).

Although the EPA excluded infectious waste from its hazardous waste regulations, it released a guidance document in 1986 addressing the waste stream. This document entitled, *EPA Guide for Infectious Waste Management* provides information regarding the definition of infectious waste and acceptable infectious waste management practices including recommendations for an infectious waste management plan and specific

treatment methods for the different types of infectious waste. The definitions and recommendations contained in this document served as the basis for many state level infectious waste regulations and therefore are summarized below.

In this guidance document, the EPA defines infectious waste as "waste capable of producing infectious disease", but notes that consideration must be given to the factors necessary for disease transmission including the presence of a virulent pathogen, dose, portal of entry, and host susceptibility (EPA, 1986). Therefore a risk assessment performed by a responsible authorized person may be required to truly define infectious waste. Nonetheless, EPA did define categories of infectious waste and provide examples as listed in the table on the following page.

Table 1: EPA Infectious Waste Categories*

Waste Category	Examples
Isolation wastes	• EPA referred to CDC's Guidelines for Isolation Precautions in Hospitals (latest version, 1996)
Cultures and stocks of infectious agents and associated biologicals	• Specimens from medical and pathology laboratories • Cultures and stocks of infectious agents from clinical, research, and industrial laboratories; disposable culture dishes, and devices used to transfer, inoculate and mix culture • Wastes from production of biologicals • Discarded live and attenuated vaccines
Human blood and blood products	• Waste blood, serum, plasma, and blood products
Pathological Waste	• Tissues, organs, body parts, blood, and body fluids removed during surgery, autopsy and biopsy
Contaminated sharps	• Contaminated hypodermic needles, syringes, scalpel blades, Pasteur pipettes, and broken glass
Contaminated animal carcasses, body parts, and bedding	• Contaminated animal carcasses, body parts, and bedding of animals that were intentionally exposed to pathogens
Miscellaneous contaminated wastes (may be infectious under certain conditions)	• Wastes from surgery or autopsy (i.e. soiled dressings, sponges, drapes, etc.) • Miscellaneous laboratory wastes (i.e. specimen containers, slides and cover slips, disposable gloves, etc.) • Dialysis unit wastes (i.e. tubing, filters, disposable sheets, etc.) • Contaminated equipment used in patient care, laboratories or research.

Information adapted from EPA Guide for Infectious Waste Management, 1986

The EPA Guide (1986) also recommended that facilities appoint a responsible person or committee to prepare an infectious waste management plan that included definition of infectious waste, procedures for the management of waste from the point of generation through disposal, contingency planning and staff training. Additionally, the EPA made specific treatment recommendations for the treatment and disposal of each waste category.

Isolation wastes, such as contaminated solid items from patient care, should be steam sterilized or autoclaved. Liquid isolation wastes, such as urine and feces, should be discharged to the sanitary sewer within the patient care unit if possible. The EPA recommended that cultures and stocks be steam sterilized on site if a sterilizer was available. Incineration and thermal inactivation were listed as acceptable alternatives.

Steam sterilization and incineration were recommended by the EPA for treating human blood and blood products when possible. Discharge to the sanitary sewer was listed as an acceptable alternative. Pathological waste should be incinerated whenever possible due in part to aesthetics. Steam sterilization, followed by grinding and discharge to the sanitary sewer was listed as an alternative.

The EPA recommended a single uniform management system for all sharps due to the inherent puncture hazard of sharp materials. Sharps should be placed in rigid, puncture-resistant containers after use. Both incineration and steam sterilization were recommended as treatment methods. However, in the case of steam sterilization, compaction or grinding was suggested to meet state or local regulatory requirements.

Incineration was the recommended method of treatment for animal carcasses, body parts and bedding to both eliminate the infectious hazard as well as the carcass. Steam sterilization was listed as an alternative for carcasses, but only if the carcass material was limited in quantity and was ground up and flushed to the sewer. Steam sterilization of bedding was not recommended. Regarding miscellaneous wastes, the EPA recommended steam sterilization or incineration as effective treatment methods.

Although the EPA guidelines provided a wealth of information about the proper management of infectious waste, issues related to the mismanagement of this waste stream came to light and forced the EPA to further address the issue. In the summer of 1988, there were beach wash-ups of medical waste in 5 states. Coupled with other incidents of illegal dumping of medical waste at that time, the U.S. government reacted by enacting the Medical Waste Tracking Act of 1988 (Council of State Governments, 1992). The MWTA was an interim standard that was codified at 40CFR259 and appeared as Subtitle J under RCRA. The goals of the Act were to define medical waste, establish a tracking system in order to determine the size and origin of the waste stream in four states, and to define management practices. The regulation required regulated medical waste generators (those producing in excess of 50 pounds of waste per month) in New York, New Jersey, Connecticut, Rhode Island and Puerto Rico to identify, quantify, manage, and track (manifest) their waste in a manner similar to other RCRA hazardous wastes. The MWTA expired in 1991 with 2 interim reports, but no final reports as required by the Act, generated regarding this waste stream (Turnberg, 1996).

The treatment and disposal of biohazardous waste is also impacted by air quality standards due to the common use of incineration. The EPA Clean Air Act (CAA) was originally passed in 1955 and was intended to address smoky, dirty air in industrial cities. Since that time, the CAA was amended in1970, 1977 and 1990. The 1990 amendments were implemented to put strict controls on 189 hazardous air pollutants using a two-phase standard process and requiring emissions generators to install Maximum Achievable Control Technology (MACT) to reduce emissions (Cox, 1992).

In 1997, the Clean Air Act Amendments reached the biohazardous waste generator (specifically the medical waste generator) when the EPA promulgated the "Standards for Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Hospital/Medical/Infectious Waste Incinerators," codified at subpart Ce of 40CFR60. Under these regulations, a hospital/medical/infectious waste incinerator (HMIWI) is defined as an incinerator whose calendar quarterly waste by weight consists of hospital

and/or medical/infectious waste in a portion of 10% or greater. Although incinerator facilities that burn less than 10% of this waste type on a quarterly basis by weight are exempt from the main provisions of the standard, they are still required to file an exemption with the appropriate state agency and keep records of the fuels and wastes burned.

Although the HMIWI regulations are a federal statute, the regulation was written in such a way as to give states the opportunity to develop their own plans to address the provisions of the regulations. Timeline options are available for the states if increments of progress for compliance can be demonstrated. However, all HMIWI will be subject to the federal statute requirements on September 15, 2002. These requirements include: emission limits for particulate matter, dioxins and 8 other pollutants, performance testing, ongoing parameter monitoring, inspections, operator training, waste management plans, reporting and recordkeeping, and a Title V permit (US EPA Region V, 1999).

There were over 5000 medical waste incinerators in the U.S. in 1996. It is expected that over 80% of these will shut down as the result of the HMIWI regulations (Brunner, 1996).

Other Federal Regulations

With the onset of the HIV epidemic in the U.S. in the late 1980's, the CDC published "Recommendations for Prevention of HIV Transmission in Health-Care Settings" to address associated infection control issues. These guidelines included recommendations for the handling of infectious wastes in this context. In 1992, the U.S. Occupational Health and Safety Administration (OSHA) enacted the Bloodborne Pathogens standard (29CFR1910.1030) based on these guidelines. The standard defined specific infectious wastes and called for specific containment and labeling of these waste types. The standard applies to employees who have a "reasonably anticipated risk of exposure" to human blood or OPIM as defined by the standard. The definition of reasonably

anticipated risk is based on the employer's determination. Because the standard was based on CDC recommendations for the healthcare setting, it was written to address occupational exposure primarily in that setting.

Transportation of infectious waste on public roads is regulated by the U.S. Department of Transportation (DOT). Under this regulation, an infectious substance is defined as "a material known to contain, or reasonably expected to contain pathogens." Pathogens are defined as "microorganisms or recombinant microorganisms that are known or reasonably expected to cause infectious disease in humans or animals" (49CFR173.134). Regulated medical wastes, biological products, and diagnostic specimens are included in the infectious substance definition. A regulated medical waste is defined as "a waste, or reusable material, that contains an infectious substance and is generated in the diagnosis, treatment, or research of humans or animals" and does not include discarded cultures or stocks (DOT, 1999). Infectious substances must be labeled for transport with the 6.2 hazard class label. In addition, specifications for packaging must be met to assure that materials are not released during transport. Packaging requirements are listed at 49CFR173.197 and include capacity limits for single packages and net loads and performance specifications for packaging.

In August of 1999, the DOT implemented stricter safety standards for the transport of regulated medical waste. These changes are likely to impact medical waste haulers and the parties who use this type of service. In short, the changes included stricter specification for the use of plastic bags, bracing of rigid packages to reduce movement during transport, segregation of rigid packages from bags when both are placed in roll-off bins, and sign-off by the customer accepting responsibility for packaging (Grinder, 1999).

The National Institutes of Health's (NIH) "Guidelines for Research Involving Recombinant DNA Molecules" is the most inclusive regulatory document for defining biohazardous waste (NIH, 1999). Compliance with the NIH guidelines is required for all parties who receive funding through the NIH and who are conducting recombinant DNA

research. The NIH guidelines outline containment requirements for various levels of research, known as biosafety levels. The levels of research are determined based on the nature of the DNA segment to be studies, the application of the study (*in vivo* or *in vitro*), and the virulence of the microorganisms to be used as vectors or as organisms to be altered or used in challenge. In short, the lower the risk to personnel and the environment, the lower the biosafety level. A biosafety level is comprised of laboratory practices and techniques, safety equipment (primary barriers), and facility design (secondary barriers). The NIH guidelines define the requirements for each of these components as well as refer readers to the *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories* (1999) for further guidance. Unlike other federal documents, the NIH guidelines do address infectious agents for plants and the waste products produced in those processes. A summary of waste treatment requirements for plant, animal and laboratory biosafety levels (BL) 1 through 3 is presented on the following page.

TABLE 2: NIH Guidelines Waste-Related Requirements*

Waste-Related Requirements: Plant Research	
BL 1	Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside the greenhouse.
BL 2	An autoclave shall be available for the treatment of contaminated greenhouse materials.
BL 3	All waste experimental materials shall be sterilized in an autoclave or rendered biologically inactive by appropriate methods before disposal.

Waste-Related Requirements: Animal Research	
BL 1	A carcass shall be disposed of in a manner to avoid its use as food for human beings or animals unless specifically authorized by an appropriate federal agency.
BL 2	Contaminated materials that are decontaminated at an off-site location shall be placed in a closed durable leakproof container prior to removal from the area. Needles and syringes shall be promptly placed in puncture –resistant containers and decontaminated, preferably by autoclaving, before discard or reuse. An autoclave shall be available for decontamination of laboratory wastes.
BL 3	Needles and syringes shall be promptly placed in puncture –resistant containers and decontaminated, preferably by autoclaving, before discard or reuse. Liquid effluent from containment equipment (i.e. sinks, BSCs, animal rooms, florr drains, sterilizers) must be decontaminated by heat treatment prior to release to the sanitary sewer. Temeprature monitoring must be conducted for this process. Validation of effectiveness must be performed with an indicator organism every 30 days. All animals shall be euthanized at the end of the experimental usefulness and the carcasses decontaminated before disposal in an appropriate manner.

Waste-Related Requirements: Laboratory Research	
BL 1	All contaminated liquid or solid wastes are decontaminated before disposal. Contaminated materials that are decontaminated at an off-site location shall be placed in a closed durable leakproof container prior to removal from the area.
BL 2	Same requirements as BL 1. Additionally: Needles and syringes shall be promptly placed in puncture –resistant containers and decontaminated, preferably by autoclaving, before discard or reuse. An autoclave for decontaminating waste is available.
BL 3	Same requirements as BL 2. Additionally: An autoclave for decontaminating lab wastes is available preferably within the lab.

**Information adapted from NIH Guidelines for Research Involving Recombinant DNA Molecules, 1999*

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) also recognizes the principles of biological containment. One responsibility of this agency is the control of importation, interstate shipment and environmental release of plant pests. Under APHIS regulations, a plant pest is defined as:

> "any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease in or damage to any plant or parts thereof; or any processed, manufactured, or other product of plants (7CFR340.1)."

This definition includes genetically modified organisms involving plant pests listed in the APHIS regulations. To conduct research involving plant pests that will involve an environmental release (i.e. field trial) or interstate shipment of the item, a researcher must obtain a permit through APHIS. To obtain a permit, the researcher must comply with specified APHIS protocols for the proper containment of the pest (7CFR340). Management of the waste is included in these protocols when appropriate and usually involves biological inactivation of plant pests prior to disposal, similar to NIH Guideline requirements for plant research.

Accreditation Requirements

In order to be eligible for certain sources of funding, facilities may need to be accredited by an agency associated with their area of operation. For hospitals and certain health care facilities, this accreditation body is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The JCAHO has standards manuals that outline policies and procedures that must be implemented in order for a facility to receive JCAHO accreditation. Regarding waste management procedures, the JCAHO requires

the facility to have a written plan that includes policies, procedures performance standards, written criteria, and goals and objectives of the waste management program. Additionally, the program must address any state, local and federal requirements related to the management of this waste stream (Turnberg, 1996).

The Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) is an agency that accredits facilities where animal research is conducted. Like the JCAHO, performance manuals and related documents must be followed by the accredited facility. AAALAC requires facilities seeking accreditation to follow The Guide for the Care and Use of Laboratory Animals, published by the National Research Council (1989), for the establishment of facility standards. According to this document, hazardous wastes must be rendered safe through sterilization and containment practices. Additionally, procedures should be established and integrated into occupational safety and health policies specifically addressing on-site packaging, labeling, transportation and storage of such wastes.

State Environmental Regulations

In 1992, the Council of State Governments produced *Model Guidelines for State Medical Waste Management.* Using survey information compiled from state agencies and national associations, this document was generated as part of the EPA's commitment to identify alternative approaches to medical waste management as mandated by the MWTA of 1988. The document was generated to serve as a ready-reference for states implementing medical waste regulations, containing information about essential elements for waste management programs including: public education, minimization, transport, treatment, disposal and worker training.

In 1998, *Waste Age/Infectious Waste News* conducted a medical waste regulatory survey that included information from all U.S. States and the District of Columbia. Based on this survey, 43 states had specific medical/infectious waste regulations in place

at that time. Even though most states have regulations in place, the provisions of these regulations are highly variable. For example, 15 states indicated that their regulations permitted the landfilling of untreated medical waste. On the opposite end of the spectrum, 16 states indicated that their regulations require medical waste to be rendered unrecognizable. One common provision noted by 29 states was the approval of alternative technologies. This may be the result of more stringent incineration regulations at both the state and federal level (US EPA Region V, 1999).

Related Research

Based on a literature review using several on-line indexes, no studies were identified that specifically addressed biohazardous waste management practices in the large research-based university environment. Perhaps the study most closely related to the research presented here is a survey conducted by Klangsin in 1993. In this study, a survey was administered to hospitals in Idaho, Oregon and Washington (Klangsin, 1993). The goals of this study were to investigate and compare medical waste practices and treatment techniques used by hospitals in this region. Because this study was regional in nature and specifically addressed hospitals, the results are not relevant to the present study. However, the current study was initiated in part to address one of the recommendations of the Klangsin study- the need to examine waste management practices in environments beyond the hospital.

Several studies have been conducted regarding medical waste management practices in the health care environment both nationally and regionally (Klangsin, 1998). One study was conducted in Oklahoma to assess biohazardous waste generation in that state (Boatright, 1995) but was not restricted to a specific generation source or industry.

Current Events

Issues related to the improper treatment and disposal remain unresolved. An example of this is the recent occurrence of medical waste discovered on the shores of New York's Rockaway Beach in July of 1998 (*NY Times*, 1998). In addition, occupational exposure for waste handlers have occurred over the years creating "fear of AIDS" cases. The New Jersey case of *Williamson v. Waldman et al* is just one of many examples involving waste handling personnel who have sustained puncture wounds from sharp items that are presumably biologically-contaminated and improperly disposed of (Chenoweth, 1996). These issues are related to the handling and disposal practices of this waste stream and can only be addressed through strong and vigilant administrative policy. Perhaps the most significant development that is likely to affect the large research-based university is the change to incinerator regulations.

With the implementation of EPA's HMIWI regulations, waste generators as well as the public have become aware of the potential adverse health effects associated with incinerating medical waste. One clear example of this occurred in 1999 when a Philadelphia hospital and affiliated incinerator operator were fined $250,000 and required to conduct a $250,000 asthma screening project for local children after violating CAA and state air emission standards (Geiselman, 1999).

The university environment is already starting to feel the impact of HMIWI requirements and public relations issues associated with this practice. In November of 1999, the *Stanford Daily* reported on student protests and plans for educating the community about "environmental racism" in regards to Stanford's use of an incinerator for disposal of medical waste. Students opposing incineration are concerned about the release of dioxin to low income communities located near the incinerator (Chao, 1999). The *Minnesota Daily* (University of Minnesota) published an article in October of 1998 regarding medical waste incineration. Again, the focus of this article was on dioxins produced through the incineration process. Alternatives to incineration and actions to be taken on the part of the medical facilities associated with that university were highlighted

as well (Huiras, 1998). Based on these recent articles, it is evident that the university community is becoming more aware of the health implications related to incineration and are likely to oppose ongoing use of incineration as a means of treating biohazardous waste.

CHAPTER 3

METHODS

To answer the research questions proposed in this thesis, a survey was administrated to environmental health and safety professionals employed by large, research-based universities in the United States.

Sample Population and Selection of Subjects

The sample population for this study was universities that have been classified by the Carnegie Foundation for the Advancement of Teaching as Research I and Research II universities. Research I universities are defined as giving high priority to research and receiving $40 million or more annually in federal funding. There are currently 88 universities in this classification (see Appendix A). Research II universities are also defined as giving high priority to research but receiving between $15.5 million and $40 million annually in federal funding. There are currently 34 universities in this classification for a total sample population of 122 (see Appendix A). This population was selected because these universities are most likely to be conducting research in areas such as microbiology, biochemistry or animal science where the generation of medical or biohazardous waste outside of the clinical environment is likely to occur. Additionally, these universities are likely to have an environmental health and safety staff who are knowledgeable of, and possibly responsible for, the administration of the university's program for managing medical waste.

Survey respondents were selected based on information solicited from the universities' environmental health and safety department. Each university's EHS department was contacted by phone to identify the appropriate person to complete the survey. Once identified, the potential respondent was contacted by phone to verify that they were indeed the best person to complete the survey, as well as to introduce myself,

provide an overview of the survey and its significance, and verify mailing information. This first contact with respondents was done in accordance with OSU Institutional Review Board requirements (see Appendix B).

Survey Instrument

A questionnaire sent by mail was used as the survey instrument for this study (see Appendix C). Based on principles from Salant and Dillman's (1994) *How To Conduct Your Own Survey*, the questionnaire was designed to attract the interest of the respondent, and be simple to complete for the respondent.

The questionnaire was 4 pages, printed on the front and back on standard 8 ½ " x 11" white paper, stapled twice down the left-hand side bookstyle. Times New Roman font was used for the text of the instrument, with 10 to 12 point font used for the body of the questionnaire.

The first page was used as a cover. To grasp the attention of the respondent, the cover included the title of the study, a graphic design to further identify the study (in this case, the biohazard logo), the name of the study's sponsor, and the return address. The back of this page was used as a respondent reference page and included a brief instructions summary and operating definitions (see Appendix C).

The following 2 ½ pages of the questionnaire contained 17 questions based on the research questions previously stated. The questions were categorized and presented in the order that they appeared in the cover letter introducing the survey. To further guide respondents, the category was listed in bold print at the beginning of each set of questions in that category. Questions were designed to be closed-ended and exhaustive when possible. This was achieved through listing options for each question, including an "other" option for write-in responses, and asking the respondent to circle or check the appropriate response. All questions using this format were limited to 6 options to

minimize the possibility of category order effect whereby the respondent may be influenced to pick the first option if the list of options is substantial. An example of this format is demonstrated below:

3. Who has primary responsibility for the development and maintenance of your institution's biohazardous waste management procedures? *(Please check one box.)*

   - ❑ Biological Safety Officer
   - ❑ Biological Safety Committee
   - ❑ Hazardous Waste Specialist
   - ❑ Other:_____

   (Please write in response if applicable.)

In some instances, similar items were grouped together in a table format to reduce the number of individual questions and expedite completion of the survey for the respondent. An example of this format is demonstrated below:

1. Which agency definitions, guidelines or regulations were used to develop your institution's biohazardous waste management procedures? *(Please circle **NO** or **YES** for all categories.)*

Agency		
a. EPA Regulations (e.g. Medical Waste Tracking Act)	**NO**	**YES**
b. Local Waste Regulations (e.g. Publicly Owned Treatment Works)	**NO**	**YES**
c. State Waste Regulations	**NO**	**YES**
d. OSHA Regulations (e.g. Bloodborne Pathogens Standard)	**NO**	**YES**
e. CDC/NIH Guidelines (e.g."Biosafety in Microbiological and Biomedical Laboratories")	**NO**	**YES**
f. USDA/APHIS Regulations (e.g. "Introduction of Regulated Articles"; 7CFR340)	**NO**	**YES**
g. Accreditation Agency Requirements (e.g. JCAHO, AAALAC)	**NO**	**YES**
h. USDOT Regulations (e.g.49CFR171-180)	**NO**	**YES**
i. Other:_____ *(Please write in response if applicable.)*	**NO**	**YES**

Not all questions were applicable to all respondents, such as questions pertaining to autoclave use and surveillance. In these instances, instructions were added to the response option to guide respondents to the next applicable question.

The back side of the final page was used as a back cover for the questionnaire. This page included a large box for written comments, an acknowledgment of participation, and the return address for the questionnaire.

Validity and Reliability of the Instrument

Several steps were involved in establishing the validity and reliability of the questionnaire before the survey was distributed for data collection. The initial draft of the questionnaire was submitted to 10 colleagues and professionals in the public health and EHS fields for comment on the content and layout of the questions. Based on initial response, revisions were made, and the questionnaire was resubmitted to the same group for further comment. After final revisions of the initial survey, a pilot test was conducted to establish validity and reliability. The pilot test was conducted after the initial survey and research plan was reviewed and approved by the OSU Institutional Review Board.

The pilot test was conducted using principles from the Portney and Watkins (1993), *Foundations of Clinical Research: Applications to Practice*. In an ideal pilot test situation, a pilot group will consist of individuals who are part of the population being sampled. Because the survey population used in this study was actually a census population (not a sample population) of individuals who are most knowledgeable and responsible for biohazardous waste management at their institutions, an alternative form of pilot group was used. The pilot group consisted of 5 EHS professionals who worked for institutions to be surveyed, and who were knowledgeable of their institution's biohazardous waste procedures, but they were not primarily responsible for biohazardous waste programs.

The survey was mailed to the pilot group with a request to complete and return it within two weeks. All surveys were returned within that time frame. One week later, the survey was again sent to the pilot group with the same instructions. Responses were again returned within two weeks. This two-time administration over a one month period was used to establish reliability of the instrument. Based on the comparison of the two surveys, reliability was questionable for certain parts of the final question on the survey. The challenge to the reliability of this question was likely due to the position of the question in the survey, and the fact that the question had 11 items that contained overlapping concepts. Responder fatigue was a likely factor under these circumstances. To address this in the final questionnaire, the question was rewritten and reduced to 7 items and was moved up in the questionnaire. Comments regarding question clarity were also incorporated into the final questionnaire (See Appendix C).

Administration of the Survey

The administration of the survey began with a mailing in early September 1999. Respondents were mailed a survey packet that included:

- a cover letter explaining the goals of this study, instructions for completing the and returning the survey, and researcher contact information
- a questionnaire; and
- a self-addressed stamped return envelope.

To assure that responses were received, a post office box was secured for the duration of the study. Respondents were asked to return their completed survey within 30 days. After the 30-day period, non-responders were contacted via electronic mail or by phone to remind them of the survey. Completed questionnaires were accepted until December 15, 1999 for inclusion in the data analysis.

Data Analysis

Upon receipt of a completed survey, identification numbers from the back of the survey were recorded for follow-up purposes and then removed. Next, the survey was reviewed for completion. If the survey was complete for at least 14 of the 17 questions, it was included in the data entry and analysis. This minimum criteria reflects an 80% completion of the survey questions. It was used to eliminate surveys that were likely to be invalid, where the respondent was not attentive to the instructions or content of the survey.

Survey responses were numerically coded for data entry. Where appropriate, "YES" responses were coded as a "1" and "NO" responses were coded as a "0". For questions asking the respondent to check the appropriate category, options were numerically coded "1", "2", "3", etc. depending on the number of options. All data was entered and analyzed by the graduate candidate using the Microsoft Excel 2000 spreadsheet program. The entered data was reviewed twice to assure that data entry criteria was consistent and free from error.

