REPORT AND RECOMMENDATIONS ON THE REGULATION OF INFECTIOUS WASTE

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Acknowledgements

The recommendations which are contained within the text of this report were developed in consultation with an interagency task force which was convened by the Attorney General's Office to examine the infectious waste issue. The representatives on the task force included the following agencies: the Minnesota Pollution Control Agency, the Minnesota Department of Health, the Minnesota Waste Management Board, the Metropolitan Waste Control Commission, the Metropolitan Council and a county health department representative. Representatives of the federal and state Occupational Safety and Health (OSHA) programs also participated.

Advice was provided throughout the writing of this report by the Centers for Disease Control and the National Institutes of Health. The report was also reviewed and comments received from Dr. Donald Vesley, University of Minnesota - Twin Cities and Dr. William Rutala, Research Associate, Professor and Director of the Statewide Infection Control program at the University of North Carolina School of Medicine.

We also acknowledge the contributions of the many representatives of biomedical waste generators, waste haulers, and waste treatment and disposal facilities who met with the task force or provided comments on drafts of this report.

I. INTRODUCTION

A number of reports of inappropriate disposal of biomedical waste over the past year have focused attention on biomedical waste management practices. For example, beaches were closed in New Jersey fifteen times during the summer of 1987 when tons of medical waste, including intravenous tubes and hypodermic needles, washed up on the beach. Throughout the summer of 1988, beaches in New York and Rhode Island were closed on several occasions when biomedical wastes were washed ashore. Elsewhere, children have been found playing in open dumpsters containing blood vials in Marion, Indiana and playing with syringes in Boardman, Ohio. Abandoned trailers containing medical wastes have been discovered in Pennsylvania and abandoned warehouses containing medical wastes have been identified in New York. Here, in Alexandria, Minnesota, a biomedical waste recycling facility was ordered to cease operation due to allegations of improper waste handling. These and other incidents around the country have prompted concerns regarding the management of the biomedical waste stream.

Waste disposal haulers and handlers have also become increasingly concerned about biomedical waste. Their concerns derive in large part from a fear that they could contract human immunodeficiency virus (HIV) associated with AIDS from biomedical waste. This concern exists despite the fact that there is, to date, little in the way of documented evidence to suggest that the proper handling of biomedical waste can cause any type of disease and the fact that there have been no reports of occupationally-derived AIDS transmission among waste handlers.[1] Nevertheless, fears about the infection potential of biomedical waste have created problems for persons who generate the waste. Concerns have been particularly acute at refuse derived fuel facilities since workers at this type of facility hand sort much of the waste received by the facility.

At some facilities, the fear has become so acute that <u>all</u> waste materials generated by biomedical facilities are simply refused. Little distinction is made between biomedical wastes that have a significant infection potential and those that do not have a significant infection potential. Instead, all biomedical wastes are perceived to be hazardous to the waste handler.

The existing rules governing infectious waste (see Appendix A) are not very helpful in determining which biomedical wastes present a significant infection hazard. There are at least two reasons why the rules fail to adequately address infectious waste management. First, the definition of infectious waste in the Minnesota Pollution Control Agency's (MPCA) rules is different from the definition in the Minnesota Department of Health's (MDH) rules. This creates unnecessary confusion for both the waste

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1/ Even for health care workers who have had needlestick or mucous-membrane exposures to the blood or other body fluids of HIV-infected patients, transmission of the HIV virus is extremely rare (4). For example, a recent National Institutes of Health study showed that of 332 health care workers with a total of 453 needlestick or mucous-membrane exposures to the blood or body fluids of HIV-infected patients, none had seroconverted (11).

generator and the waste handler. Second, the current rules base their definition of infectious waste on the infection status of the source (i.e., whether the patient has a contagious disease) rather than the potential of the waste itself to serve as a vehicle of disease transmission. Focusing on the source of the waste as the basis for defining it as infectious creates unnecessary difficulty in the on-site management of the biomedical waste stream. For example, according to both the MPCA and MDH rules, in order to make a determination as to whether a particular used bandage is infectious waste, a person would have to determine whether the bandage had been in contact with a wound, burn, or incision "of a suspected, known, or medically identified hazardous infectious nature."

In order to (a) protect those at risk from the potential hazards of infectious waste and (b) facilitate the establishment and maintenance of a functional waste management system, infectious waste regulatory programs must include four essential elements. First, there must be a standard definition of infectious waste that includes, but is restricted to, all wastes that realistically present an infection hazard. Second, an infectious waste regulatory program must set forth a disposal program that is practical and that can be implemented by all of the waste generators and waste management personnel. Third, the regulatory program should include an effective enforcement system in order to keep the waste that has been defined as infectious waste out of the general waste stream. Finally, to successfully implement any regulatory initiatives, the regulated community and the public must be educated to distinguish those wastes that present an infection hazard from the bulk of the waste stream.

To assist in examining the problems associated with the management of biomedical waste and to develop a set of recommendations that would address the difficulties associated with the current rules, an interagency task force was established by the Attorney General's Office in November of 1987. The task force included representatives from the Department of Health, a metropolitan county health department, the Metropolitan Council, the Occupational Health and Safety Division of the Department of Labor and Industry, the Pollution Control Agency, and the Waste Management Board.

The task force held four meetings with a total of 21 persons involved in various segments of the biomedical waste management process. Included were representatives from biomedical waste generating facilities (hospitals, nursing homes, clinics, physician and dental offices, veterinary offices, clinical and biomedical research laboratories) and waste transport and disposal facilities.

A set of recommendations was then drafted and reviewed by the task force. On May 7, 1988, a public meeting was held at which the draft recommendations were presented, copies of the draft recommendations were distributed, and comments on the draft were requested to be submitted by May 27th.

This report incorporates the recommendations of the interagency task force into a general analysis of the generation and disposal of biomedical and infectious waste. The recommendations which are listed this report are designed to:

1. Protect the health and safety of persons at risk from exposure to infectious waste;

2. Define biomedical waste stream segments as infectious on the basis of scientific evidence that the waste itself posseses a realistic potential to transmit a disease;

3. Enable persons who generate and manage biomedical waste to readily differentiate between infectious and non-infectious waste;

4. Suggest a proposed waste management program that is readily implementable in all parts of the state;

5. Enhance the enforcement program for infectious waste management; and

6. To accomplish tasks 1-5 above while minimizing additional costs and paperwork.

II. OVERVIEW OF RECOMMENDATIONS

The following is a summary of the recommendations contained in this report. The detailed explanation of the basis for each recommendation is set out in sections III through VIII.

Definition of Infectious Waste

1. Laboratory wastes such as cultures and stocks of infectious agents should be defined as infectious waste.

2. Human blood, blood products and certain body fluids should be defined as infectious waste.

3. Sharps, such as hypodermic needles, scalpels and glass vials containing material otherwise defined as infectious should be included in the definition of infectious waste.

4. Waste derived from animals afflicted with zoonotic disease[2] or purposely infected with agents infective to humans should be classified as infectious waste.

5. Human pathological/anatomical waste should be segregated from ordinary solid waste and disposed of separately, but should not be classified as infectious waste.

6. Waste from patients in isolation should not be defined as infectious waste unless it falls within 1 through 3 above.

7. Other miscellaneous biomedical wastes such as bandages, dressings, casts, catheters, disposable pads, tubing and dialysis waste should not be classified as infectious waste.

2/ Zoonotic diseases are diseases which are transmissible from animals to humans.

Collection and Storage of Infectious Waste

1. All infectious waste should be separated from the general waste stream and clearly identified as infectious.

2. Sharps should be collected in puncture resistant containers.

Treatment and Disposal of Infectious Waste

1. Autoclaved (steam decontaminated) wastes should be labeled "autoclaved" or "non-infectious."

2. Process controls should be used as the principal method of monitoring the effectiveness of autoclaving.

3. A log of the autoclave operations should be maintained by the operator.

4. Autoclaved waste should either be separately collected without compaction or the generator should provide a written notice to the waste hauler that the facility's infectious waste has been autoclaved.

5. Sewering of blood, blood products and designated body fluids should be authorized.

6. Compacting of untreated infectious waste should be prohibited.

7. The Minnesota Pollution Control Agency (MPCA) should study the impact that the changing composition of biomedical waste stream has on the emissions produced by incinerators which burn biomedical/infectious wastes. The

legislature should provide the necessary funds for the Agency to conduct the study.

8. The existing prohibition on landfilling of pathological waste should be retained.

9. Permitting of specific landfill sites should be considered as a disposal option. Environmental and occupational hazards should be assessed for landfill disposal in light of alternative disposal methods.

Enforcement

1. The existing infectious waste rules should be revised to clarify the responsibility of generators, haulers, and disposal facilities.

2. Generators should be responsible for segregating infectious waste, properly containing and identifying the waste, and insuring that it is not disposed of with general refuse.

3. Solid waste haulers should be responsible for not delivering to an unpermitted facility waste that has been identified by the generator as infectious or is known by the hauler to be infectious. Haulers of infectious waste should be responsible for insuring the safe and secure transport of infectious waste to a legal treatment or disposal site.