CHAPTER 4

RESULTS

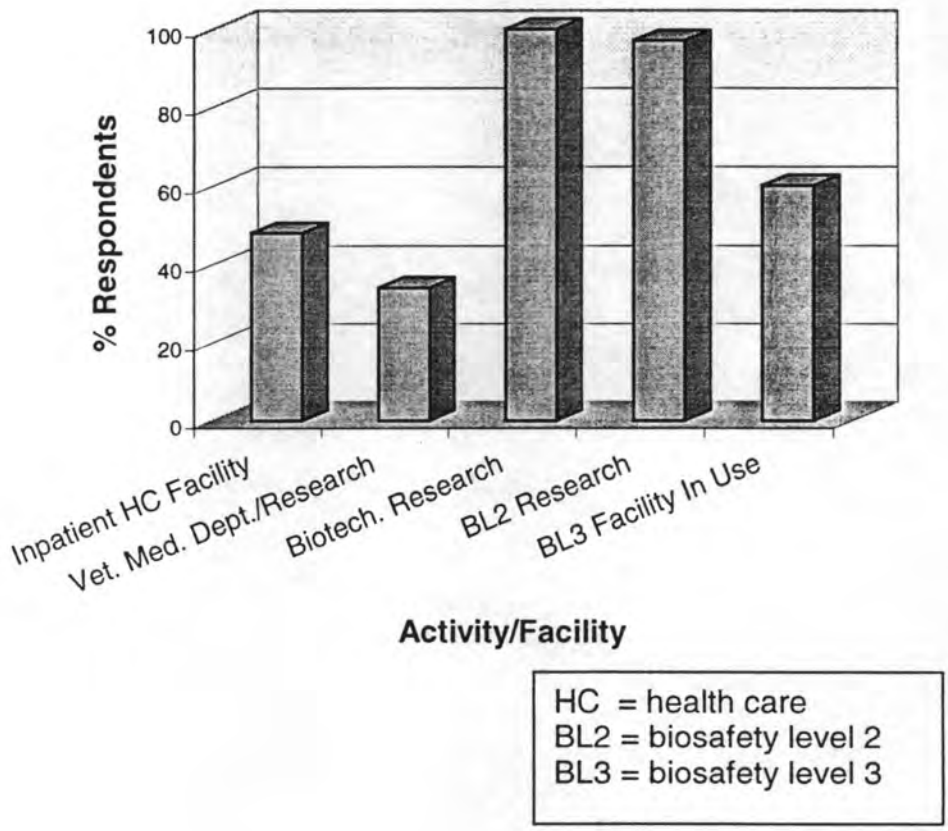
Of the 122 research institutions solicited, 121 agreed to participate in the survey. Upon termination of data collection in December of 1999, 102 surveys had been returned. Two of these surveys were discarded due to lack of completion (less than 14 questions answered). The total number usable responses was 100 for an overall response rate of 82.6%. Of the 100 respondents, 71 were from Research Classification I institutions for an 81.6% response rate from this group. Twenty-nine respondents were from Research Classification II institutions, for an 85.3% response rate from this group.

To rule out attrition effects, information was solicited (via electronic mail) from 6 non-responders regarding why they had not completed the survey. Two individuals responded. One indicated that the survey had been completed and passed on for mailing and may have gotten lost. The other individual indicated that the biosafety department at that particular institution was fairly new and that development of uniform policies was currently underway. Therefore, she was unsure how to respond to some of the survey questions and chose not to respond. Based on this limited feedback and the closeness of the response rates between the two Research Classifications, attrition was an unlikely source of error in this study.

Institutional Profile

Information about the kinds of activities and/or facilities that the institution had that would be likely to impact biohazardous waste generation are shown in Figure 1.

FIGURE 1: Institutional Activities and Facilities



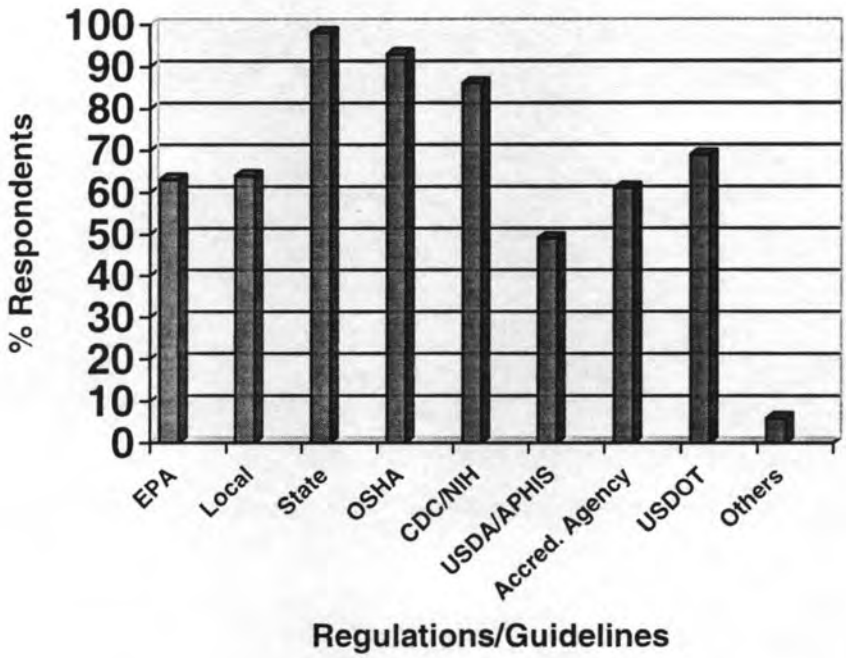
The response rate for this question was 99% to 100%, depending on the activity category in question. Forty-three percent of respondents indicated that their institution had an in-patient medical treatment (HC) facility. Thirty-four percent indicated that their institution had a veterinary medicine school that performs teaching, treatment and research. All respondents (100%) indicated that biotechnology research is conducted at their institution, while 97% indicated that BL2 research was being conducted at their

institution. Sixty percent of respondents indicated that their institution has a BL3 facility that is currently in use.

Biohazardous Waste Management Procedure Development

Two questions in the survey assessed what regulations or guidelines were used to develop biohazardous waste management policies and who is responsible for the development of those policies.

FIGURE 2: Regulations and Guidelines Used to Develop Policies

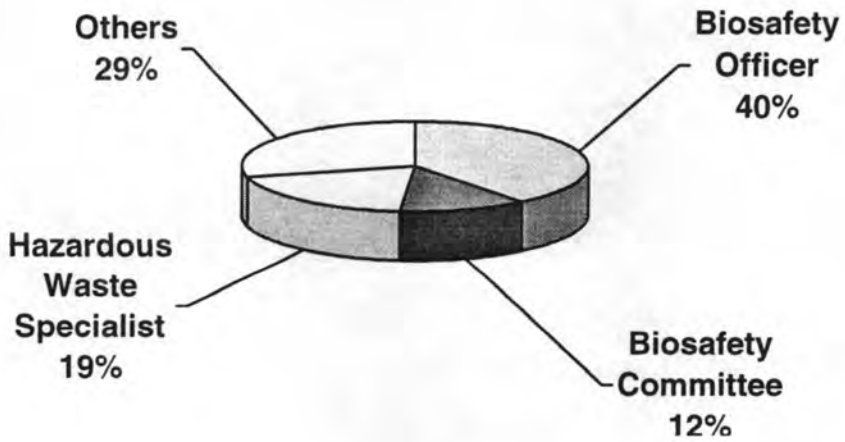


The total response rate for the categories in this question ranged from 87% (for the USDOT category) to 97% (for the OSHA category). Percentages for each category, as demonstrated in Figure 2 were determined based on total number of respondents for that particular category. Sixty-three percent of respondents indicated that EPA regulations (i.e. MWTA) had been used as a basis for their policies. Sixty-four percent indicated that

local regulations were used while 98% indicated that state regulations were used. OSHA regulations were cited by 93% of respondents. Eighty-six percent of respondents indicated that CDC/NIH guidelines were used in the development of policies. Forty-nine percent indicated that USDA/APHIS requirements were used. Accreditation agency requirements were cited by 61% of respondents and USDOT requirements were cited by 69% of respondents. Five respondents also listed other regulatory requirements including state agricultural regulations, state health codes and Nuclear Regulatory Commission requirements.

Information was gathered on who has the responsibility for biohazardous waste management policy development in the large research-based university environment as shown in Figure 3.

FIGURE 3: Personnel Responsible for Biohazardous Waste Management Policies



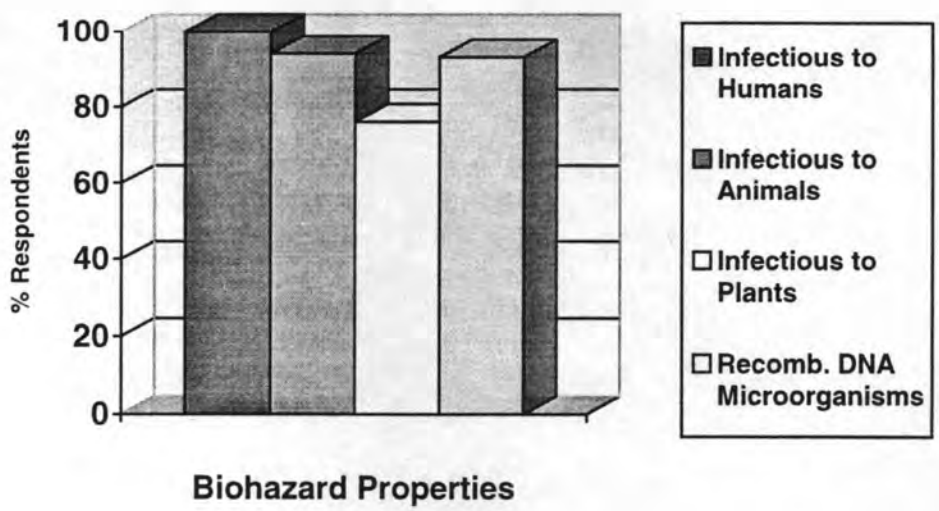
The response rate for this question was 99%. The Biosafety Officer was the most frequently designated responsible individual for 40% of the institutions. The Biosafety Committee was cited as the responsible body at 12% of the institutions. Nineteen percent of respondents indicated that the Hazardous Waste Specialist was the responsible individual.

Twenty-nine percent of respondents indicated that other individuals were responsible for the biohazardous waste management policies. Nine of these responses indicated that it was a responsibility for environmental affairs or environmental health and safety personnel. Four listed safety professionals as the responsible individual. Two institutions indicated that it was the responsibility of the individual departments, and the remainder of respondents noted a joint responsibility between safety committees and EHS professionals.

Defining Biohazardous Waste

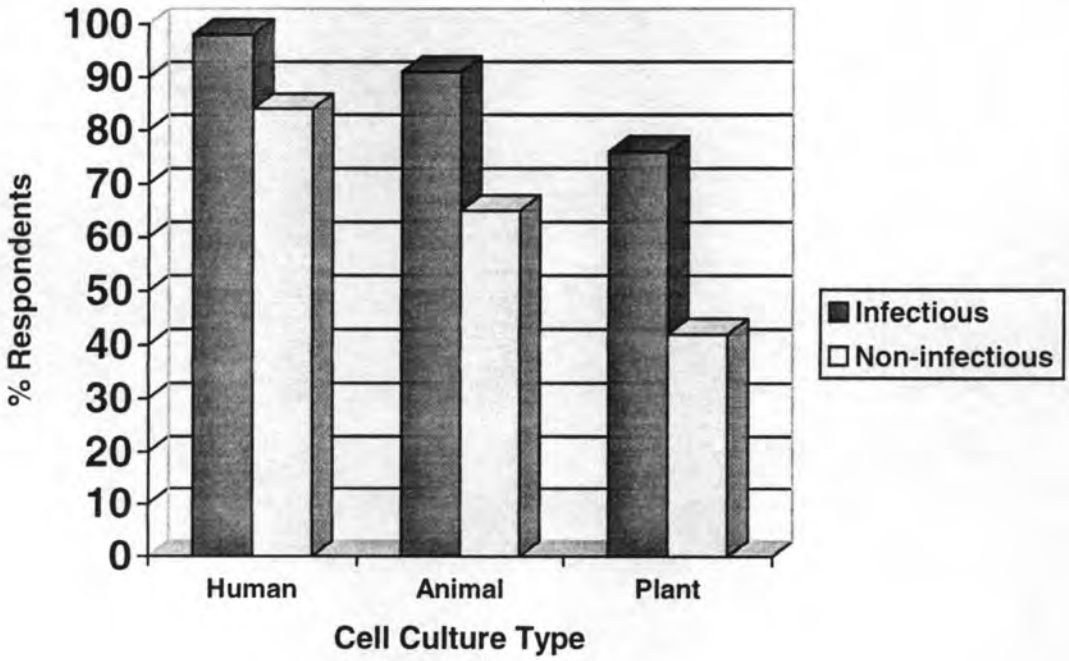
Questions were asked in the survey regarding what items institutions consider to be biohazardous waste and under what conditions. Respondents were first asked to indicate which non-sharp solid waste items commonly found in the research environment are treated and disposed of as biohazardous waste. Items were broken down into 5 categories which were: cultures and stocks of infectious agents (category 1), cell cultures (category 2), human tissues and body fluids (category 3), animal research and diagnostic wastes (category 4), and plant materials (category 5).

FIGURE 4: Treatment and Disposal of Cultures and Stocks & Items Contaminated With These Materials (Category 1)



The response rate for this question was 97% to 100%, depending on the category in question. Regarding cultures and stocks of infectious agents (and items contaminated with such materials), 100% of respondents indicated that items were treated and disposed of as biohazardous waste when the agent was infectious to humans. Ninety-four percent of respondents indicated that waste regarded as infectious to animals was treated as biohazadous. The lowest response category for biohazardous waste treatment was items infectious to plants with a 76% positive response. Ninety-three percent of respondents indicated that recombinant DNA microorganism waste was regarded as biohazardous by their institution.

FIGURE 5: Treatment of Cell Cultures as Biohazardous Waste (Category 2)

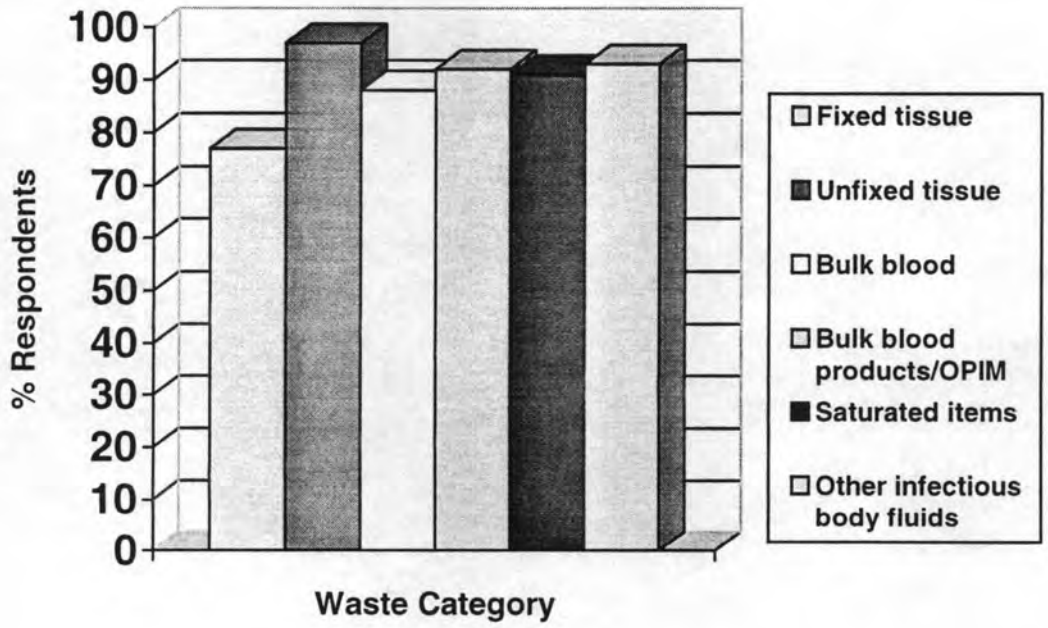


Ninety-eight percent of respondents indicated that human cell cultures regarded or known to be infectious were treated as biohazardous waste. Non-infectious human cultures were also regarded as biohazardous by 84% of respondents. Regarding animal cell cultures, 91% of respondents indicated that these items were treated as biohazardous

waste if known to be infectious and 65% indicated that non-infectious animal cell cultures were also treated as biohazardous waste. Regarding plant cell cultures, 76% of respondents indicated that these items were treated as biohazardous waste while 42% indicated that non-infectious plant cell cultures were additionally regarded as biohazardous waste.

The third category of wastes addressed in the waste definition question addressed wastes related to human body fluids and tissues.

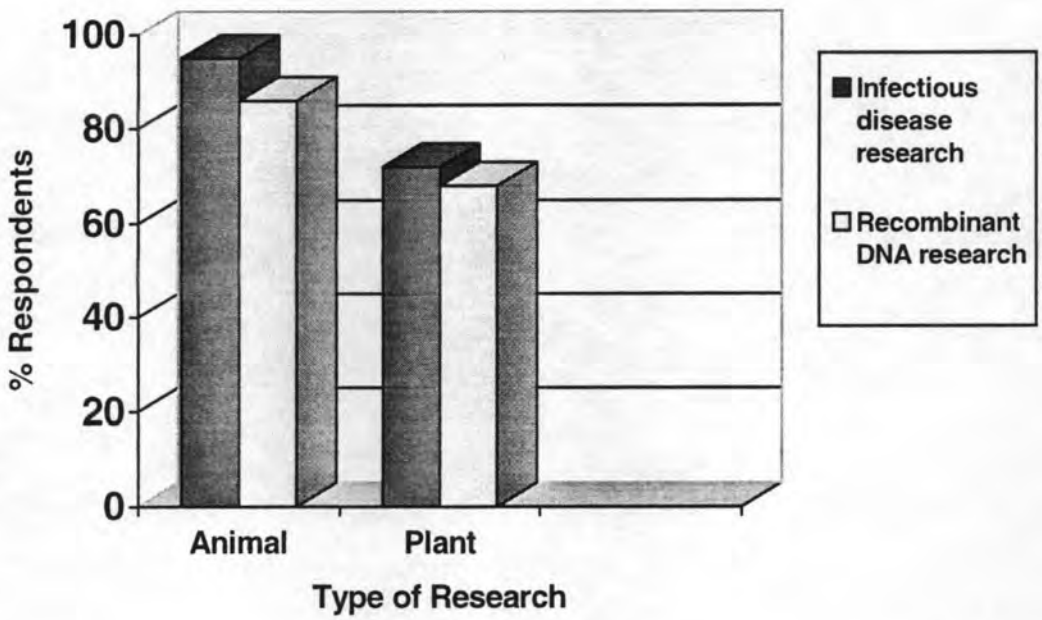
FIGURE 6: Human Tissues and Body Fluids Treated as Biohazardous Waste (Category 3)



Seventy-seven percent of respondents indicated that fixed human tissues were regarded as biohazardous wastes. Unfixed tissues were treated as biohazardous by 97% of respondents. Bulk blood and bulk blood products or other potentially infectious materials (OPIM) were treated as biohazardous waste by 88% and 92% of institutions respectively. Items saturated with human blood or OPIM are managed as biohazardous

wastes by 91% of respondents. Ninety-three percent of respondents indicated that body fluids other than blood or OIM are managed as biohazardous if the source is known to be infectious (i.e. isolation wastes). These high percentages are the likely result of the strong influence of OSHA's Bloodborne Pathogen standard which was noted as a regulatory basis for biohazardous waste management policies by 93% of respondents.

FIGURE 7: Animal Carcasses and Plant Wastes Conditionally Treated as Biohazardous Waste (Categories 4 and 5)



Under Category 4 addressing animal research and diagnostic wastes, 95% of respondents indicated that animal carcasses, tissues and solid wastes generated in infectious disease research were treated as biohazardous waste under institutional policies. Eighty-six percent of respondents indicated that the same types of items generated in recombinant DNA research were also regarded as biohazardous waste.

Under Category 5 addressing plant materials using the same conditions mentioned in the animal research category, 72% of respondents indicated that plant materials and wastes generated in infectious disease research were treated as biohazardous. Sixty-eight percent indicated that plant materials and wastes generated in recombinant DNA research were also treated as biohazardous waste.

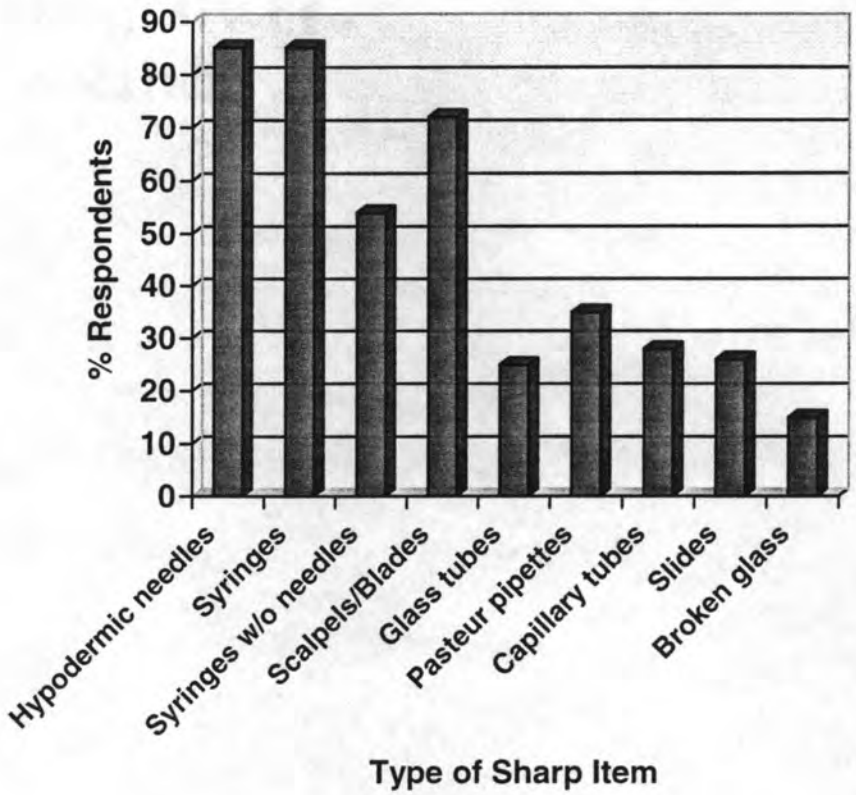
In addition to the waste categories listed in this question, respondents were asked to indicate whether other items not previously addressed were managed as biohazardous waste. Twenty-three respondents (or 23%) indicated other wastes. These responses are summarized in the following table.

TABLE 3: Other Items Managed as Biohazardous Waste

Category	Number of Responses
All animal carcasses	1
All microbiology wastes	4
Biotoxins	3
Chemotherapy agents	2
Animal Blood/OPIM	1
Clonal derivatives of human tissue	1
Fixed animal tissues	1
"Look-alike wastes"	6
Pharmaceuticals	2
Rodent carcasses and bird droppings	1

Management of sharp items as biohazardous waste was also assessed. Because sharps present a puncture hazard and a disease transmission hazard, and are likely to raise public perception concerns, waste management decisions for these items may be variable. This question was intended to examine which sharps are likely to be managed as a biohazardous waste regardless of contamination status. Additionally, the question was intended to examine the contamination conditions that are likely to result in a sharp object being managed as a biohazardous waste if this is a factor.

FIGURE 8: Sharp Items Disposed of As Biohazardous Sharps Waste (Regardless of Contamination Status)



Response rate for this question was 99%. As shown in Figure 8, eighty-five percent of respondents indicated that all hypodermic needles and syringes with needles were managed as biohazardous sharps by their institutions regardless of contamination status. All syringes without needles were treated as biohazardous sharps by 54% of institutions. All scalpels and/or razor blades were managed as biohazardous sharps by 72% of institutions.

Twenty-five percent of institutions indicated that all glass specimen tubes managed as biohazardous sharps regardless of contamination status. All pasteur pipettes were managed as biohazardous sharps by 35% of institutions. All capillary tubes were treated as biohazardous sharps by 28% of institutions. Twenty-six percent of respondents indicated that all slides and cover slips were managed as biohazardous sharps. Only 15%

of institutions indicated that broken glass, regardless of contamination, was treated as biohazardous sharp material.

Respondents were also asked to indicate under what specific conditions an item would be managed as a biohazardous sharp. If a respondent did not check the box indicating that all items in a category were managed as sharps regardless of contamination, their responses in the various contamination condition categories for each item were compiled for the two following figures. The percentages reflected in the figures were tabulated by dividing the number of responses for the contamination category by number of total "conditional" responses for the item category, and multiplying this value by 100.