4. Solid waste disposal facilities, should be responsible for accepting only those wastes which their facility is authorized to accept. Infectious waste treatment and disposal

facilities should be responsible for the proper treatment, storage and disposal of the infectious waste they receive.

5. The legislature should authorize additional staff and provide increased funding for the Pollution Control Agency and the Department of Health to develop and enforce revised infectious waste rules.

6. Primary enforcement responsibility for infectious waste once the waste leaves the generating facility should reside with the Pollution Control Agency.

7. The Pollution Control Agency and the Department of Health should be authorized to conduct generator inspections.

8. The Department of Health should provide technical assistance to the Pollution Control Agency in developing and enforcing infectious waste rules.

9. The Minnesota Employee Right-to-Know requirements applicable to infectious agents should be extended to all facilities involved in the handling of waste that may present an an infection hazard.

10. Each infectious waste generator should prepare and maintain in its files an infectious waste management plan.

11. The Department of Health should consider requiring all infectious waste generators to notify the Department of their existence and to certify that an infectious waste management plan has been prepared. The Pollution Control Agency should consider the same procedure for infectious waste haulers and for treatment and disposal facilities.

12. The Pollution Control Agency and the Department of Health should be authorized to assess administrative penalties as one method of enforcing the infectious waste rules.

13. The Pollution Control Agency, the Department of Health, and interested counties should identify those persons who would be subject to the revised infectious waste rules and should provide them with information on how to comply with the new rules once they are adopted.

Education

1. The state agencies should prepare and distribute educational materials explaining the types of biomedical wastes that are potentially infectious and on how to properly manage these wastes.

III. DEFINING INFECTIOUS WASTE

THE PROCESS OF DISEASE TRANSMISSION

In light of the growing concerns surrounding biomedical waste management, a review of how these wastes are regulated is in order. The analysis of the rules governing biomedical waste management should be founded upon the principles of sanitation that preclude disease transmission. Knowledge of the process of disease transmission is fundamental to the development and formulation of a sound definition of "infectious waste." The differentiation of truly infectious waste from the bulk of the solid waste stream - all of which could theoretically be considered "contaminated potentially infectious material" - is a somewhat difficult task. Thus, a working knowledge of the way in which infectious agents grow, multiply and actually induce infection is essential to the development of effective policy.

This report therefore begins with an overview of the principles of disease transmission. This discussion will then serve as the basis for the designation of specific waste stream segments as infectious.

The process of disease transmission is most readily conceptualized as a chain comprised of a series of six links with each link representing an essential step in the transfer of an infectious agent from one susceptible host to the next. If a break occurs in any of the links along the chain, then the process of disease transmission is inhibited. The six links of the chain of disease transmission are:

(1) an adequate dose of an infectious agent; (2) the existence of a viable source of infectious agents; (3) a mode of escape for infectious agents; (4) an infectious mode of transmission; (5) an infectious route of entry and; (6) a susceptible host.

1. An Adequate Dose of an Infectious Agent

The first link in the chain of disease transmission is the existence of an infectious agent - an organism which possesses the pathogenic or disease-causing properties necessary to induce disease in a susceptible host. However, the mere existence of a single infectious agent is not in itself adequate to induce an infection. In order to be able to induce disease, the infectious agent must be present in quantities sufficient to constitute an infectious dose (26,27). All environments except for those which are maintained under sterile conditions harbor some population of viable microorganisms. Thus, it can be inferred that the ability of a particular agent to induce infection in a healthy host is largely a function of its ability to survive in quantities sufficient to constitute an infectious dose despite any unfavorable environmental conditions to which it is exposed.

2. The Existence of a Viable Source of Infectious Agents

The environment in which an infectious agent resides is crucial to its survival. An environment which offers an infectious organism conditions conducive to survival constitutes a "source" of that agent. An environment which offers the organism conditions conducive to growth and proliferation constitutes an active "reservoir" of the agent. With the exception of laboratory facilities designed for the cultivation of human pathogens (disease-causing agents), the environment outside the body of humans or animals does not afford most infectious agents conditions which favor growth and/or survival. Further, a certain concentration or type of an infectious agent often must be achieved in order for that agent to pose a threat of inducing disease.