FIGURE 9a:
Conditional Treatment of Various Sharp Items as Biohazardous Waste

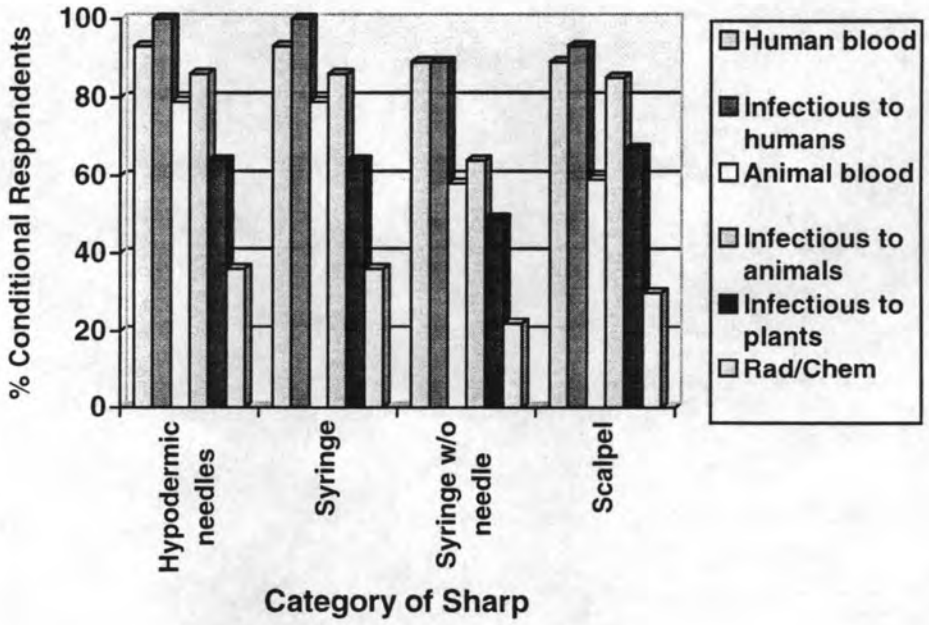
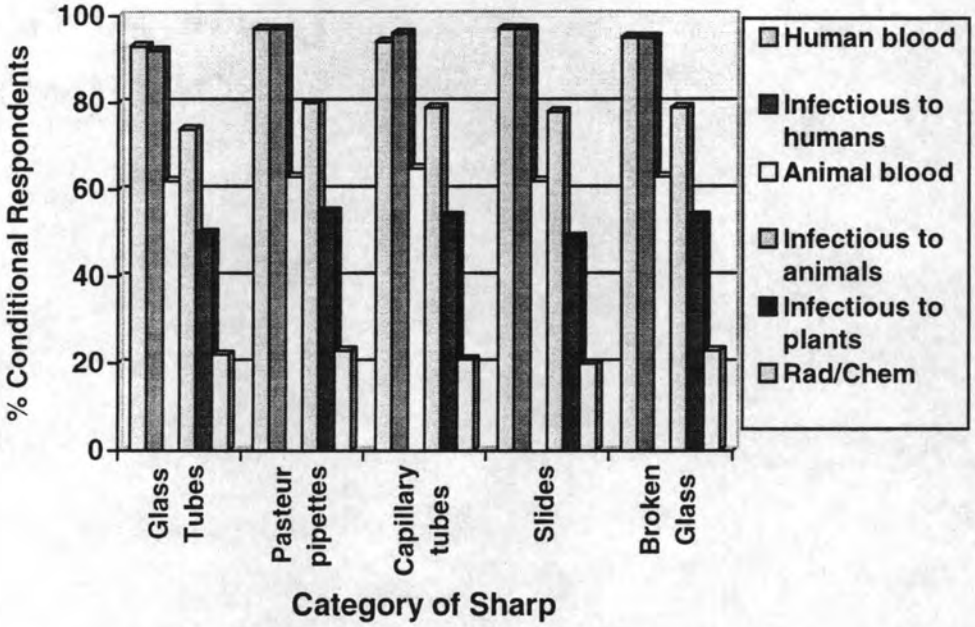
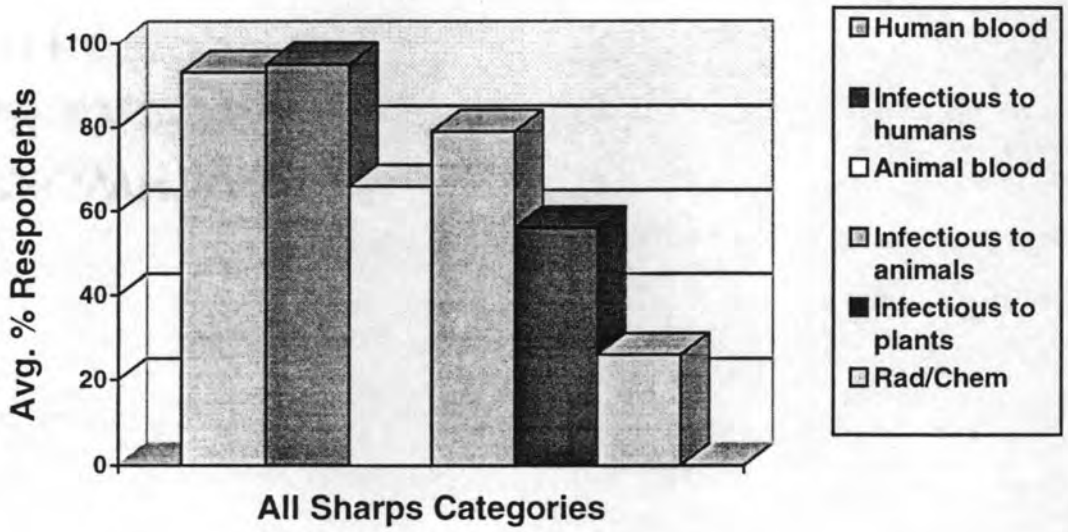


FIGURE 9b:
Conditional Treatment of Various Sharp Items as Biohazardous Waste



As illustrated in Figures 9a and 9b, there was a common trend across the item categories regarding the contamination conditions that resulted in the items being treated as biohazardous sharps waste. Therefore, rather than examine percentages for each item category and contamination condition, it is perhaps more useful to examine the effect of contamination status over all of the sharp item categories by averaging the percentage across each item category.

FIGURE 10: Average Percent of Sharps Treated as Biohazardous Waste Based on Contamination Condition

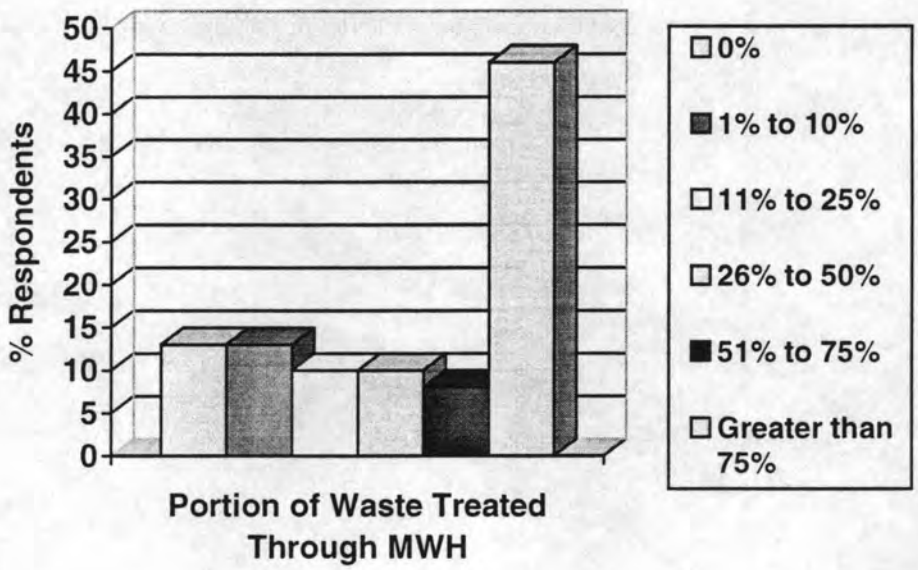


An average of 93% of "conditional" respondents indicating that sharp items were treated as biohazardous waste if they were contaminated with human blood. An average of 95% of "conditional" respondents treated sharp items as biohazardous waste if the items were contaminated with material that was infectious to humans. A 66% average of such responses indicated that sharps items contaminated with animal blood were managed as biohazardous sharps by their institutions. An average of 79% of "conditional" respondents indicated that sharp items contaminated with material infectious to animals were managed as biohazardous sharps. An average of 56% of "conditional" respondents indicated that sharps contaminated with material infectious to plants were treated as biohazardous sharps. Only an average of 26% of "conditional" respondents indicated that radioactively or chemically contaminated sharp materials were managed as biohazardous waste.

Off-site Biohazardous Waste Treatment Methods

The portion of biohazardous waste that is managed off-site by large research-based institutions was assessed.

Figure 11: Portion of Biohazardous Waste Managed Through a Medical Waste Hauler



The response rate for this question was 100%. As shown in Figure 11, thirteen percent of the respondents indicated that their institution did not use a licensed medical waste hauler (MWH) for management of any portion of its biohazardous waste stream. Thirteen percent of respondents indicated that between 1% and 10% of their biohazardous waste was treated and disposed of through a licensed MWH. Ten percent of responding institutions indicated that a licensed MWH was used for treatment and disposal of between 11% and 25% of their biohazardous waste stream. Another 10% of respondents indicated that a licensed MWH was used for between 26% and 50% of their biohazardous waste. Eight percent of respondents indicated that between 51% and 75% of their biohazardous waste stream was managed through a licensed MWH. Finally, 46% of respondents indicated that over 75% of their institution's biohazardous waste was

treated and disposed of through a licensed MWH. Of this last category, 57% of these institutions also indicated that they had an in-patient health care facility.

On-Site Biohazardous Waste Treatment Methods

The use of autoclaves, incineration and other forms of on-site waste treatment methods was determined. Four questions in the survey pertained to the use of autoclaves, post-treatment disposal, and equipment performance criteria.

Response rate for the question addressing use of autoclaves as a form of on-site treatment was 100%. Ninety percent of the respondents indicated that autoclaves were used for this process in accordance with their institution's biohazardous waste policies. Of these 90 respondents, 85 indicated that waste generators treat their own waste in autoclaves located within their facility or building. Twenty respondents indicated that waste was collected from waste-generating sites, then transported to a central location for treatment by waste management personnel.

Respondents were also asked to indicate the various means by which waste was disposed of once treated by autoclave. Of the 89 respondents for this question:

- 67 (or 75%) indicated that waste was landfilled as non-hazardous waste;
- 39 (or 44%) indicated that waste was incinerated;
- 14 (or 16%) indicated "other" options with write-in responses including further management through a MWH and shredding.

For those respondents using autoclaves for on-site biohazardous waste treatment, they were further asked to indicate how autoclave performance was validated, and with what frequency, to assure effective decontamination of waste.

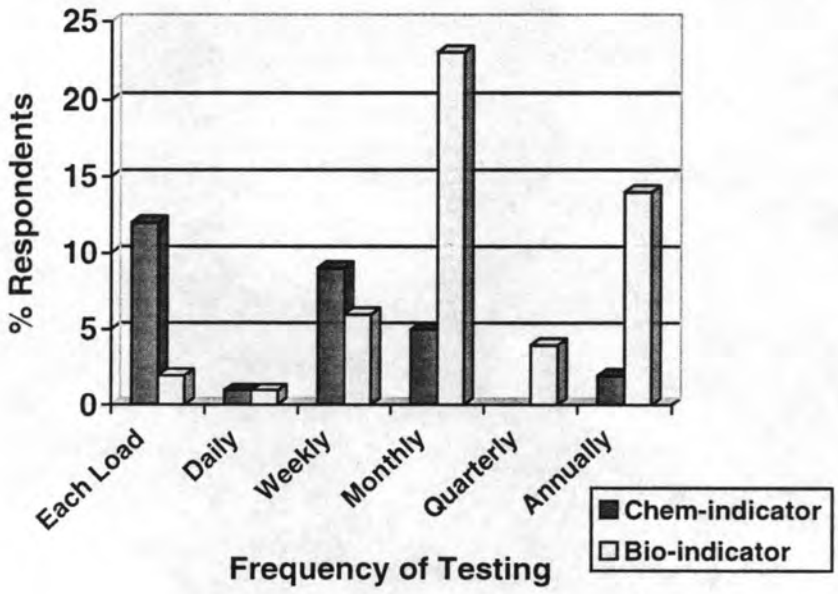
Of the 90 respondents who indicated that autoclaves were used for this purpose, 6 respondents (7%) did not indicate that any form of formal validation testing procedures

were in place. All of these respondents had indicated that autoclaving of waste was performed independently by the waste generator in their research area.

Regarding the institutions that indicated formal use of testing procedures, 53 used autoclave tape on each load. Eight respondents indicated the use of tape at various other frequencies.

As shown in Figure 12, more formal testing methods and frequencies were evident in the use of chemical indicator strips (chem-indicators) and *Bacillus stearothermophilus* ampoules (bio-indicators).

FIGURE 12: Frequency and Type of Autoclave Performance Testing



Twelve respondents indicated that chem-indicators were used on each load. One institution used the chem-indicator method daily. Weekly testing using this method was indicated by 9 respondents. Five respondents indicated that autoclaves were tested

monthly by this method, and 2 respondents indicated that chem-indicators were used for annual testing.

Regarding the use of bio-indicators, 2 respondents indicated that this test method was used for each load, and one respondent indicated that this method was used daily. Six respondents indicated that bio-indicators are used for weekly testing. Monthly testing employing a bio-indicator was used by 23 institutions. Four respondents indicated that this method is used quarterly. Fourteen institutions used this test method for annual performance validation. Two respondents indicated that this test method was used for validation after every 40 hours of autoclave use.

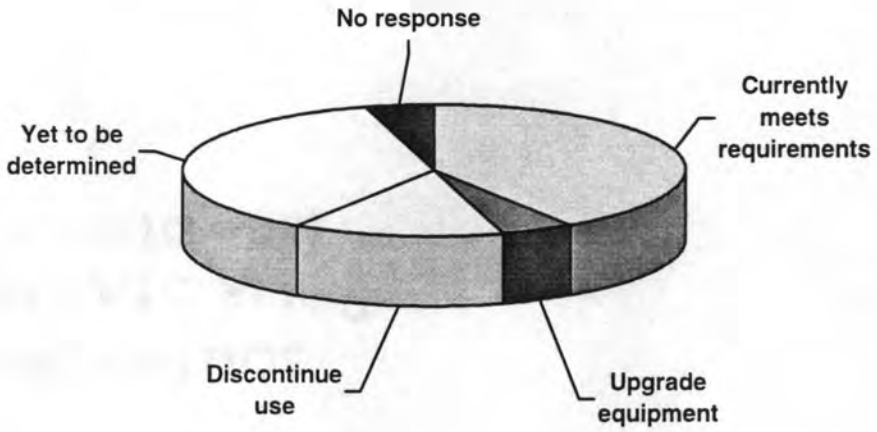
Seven respondents indicated "other" testing methods. Of these methods:

- 4 were related to service contractor assessment;
- 1 institution used review of autoclave run logs; and
- 2 institutions used *B. stearothermophilus* indicator strips.

Information was then collected regarding the use of on-site incineration as a waste treatment and disposal method. The response rate for this group of questions was 100%. Forty-two respondents indicated that they had an on-site incinerator used for treatment and disposal of biohazardous waste. Of those institutions with incinerators, 22 indicated that their incinerators were classified as medical/infectious waste incinerators as defined by the EPA regulations. As anticipated, 12 of these respondents had indicated that their institutions have an in-patient medical care facility that would result in the generation of medical waste.

The respondents who indicated that their incinerators were HMIWI's were further asked about their plans for compliance with the recent enactment of EPA's HMIWI regulations as shown in Figure 13.

FIGURE 13: Compliance Plans for Institutions with HMIWI's



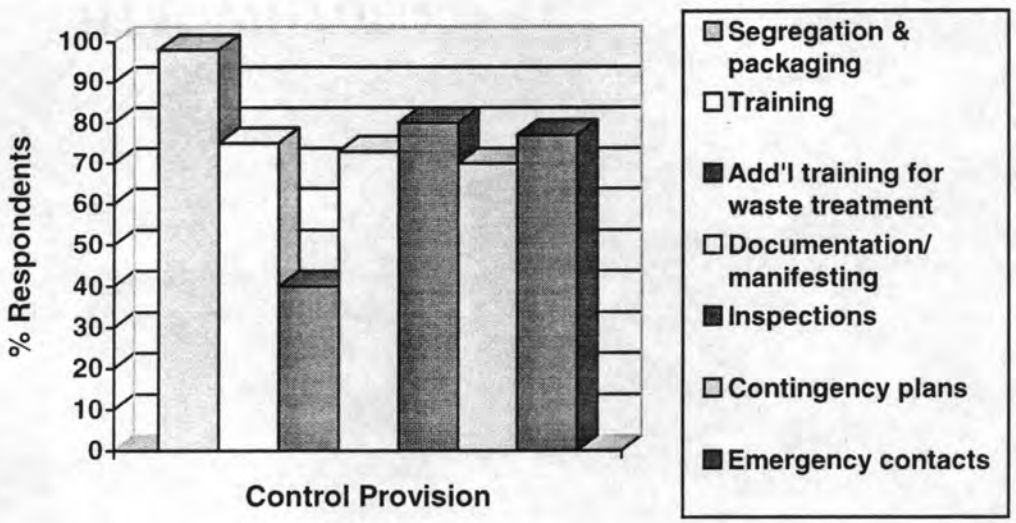
Of the 22 respondents to be affected by EPA's HMIWI regulations, 9 indicated that their current equipment and management systems would meet the requirements for that regulation. One respondent indicated that the institution's equipment would be upgraded to meet regulatory requirements. Three respondents indicated that their institution will discontinue incineration. Eight responded that their institution's course of action regarding future incineration use has yet to be determined, and one respondent did not complete this portion of the question series.

The use of other forms of on-site treatment for biohazardous waste was also assessed. Twenty-three respondents did not indicate that any additional forms of treatment were used by their insitution. Seventy-two respondents indicated that chemical disinfection was used for some biohazardous waste treatment. Four respondents indicated that irradiation was used. Only one respondent noted an alternative technology described as "high water pressure grinding."

Biohazardous Waste Management Program Compliance

Information was collected regarding the control provisions of the institutions' biohazardous waste management programs. Respondents were asked to identify the control provisions included in their current programs (Figure 14).

FIGURE 14: Biohazardous Waste Management Plan Control Provisions



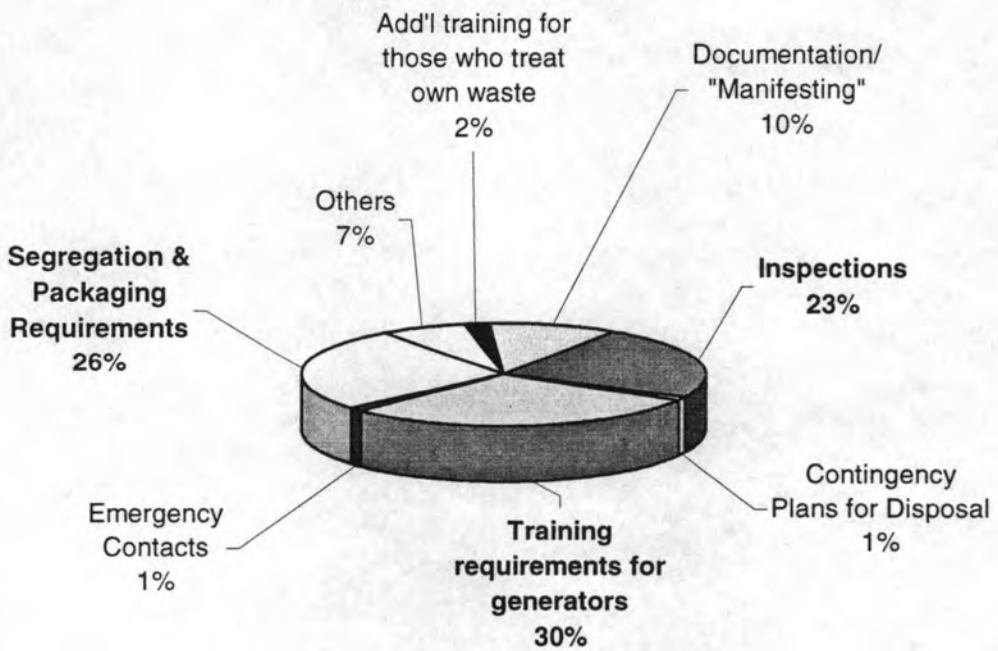
Response rate for this question varied between 97% and 99%, depending on the category. Ninety-eight percent of respondents indicated that their programs included segregation and packaging requirements for biohazardous waste. Training requirements for biohazardous waste generators were included in the provisions for 75% of the responding institutions. Forty percent of respondents indicated that there were additional training requirements for personnel performing their own on-site waste treatment. Documentation to assure the proper treatment and final disposal of waste (i.e. "manifesting") was indicated as a requirement by 73% of respondents. Eighty percent of respondents indicated that inspections of waste generating areas were used as a means of controlling compliance at their institutions. Contingency plans for waste disposal were

included as a provision by 70% of responding institutions, and emergency contacts were included as a provision by 77% of institutions.

Respondents were also asked to write in additional provisions not previously included. Fourteen respondents indicated additional provisions including procedural requirements imposed by the MWH or institution's maintenance departments, and research restrictions on violators.

Finally, as shown in Figure 15, respondents were asked to identify the control provisions that were most critical to the effectiveness of their biohazardous waste management programs.

FIGURE 15: Most Critical Provisions for Assuring Compliance with Policies



Response rate for this question was 89%, which may have been due to the fact that it was the last question on the survey. Based on the responses collected, training requirements for waste generators (30%), segregation and packaging requirements (26%), and inspections (23%) appear to be the control provisions that are most critical to the success of biohazardous waste management programs at the responding institutions.

CHAPTER 4

DISCUSSION

There were several important findings of this study. Ninety-eight percent of respondents indicated that human cell cultures regarded or known to be infectious were treated as biohazardous waste, while non-infectious human cell cultures were regarded as biohazardous by 84% of respondents. Human cell lines are considered to be potentially infectious materials in accordance with OSHA's Bloodborne Pathogens standard unless they are tested and determined to be virus-free (OSHA, 1994). Ninety-three percent of respondents indicated that they based their biohazardous waste management plans on OSHA BBP requirements while only 84% of respondents are treating all human cell cultures as biohazardous waste. This implies that 9% of respondents are either testing their cell lines to assure that they are virus-free or they are not managing these items properly for disposal.

With respect to the treatment of human tissues and body fluids, all categories with the exception of fixed tissues were regarded as biohazardous waste by at least 88% of respondents. This result was expected based on the fact that 93% of respondents indicated that they based their biohazardous waste management plans on OSHA requirements. Interestingly, 77% of respondents indicated that they treat fixed human tissues as biohazardous waste, even though these tissues are not considered to be potentially infectious materials under the OSHA Bloodborne Pathogens standard (OSHA, 1992). This may be explained by the fact that 98% of respondents indicated that state environmental regulations were used as a basis for their biohazardous waste management plans. State environmental regulations are often modeled after the *EPA Guide for Infectious Waste Management* (1986) which includes tissues, organs or body parts removed during surgery, autopsy or biopsy in its definition of pathological waste.

Eighty-six percent of respondents indicated that they used CDC/NIH guidelines in the development of their biohazardous waste policies. Based on these findings, it is not surprising that 95% of respondents regarded animal carcasses generated in infectious disease research as biohazardous waste, and 86% of respondents regarded animal

caracasses generated in recombinant DNA as biohazardous waste. In contrast, under the plant waste category, 72% of respondents indicated that wastes generated in infectious disease research are regarded as biohazardous waste. However, only 68% of respondents indicated that plant wastes generated from recombinant DNA research are treated as biohazardous wastes. This response was lower than expected based on the 86% of respondents who indicated they used CDC/NIH guidelines as a basis for their waste policies. The fact that only 68% of respondents treat this waste as biohazardous may indicate an oversight of NIH requirements for conducting recombinant DNA plant research.

Respondents were given the opportunity to write in other items that were not listed in the survey, but were also managed as biohazardous waste by their institutions. Six indicated that biotoxins are managed as biohazardous waste. This suggests an emerging issue involving the proper disposal of biotoxins and one that should be addressed in future research. Public perception of waste is an evident consideration for institutions as indicated by the 6 respondents who indicated that "look-alike waste" (i.e. items that bear a resemblance to biohazardous waste like disposable gloves and pipette tips) is managed as biohazardous waste.

Regarding the management of sharps as biohazardous waste, 3 particular items were consistently managed as a biohazardous waste regardless of their contamination status including: hypodermic needles (85%), syringes with needles (85%), and scalpels/blades (72%). These items present a puncture hazard by design and are identified as sharps under the Bloodborne Pathogens standard if biologically contaminated (OSHA, 1992). Syringes with needles and hypodermic needles are also commonly associated with mismanagement of medical waste as demonstrated in beach wash-up incidents (*NY Times*, 1998; Turnberg, 1996). Therefore, the unconditional treatment of these items as biohazardous waste may be the result of OSHA requirements as well as prudent practice to eliminate public perception concerns. Syringes without needles attached were managed unconditionally as biohazardous waste by 54% of respondents. This finding may be the result of state environmental regulations that may be more restrictive on the definition, management and disposal of biohazardous wastes (*Waste Age/Infectious Waste News*, 1998).

Waste treatment methods used by large, research-based universities included incineration, steam sterilization by autoclave and management through a licensed medical waste hauler (MWH). Surprisingly, 46% of the universities were using a MWH for management of over 75% of their biohazardous waste stream. This indicates a growing market sector for the MWH industry.

Regarding on-site waste treatment methods, 90% of respondents indicated that they were using autoclaves for treatment of biohazardous waste. Seventy-five percent indicated that their waste was being landfilled as non-hazardous waste following this treatment. Yet, only 47 of the 90 (52%) institutions using autoclaves for this purpose indicated validation of their decontamination process using a biological indicator (*B. stearothermophilus*) with any frequency. The *Model Guidelines for State Medical Waste Management* (Council of State Governments, 1992) recommends the biological indicator method for validating autoclave performance over other methods and further recommends testing after every forty hours of use. Eight (9%) respondents indicated using this validation method on a weekly or less frequent basis. Twenty-three (26%) indicated monthly testing, 4 (4%) indicated quarterly testing, and 14 (16%) indicated annual testing. This variability in testing frequency may be the result of individual state regulatory requirements for this process or indicate a general weakness in validation process.

Importantly, results of this study indicate that nearly 50% (10 out of 22) of HMIWI's used in the large research-based university environment will continue to operate in light of stricter EPA regulations. This is a contrast to the statistics that project that more than 80% of incinerators will cease to operate under stricter regulations (Brunner, 1996). Only 3 out of 22 (14%) respondents that indicated their institution currently used an HMIWI said that they would be discontinuing this form of treatment, and eight (36%) respondents indicated that actions were yet to be determined.