When infectious agents are removed from their natural source or reservoir and exposed to the physical, chemical and biological stresses of the inanimate environment, there is usually a diminution in viability (the number of organisms) and therefore in the magnitude of the infectious dose (13). Generally speaking, microbial growth requires very specific temperature, moisture, light, nutrient and pH conditions (16,20). Though it is sometimes tempting to rank different microbes according to their hardiness or ability to survive, a complex interplay of many different factors impose so many modifying qualifications that such rankings are often of greater academic than practical use. The only safe generalizations to make are (1) that a culture of organisms that is not growing is often decaying and (2) the farther a population of disease-causing agents is from its original source in time or distance, the greater the likelihood that its capacity to induce infection will be diminished (13).

3. A Mode of Escape

The third link of the disease transmission chain is a "mode of escape." If an infectious agent cannot escape from its source or reservoir then it will not pose a threat of disease. It is thus apparent that the containment of infectious agents within the source known to harbor them is an important element in the handling of infectious materials. The containment of infectious organisms is far more easily accomplished with an inanimate as opposed to an animate source. For example, contaminated materials can be packaged and handled in such a manner as to preclude the possibility of human exposure whereas the containment of an infected person who is an active source of disease is a far more difficult and complicated task.

4. An Infectious Mode of Transmission

An "infectious mode of transmission" is the fourth link in the chain of disease transmission. The mode of transmission of an infectious agent is crucial to its survival and ability to establish itself in a host and induce disease. Diseases can be transmitted via either a direct or an indirect mode of transmission. The indirect transmission of disease involves the interposition of an insect, crustacean or rodent which harbors and carries the infectious agent between one human host and the next. Diseases which are directly transmissible from one host to the next without the interposition of an animal vector, can be transmitted via any one of a number of routes such as sexual, inhalation, ingestion or dermal (skin-contact). The route of transmission of any infection, be it direct or indirect, varies with the particular agent. For example, Vibrio cholerae which causes cholera must usually be ingested and gain access to the gastrointestinal system in order to be infectious. Legionella pneumophila which causes Legionnaire's disease must be inhaled in order to gain access to the respiratory system. The HIV virus which causes AIDS must be transmitted either sexually, through a direct inoculation into the blood stream, or through a blood splash to mucosal membranes in order to be infectious.

In order to cause disease, an infectious agent must gain access to a susceptible host via an infectious mode of transmission.

5. An Infectious Route of Entry

Once sufficient quantities of viable infectious agents have escaped from their growth reservoir via an infectious mode of transmission, they are capable of inducing disease upon invasion into a susceptible host. Link five of the disease transmission chain characterizes the mode by which an infectious agent gains entry into a susceptible host. The 'infectious mode of transmission' and 'infectious route of entry' are closely linked in the disease induction process. In order to induce an infection, an infectious agent must travel from its reservoir and enter the body of the susceptible host via an infectious route. For example, if a person was inoculated intradermally (into the skin) with Vibrio cholerae, the person would most likely not contract cholera since Vibrio cholerae must generally gain access to the digestive system via ingestion in order to be infectious. The entry of Vibrio cholerae into the skin does not therefore typically constitute an infectious mode or entry.

The concept underlying barrier protection (i.e., glove, face masks, etc.) is to impede the entry of a hazardous agent - be it physical, chemical or infectious - into the body. Laboratory and clinical technicians who run the risk of exposure to infectious agents on a routine basis often wear personal protective gear to minimize the chances of exposure.

6. A Susceptible Host

The existence of a susceptible host is the sixth and final link of the disease transmission chain. Susceptibility of a host can vary with the age, disease status, immunity and occupational exposure. The very young, very old, immune-compromised and certain occupational groups that are routinely exposed to infectious agents are examples of susceptible subsets of individuals within the general population. Assuming proper waste disposal practices, the susceptible host population in the context of infectious waste disposal is primarily the waste haulers and handlers. Under normal waste disposal conditions, the general population would not incur exposure to infectious waste (22,26).

THE PROCESS OF DISEASE TRANSMISSION AS IT RELATES TO WASTE MANAGEMENT

The principles of disease transmission serve as a logical basis for the classification of infectious waste. Since virtually no waste is sterile and thus devoid of microbial contamination, it is necessary to assess the various segments of the waste stream with regard to their relative infectivity. A determination of the probability of any given waste to preserve intact the chain of disease transmission provides a system for determining relative infectivity. Under this system, a waste-type that is likely to maintain the chain of disease transmission would be classified as an infectious while a waste-type that is likely to produce a break in one or more links of the chain, would be regarded as non-infectious.