The most common control provision for compliance with biohazardous waste management plans was segregation and packaging. Due to the nature of biohazardous materials (contaminated sharp materials, potentially infectious liquid materials) segregation and packaging are basic requirements of many of the regulations that would affect virtually all generators including the OSHA Bloodborne Pathogens standard, state

environmental regulations, and DOT requirements for transportation of hazardous wastes. Thus, the high percentage of respondents noting control provision was expected. The least noted control provision was additional training for waste treatment (40%). Although about half of the universities (46%) indicated that they are using a medical waste hauler for management of over 75% of their biohazardous waste stream, 90% of universities responded that they use autoclaves for treatment of waste. Of those 90 respondents, 85 indicated that generators treat their own waste in autoclaves located within their facility. This data indicates that a large proportion (roughly 50%) of personnel who are treating their own waste by autoclave may not be receiving training in the effective and safe techniques required for this process. Surprisingly, when asked to indicate which control provisions were found to be most critical for assuring compliance with policies, only 2% of respondents indicated that additional training for those who treat their own waste was a critical provision.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

Findings of this study indicate that biohazardous waste management programs in large, research-based universities are highly variable in some respects, but all have some common underlying qualities that drive their programs.

Virtually all universities indicated that they are conducting biotechnology and BL2 level research while less than half indicated that their university had an in-patient healthcare facility. Results of this study demonstrate that biohazardous waste management in large research-based universities can not rely solely on policies and regulations addressing only medical waste. This was reflected through the most frequently cited regulations and guidelines used as the basis waste management programs- state, OSHA Bloodborne Pathogens standard, and CDC/NIH guidelines.

Compliance with regulations and recommendations related to research was investigated in this study. All items that were potentially infectious to humans were treated as biohazardous waste as required under OSHA's Bloodborne Pathogens standard. The vast majority of respondents relied on this standard as a basis for program development. Items contaminated with animal blood or potentially infectious to animals were also regarded as biohazardous waste by the majority of institutions. In contrast, items potentially infectious to plants were the least likely to be treated as a biohazardous waste, indicating that more attention may need to be given to this category of waste.

The scope of the research presented here was limited to examining general information regarding biohazardous waste management in the large, research-based universities in the U.S. The study did not include quantification of the waste stream. Further studies should be conducted to examine the quantity of biohazardous waste

generated in these environments in order to assess the need for developing waste treatment alternatives for this environment. As biohazardous waste treatment and disposal becomes more complex and costly, there will be a growing need for examination of alternative technologies by the large, research-based university. This study provides valuable information for universities in general regarding the topic. However, it is not directly applicable to universities outside the U.S. or to small and medium universities. Similar research adapted to small or medium universities may be especially beneficial to these institutions. EHS personnel responsible for biohazardous waste management at institutions of this size are likely to be dealing with multiple EHS programs and may not necessarily have the time or resources required to develop a comprehensive biohazardous waste management program.

Recommendations for Biohazardous Waste Program Development

Based on the findings of this study, the following recommendations can be made to EHS staff or biosafety personnel regarding biohazardous waste program development:

1. Identify business operations and research activities at the university that are likely to result in biohazardous waste generation. Research applicable regulations and guidelines pertinent to these business operations and activities and integrate these requirements in the management plan.

2. Assess waste treatment techniques to assure that waste is treated in the safest, and most cost-effective manner. In situations where waste generation is limited, management through a MWH may be the best alternative.

3. Periodically review the effectiveness of treatment techniques and stay current with technological and regulatory developments in this area. New treatment methods that are cost-justifiable are likely to be developed as regulations over treatment techniques become more restrictive.

4. Regardless of the waste disposal method chosen, include provisions for segregation and packaging, training, and inspections of waste generating areas as a minimum to assure compliance with OSHA and state environmental regulations.

5. Use guidance documents such as the EPA Guide for Infectious Waste Management and the Model Guidelines for State Medical Waste Management to develop biohazardous waste management programs. Although these documents are dated in their technological information, they contain valuable information about program development and waste handling practices that are not restricted to the medical waste portion of the biohazardous waste stream.

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APPENDICES

Appendix A

Carnegie Classification Research I & II Universities

Carnegie Classification Research I Universities (Page 1 of 3)

University	City	State
University of Alabama-Birmingham	Birmingham	AL
Arizona State University-Main	Tempe	AZ
University of Arizona	Tucson	AZ
University of California-Santa Barbara	Santa Barbara	CA
California Institute of Technology	Pasadena	CA
Stanford University	Stanford	CA
University of California-Berkeley	Berkeley	CA
University of California-Davis	Davis	CA
University of California-Irvine	City of Irvine	CA
University of California-Los Angeles	Manhatten Beach	CA
University of California-San Diego	La Jolla	CA
University of California-San Francisco	San Francisco	CA
University of Southern California	Los Angeles	CA
Colorado State University	Fort Collins	CO
University of Colorado-Boulder	Boulder	CO
University of Connecticut	Storrs	CT
Yale University	New Haven	CT
Howard University	Washington	DC
Georgetown University	Washington	DC
Florida State University	Tallahassee	FL
University of Florida	Gainesville	FL
University of Miami	Miami	FL
Emory University	Atlanta	GA
Georgia Institute of Technology	Atlanta	GA
University of Georgia	Athens	GA
University of Hawaii-Manoa	Honolulu	HI
Iowa State University	Ames	IA
University of Iowa	Iowa City	IA
University of Illinois-Chicago	Chicago	IL
University of Illinois-Urbana Champaign	Urbana	IL
Northwestern University	Evanston	IL
University of Chicago	Chicago	IL
Indiana University-Bloomington	Bloomington	IN
Purdue University	West Lafayette	IN
University of Kansas-Main	Lawrence	KS
University of Kentucky	Lexington	KY
Louisiana State University	Baton Rouge	LA
Tulane University	New Orleans	LA
Boston University	Boston	MA
Tufts University	Boston	MA

Carnegie Classification Research I Universities (Page 2 of 3)

University	City	State
Harvard University	Boston	MA
University of Massachusetts	Amherst	MA
Massachusetts Institute of Technology	Cambridge	MA
Johns Hopkins University	Baltimore	MD
University of Maryland-College Park	College Park	MD
Michigan State University	East Lansing	MI
University of Michigan	Ann Arbor	MI
Wayne State University	Detroit	MI
University of Minnesota-Twin Cities	Minneapolis	MN
University of Missouri-Columbia	Columbia	MO
Washington University	St. Louis	MO
University of Nebraska-Lincoln	Lincoln	NB
North Carolina State University	Raleigh	NC
University of North Carolina-Chapel Hill	Chapel Hill	NC
Duke University	Durham	NC
Princeton University	Princeton	NJ
Rutgers University	Piscataway	NJ
University of New Mexico	Albuquerque	NM
New Mexico State University-Main	Las Cruces	NM
Cornell University	Ithaca	NY
New York University	New York	NY
Rockefeller University	New York	NY
State University of New York-Buffalo	Buffalo	NY
State University of New York-Stony Brook	Stony Brook	NY
University of Rochester	Rochester	NY
Columbia University-City of New York	New York	NY
Case Western Reserve University	Cleveland	OH
Ohio State University-Main	Columbus	OH
University of Cincinnati-Main	Cincinnati	OH
Oregon State University	Corvallis	OR
Carnegie Mellon University	Pittsburgh	PA
Penn State-University Park	University Park	PA
Temple University	Philadelphia	PA
University of Pennsylvania	Philadelphia	PA
University of Pittsburgh-Pittsburgh	Pittsburgh	PA
Brown University	Providence	RI
University of Tennessee-Knoxville	Knoxville	TN
Vanderbilt University	Nashville	TN
Texas A&M University	College Station	TX
University of Texas-Austin	Austin	TX
Utah State University	Logan	UT
University of Utah	Salt Lake City	UT

Carnegie Classification Research I Universities (Page 3 of 3)

University	City	State
University of Virginia	Charlottesville	VA
Virginia Commonwealth University	Richmond	VA
Virginia Polytechnic & State University	Blacksburg	VA
University of Washington-Seattle	Seattle	WA
University of Wisconsin-Madison	Madison	WI
West Virginia University	Morgantown	WV

Carnegie Classification Research II Universities (Page 1 of 1)

University	City	State
University of Arkansas	Fayetteville	AR
University of California-Santa Cruz	Santa Cruz	CA
University of California-Riverside	Riverside	CA
George Washington University	Washington	DC
University of Delaware	Newark	DE
University of South Florida	Tampa	FL
University of Idaho	Moscow	ID
Southern Illinois University-Carbondale	Carbondale	IL
University of Notre Dame	Notre Dame	IN
Kansas State University	Manhatten	KS
University of Louisville	Louisville	KY
Brandeis University	Waltham	MA
Northeastern University	Boston	MA
Mississippi State University	Mississippi State	MS
University of Mississippi	University	MS
Saint Louis University	St. Louis	MO
Rensselaer Polytechnic Institute	Troy	NY
Syracuse University-Main	Syracuse	NY
State University of New York-Albany	Albany	NY
Kent State University-Main	Kent	OH
Ohio University-Main	Athens	OH
Oklahoma State University-Main	Stillwater	OK
Uiversity of Oklahoma-Norman	Norman	OK
University of Oregon	Eugene	OR
University of Rhode Island	Kingston	RI
Clemson University	Clemson	SC
University of South Carolina-Columbia	Columbia	SC
Rice University	Houston	TX
University of Houston	Houston	TX
Brigham Young University	Provo	UT
University of Vermont	Burlington	VT
Washington State University	Pullman	WA
University of Wisconsin-Milwaukee	Milwaukee	WI
University of Wyoming	Laramie	WY

Appendix B

First Contact Phone Script & Survey Cover Letter

First Contact Phone Script

The following script was used when first contact was made with universities and survey respondents were identified. Highlighted portions of the script indicate the essential information that was conveyed in all contact cases to solicit participation and satisfy human subjects regulatory requirements.

Hello. My name is Robin Mecklem. I am the Assistant Biological Safety Officer for Michigan State University. I am also a graduate student in the Environmental Health Management program of Oregon State University and am in the process of completing my master's degree thesis. To complete my thesis, I am planning to conduct a survey of environmental health and safety professionals at large, research-based universities in the United States. This survey is regarding biohazardous waste management practices used by such universities. Although many studies have been conducted regarding biohazardous waste management practices, little research has been conducted specifically addressing biohazardous waste in the university research setting. The results of this study will provide valuable insight regarding the definition, treatment, and disposal of waste in this setting and serve as a resource for other universities who are developing biohazardous waste management programs.

I received your name from your university's web site (or environmental health and safety director) and believe that you may be the person who is most knowledgeable of biohazardous waste practices at your institution. Is this correct? (If the reply is No- Can you refer me to the person who you believe would be most knowledgeable?)

May I tell you a few details about the survey? I plan to mail the survey to participants in early September 1999. The survey is 2 and one-half pages long with 14 to 16 questions- most of which can be answered by checking the appropriate box. This survey should not take more than 15 minutes to complete based on trial runs. I will be asking respondents to return the survey within 30 days of receipt. A self-addressed stamped envelope will be provided for the return of the survey. The survey does not require any information that identifies respondents or institutions. Surveys will be identified only by number for followup of those respondents who do not return their survey within 30 days. These numbers will be removed upon return receipt and prior to data analysis.

Would you be willing to participate in this survey? (If No- Is there someone else at your institution who is also knowledgeable of your institution's biohazardous waste practices that I can contact?)

Great. Can I verify that my mailing information for you is correct?

Thank you. You should receive your survey packet in mid-September with a summary of the information that I have told you today. However, I would like to give you my name and number again in case you have any further questions. I am Robin Mecklem and I can be reached at 517-355-1283. My research advisor for the survey can also answer any questions you may have. She is Dr. Cathy Neumann in the OSU Department of Public Health. Her phone number is 541-737-3833. Do you have any further questions at this time?

Survey Cover Letter

September 15, 1999

To: <Name>, <Institution>

A short time ago, you were contacted and asked to participate in a survey regarding biohazardous waste management practices used by your institution. This survey is part of a Master's thesis being completed through the Oregon State University Department of Public Health.

Biohazardous waste management presents a number of challenges in the research-based university environment. This is due to the broad range of research activities that may result in the generation of this waste, as well as the diverse range of regulations that may apply to that research. To date, the question of biohazardous waste management in the large research university environment has been virtually unexamined. Through the administration of the attached survey, we hope to address the following questions:

1. Which regulations and/or guidelines are used to define biohazardous waste and to determine proper treatment and disposal?
2. What are the most common methods of treatment and disposal for biohazardous waste?
3. What control measures are used to assure safe and proper handling, treatment and disposal of biohazardous waste?

In addition to identifying common trends in biohazardous waste management practices, the data will be used to develop an effective model biohazardous waste management plan for research-based universities.

Please complete the enclosed survey within 30 days, and return it in the self-addressed stamped envelope provided in the survey packet. Please be assured that confidentiality of all responses will be maintained by the research team. Your survey is identified by a number which will be removed upon receipt and prior to data analysis. This number will only be used to identify and follow up with individuals who do not return a completed survey.

If you have any questions regarding this study please feel free to contact me at (517) 355-1283 or Dr. Cathy Neumann at (541) 737-3833. To receive a summary of the results of this study, please e-mail me at mecklem@pilot.msu.edu. If you do not have e-mail, please fax your request to me at (517) 353-4871.

Sincerely,

Robin Lyn Mecklem
Graduate Candidate
Environmental Health Program
Department of Public Health
Oregon State University
Corvallis, Oregon 97331

Cathy Neumann, Ph.D.
Assistant Professor
Environmental Health Program
Department of Public Health
Oregon State University
Corvallis, Oregon 97331

Appendix C

Survey Tool

Defining and Managing Biohazardous Waste in Research-Based Universities in the United States:

A Survey of Environmental Health and Safety Professionals

Please return your completed survey in the envelope provided to:

Robin Mecklem
OSU Graduate Candidate
P.O. Box 261
Mason, MI 48854

Defining and Managing Biohazardous Waste in Research-Based Universities in the United States

Instructions for the Respondent:

Before proceeding with the enclosed survey, please take a moment to review the definitions below which will assist you in completing the survey.

Biohazardous Waste: Waste that is potentially infectious to living organisms. It may (depending on your local and state deifinitions) encompass medical waste as defined by occupational safety regulations and state waste regulations, as well as wastes generated in plant or animal research which are potentially infectious to these organisms, or may alter their natural genetic selection process. Any waste that requires segregation and specific treatment separate from the municipal waste stream due to its true or perceived infectious quality.

Commonly Used Abbreviations

EPA:	Environmental Protection Agency
OSHA:	Occupational Safety and Health Administration
CDC:	Centers for Disease Control
NIH:	National Institutes of Health
USDA:	United State Department of Agriculture
APHIS:	Animal and Plant Health Inspection Service
JCAHO:	Joint Commission on Accreditation of Healthcare Organizations
AAALAC:	Association For Assessment and Accreditation of Laboratory Animal Care
USDOT:	United States Department of Transportation
OPIM:	Other potentially infectious materials as defined by the OSHA Bloodborne Pathogens Standard

Please complete all applicable questions as outlined throughout the survey.

Institution Profile

1. What kind of facilities or activities are generating biohazardous waste at your institution? *(Please circle NO or YES for all categories.)*

Facilities/Activities		
a. Does your institution have an in-patient medical treatment facility (i.e. hospital) on campus?	NO	YES
b. Does your institution have a veterinary medicine school which performs teaching, treatment and research?	NO	YES
c. Is biotechnology research (i.e. recombinant DNA, human gene therapy, transgenics) currently conducted at your institution?	NO	YES
d. Is Biosafety Level 2 research currently conducted at your institution?	NO	YES
e. Does your institution have a Biosafety Level 3 research facility currently in use?	NO	YES

Biohazardous Waste Management Procedure Development

2. Which agency definitions, guidelines or regulations were used to develop your institution's biohazardous waste management procedures? *(Please circle NO or YES for all categories.)*

Agency		
a. EPA Regulations (e.g. Medical Waste Tracking Act)	NO	YES
b. Local Waste Regulations (e.g. Publicly Owned Treatment Works)	NO	YES
c. State Waste Regulations	NO	YES
d. OSHA Regulations (e.g. Bloodborne Pathogens Standard)	NO	YES
e. CDC/NIH Guidelines (e.g."Biosafety in Microbiological and Biomedical Laboratories")	NO	YES
f. USDA/APHIS Regulations (e.g. "Introduction of Regulated Articles"; 7CFR340)	NO	YES
g. Accreditation Agency Requirements (e.g. JCAHO, AAALAC)	NO	YES
h. USDOT Regulations (e.g.49CFR171-180)	NO	YES
i. Other:_____ *(Please write in response if applicable.)*	NO	YES

3. Who has primary responsibility for the development and maintenance of your institution's biohazardous waste management procedures? *(Please check one box.)*

- ☐ Biological Safety Officer
- ☐ Biological Safety Committee
- ☐ Hazardous Waste Specialist
- ☐ Other:_____
  (Please write in response if applicable.)

Defining Biohazardous Waste

4. Which of the following items (excluding sharps) are treated and disposed of as biohazardous waste in accordance with you institution's biohazardous waste management procedures? *(Please circle NO or YES for each item in each category listed below.)*

Cultures and stocks of infectious agents (and items contaminated with these)		
a. agents infectious to humans	NO	YES
b. agents infectious to animals	NO	YES
c. agents infectious to plants	NO	YES
d. microorganisms constructed with recombinant DNA	NO	YES

Cell Cultures		
a. human- noninfectious	NO	YES
b. human- infectious	NO	YES
c. animal- noninfectious	NO	YES
d. animal- infectious	NO	YES
e. plant- noninfectious	NO	YES
f. plant-infectious	NO	YES

Human Tissues, Human Blood and Body Fluids		
a. human tissues-fixed	NO	YES
b. human tissues-unfixed	NO	YES
c. bulk human blood	NO	YES
d. bulk human blood products/OPIM	NO	YES
e. items saturated with human blood /OPIM	NO	YES
f. human body fluids other than blood/OPIM if source infectious	NO	YES

Animal Research and Diagnostic Wastes		
a. animal carcasses/tissues and solid wastes (i.e. bedding) generated in infectious disease research	NO	YES
b. animal carcasses/tissues generated in recombinant DNA research	NO	YES

Plant Materials		
a. plant waste material generated in infectious disease research	NO	YES
b. plant waste material generated in recombinant DNA research	NO	YES

5. Does your institution regard any items other than those listed in Question 4 (and excluding sharps) as biohazardous waste?
   - ☐ No
   - ☐ **Yes, these items are:**_____

   (Please write in response if applicable.)

6. Under what conditions are the following items treated and disposed of as biohazardous sharps waste according to your institution's biohazardous waste management procedures? *(Please place an "X" in the appropiate boxes for each "sharp" listed in the 2 tables below.)*

Contamination status	Hypodermic needles	Syringes with needles	Syringes without needles	Scalpels/razor blades
All items in this category regardless of contamination status				
If contaminated with human blood/OPIM				
If contaminated with agents infectious to humans				
If contaminated with animal blood				
If contaminated with agents infectious to animals				
If contaminated with agents infectious to plants				
If trace contaminated with radioactive or chemical waste				

Contamination status	Glass specimen tubes	Pasteur pipettes	Capillary tubes	Slides and cover slips	Broken glass
All items in this category regardless of contamination status					
If contaminated with human blood/OPIM					
If contaminated with agents infectious to humans					
If contaminated with animal blood					
If contaminated with agents infectious to animals					
If contaminated with agents infectious to plants					
If trace contaminated with radioactive or chemical waste					

Biohazardous Waste Treatment Methods-Offsite

7. What portion of your biohazardous waste is treated and disposed of by a licensed medical waste hauler?
   - ☐ 0% (My institution does not use a licensed medical waste hauler at this time.)
   - ☐ Between 1% and 10%
   - ☐ Between 11% and 25%
   - ☐ Between 26% and 50%
   - ☐ Between 51% and 75%
   - ☐ Greater than 75%

Biohazardous Waste Treatment Methods-Onsite

8. Does your institution use decontamination by steam sterilizer (i.e. autoclave) as a form of on-site biohazardous waste treatment?
   - ☐ NO *(Please proceed to Question 12.)*
   - ☐ YES *(Please proceed to Question 9.)*

9. Where and how is decontamination by autoclave performed? *(Please check all boxes that apply.)*
   - ☐ Biohazardous waste generators treat their own autoclavable waste using autoclaves located at their facility.
   - ☐ Autoclave waste is collected from labs, clinical environments or other waste-generating facilities, then transported to central location for treatment by waste management personnel.
   - ☐ Other:_____
     (Please write in response if applicable.)

10. Once decontaminated by autoclave, how is waste managed? *(Please check all boxes that apply.)*
    - ☐ Landfilled as nonhazardous waste
    - ☐ Incineration
    - ☐ Other:_____
      (Please write in response if applicable.)

11. How frequently are autoclaves that are used for biohazardous waste treatment tested for effective destruction of microorganisms, and what test method is used? *(Please place an "X" in all boxes that apply in the table below. Please write in responses where appropriate.)*

Testing Method	Each Load	Daily	Weekly	Monthly	Quarterly	Annually	Other (please write in frequency)
Autoclave tape							
Chemical indicator strip							
Bacillus stearothermophilus ampoule							
Other (Please write in method)							

12. Does your institution currently use an onsite incinerator to burn biohazardous waste?
    - ☐ NO *(Please proceed to Question 14.)*
    - ☐ YES *(Please proceed to Question 13.)*

13. Is your incinerator a medical waste incinerator as defined by EPA regulations (40CFR part 60)?
   - ☐ NO *(Please proceed to Question 14.)*
   - ☐ YES *(Please proceed to Question 13.a.)*

13.a. How will your institution comply with EPA's Medical Waste Incinerator Requirements?
   - ☐ Current equipment and operating procedures will meet regulatory requirements
   - ☐ Upgrade existing equipment and operating procedures to meet regulatory requirements
   - ☐ Discontinue incineration
   - ☐ Yet to be determined

14. What other forms of on-site biohazardous waste treatment are used at your institution? *(Please check all boxes that apply.)*
   - ☐ Chemical disinfection
   - ☐ Irradiation
   - ☐ Other:_____

(Please write in response if applicable.)

Biohazardous Waste Management Procedure Compliance

15. Which of the following administrative controls are included as part of your institution's biohazardous waste management policies and procedures? *(Please circle NO or YES for all categories.)*

Administrative Controls		
a. Requirements for segregation, packaging & storage of biohazardous waste	NO	YES
b. Training requirements for waste generators	NO	YES
c. Additional training requirements for personnel performing their own onsite waste treatment	NO	YES
d. Documentation requirements to assure proper treatment and final disposal (i.e. "manifesting")	NO	YES
e. Periodic inspections of waste generating and treatment areas	NO	YES
f. Contingency plans for waste treatment and disposal	NO	YES
g. Designated emergency contacts for waste storage areas and waste treatment facilities	NO	YES

16. Does your institution use any administrative controls other than those listed in Question 15 to assure compliance with biohazardous waste policies and procedures?
   - ☐ No
   - ☐ **Yes, these are:**_____

(Please write in response if applicable.)

17. Of the administrative controls that you have identified as being used by your institution in Question 15 and 16, which 2 are most critical for assuring that biohazardous waste generators comply with disposal policies? *(Please list these 2 controls in the space below.)*

_____

This concludes the survey questions. Please use the space below to share comments that you may have regarding the survey.

Thank you for your help!

Please return your completed survey in the envelope provided to:

Robin Mecklem- Graduate Candidate
P.O. Box 261
Mason, MI 48854

Appendix D

Permission Letters for Use of Copyrighted Materials

2117 Medford Road #20
Ann Arbor, MI 48104

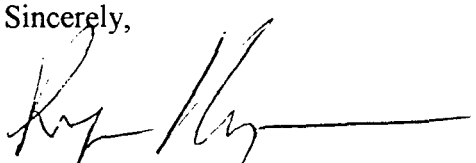
June 21, 1999

Dear Robin Mecklem:

I am writing this letter to give you a permission to use my survey, entitle "Medical Waste Treatment and Disposal Methods Used by Hospitals in Oregon, Washington, and Idaho" in your research.

I would appreciate if you acknowledge my survey in your proposal or subsequent publication.

Sincerely,



Pornwipa Klangsin

Permission Letter from Waste Age/Infectious Waste News

You have our permission to use the material you requested (below) in the form you outlined. Please credit the publication and date in your footnotes or appendix. If you have any questions, please let me know.

Bill Wolpin
Editorial Director
Waste Age
6151 Powers Ferry Road, Suite 200
Atlanta, GA 30339
(770) 618-0112
Fax: (770) 618-0349
E-mail: bill_wolpin@intertec.com
www.wasteage.comnow.

Subject: Permission to use copyrighted information
From: "Robin Lyn Mecklem" <SMTP:mecklem@pilot.msu.edu> at OverlandPark
Date: 1/4/2000 4:15 PM

Mr. Wolpin:

I am writing to request permission to cite information from "Infectious Waste News", Volume 13, No. 12 (June 8, 1998). I am writing my Master of Science thesis regarding definition and management of biohazardous waste in large research-based universities in the U.S. and wish to include information from the publication listed above as part of my introduction or literature review chapter. The information that I wish to use would be limited to the summarized information on state medical waste regulations that appears in the tables shown on page 2 & page 3 of the publication listed above. I do not plan to reproduce the tables but instead wish to only use the number of yes or no responses for several of the categories listed.

Thank you for your consideration of this request and I look forward to your response.

Robin Lyn Mecklem
Graduate Candidate
Oregon State University

Robin Lyn Mecklem
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