Generally speaking, given current sanitation practices, solid waste disposal does not constitute a significant method of disease transmission. With the advent of sanitary landfills where waste is to be covered up with soil at the end of each day, the health risks once posed by waste disposal have been greatly reduced (22,26). Sanitary landfill operations, as well as other current solid waste disposal operations, tend to reduce access to disease vectors such as rodents that can potentially transmit waste-derived disease to human populations. To date, the scientific and epidemiological literature demonstrates little evidence of a direct causal association between waste disposal and disease transmission in the absence of rodent and insect vectors (6,21, 25). With the exception of sharps (needles, scalpels, etc.), there has only been one reported instance of disease transmission associated with biomedical waste.[3] Most waste simply does not provide either an environment conducive to the growth and survival of infectious agents or the means by which the agent can escape from its source via an infectious mode of transmission.

The classification of individual types of waste as infectious is largely a function of (a) the ability of the waste to serve as a medium which can support the survival and/or growth of infectious agents and (b) the likelihood that the waste, by nature of its physical make-up, will be able to deliver an infectious dose to a susceptible host - links two and four of the disease transmission chain. Link one - the presence of an infectious agent - is a given with nearly all types of waste. Links three and five relate primarily to the handling of those wastes determined to be infectious and therefore serve as the basis for the establishment of worker-safety programs which include barrier protection and containment procedures.

3/ The one instance occurred in 1974 and involved a new hospital's chute hydro pulping waste system that was identified as the reservoir of airborne Pseudomonas and caused a two-fold increase in gram-negative bacterimias. This system is no longer used in U.S. hospitals (25).

A SEGMENT BY SEGMENT ANALYSIS OF THE BIOMEDICAL WASTE STREAM FOR RELATIVE INFECTIVITY

Although there have not been exhaustive studies conducted to determine the microbial composition of waste, there are at least two recent German studies in which municipal and hospital waste were comparatively analyzed for relative pathogen content. Within the limits of the assays utilized, these studies found similar types and numbers of pathogens in both waste streams (1,17,26). Portions of the hospital waste stream (e.g., from surgery units, nursing stations, intensive care units, etc.) have actually been found to be on the order of 10 - 10,000 times less microbially contaminated than household waste (12,25). This would seem logical since a hospital is maintained as a relatively sterile environment.

There is no microbiologic evidence to suggest that either general hospital waste is more infective than residential waste or that proper biomedical waste disposal practices have caused disease in the community (5,7,25,26). Thus, one can not assume that simply because a waste comes from a biomedical facility, it is likely to present an infection hazard. However, certain select types of biomedical waste may provide the necessary growth reservoir to be potentially infectious.

Laboratory Wastes

Microbiological wastes such as laboratory cultures and stocks of infectious agents are potentially infectious because they may act as a reservoir which will sustain microbial growth (20,25). These materials are designed to either propagate organisms taken from a patient or serve as a source of indicator or test microorganisms for clinical analysis and biological research. Other examples of laboratory-generated microbial waste which could pose a threat of infection include discarded live and attentuated vaccines and culture dishes and devices used to transfer, inoculate and mix cultures. Microbiological waste is generated by medical and pathological laboratories, research and industrial laboratories and educational laboratories, as well as by clinical facilities which house diagnostic laboratories (e.g., hospitals and outpatient clinics).

Both the MPCA and the MDH rules define some laboratory wastes as infectious. The definition in both rules is circular, however, since it defines only those laboratory wastes that are "infectious" as being "infectious."

RECOMMENDATION: All cultures and stocks of infectious agents, including specimen cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate and mix cultures should be defined as infectious laboratory waste.

Blood, Blood Products and Body Fluids

Human Blood and blood products (such as serum, plasma and other blood components) and specific body fluids are generally regarded as infectious waste. Significant quantities of whole blood and blood components can harbor infectious agents in quantities great enough to constitute an infectious dose. Direct inoculations or blood splashes to mucosal membranes are among the potential hazards of blood products traveling loose and uncontained or minimally contained in the waste stream. However, for precisely this reason, blood and blood products are often sewered and therefore normally do not enter the solid waste stream.

The Centers for Disease Control (CDC) has recently recognized certain body fluids as presenting a potential threat of disease transmission. The CDC defines body fluids which pose a threat of disease from agents such as hepatitis B virus (HBV) and HIV (AIDS), to be: cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid and amniotic fluid (3). The CDC has noted the body fluid definition should not apply to feces, nasal secretions, sputum, sweat, tears, urine and vomitus which, in an occupational setting, present little to no risk of transmission unless they are contaminated with blood. Bulk body fluids usually do not enter the solid waste stream but, like blood, are generally sewered.

Blood and body fluid waste is generated by hospitals, nursing homes, urgent care clinics, outpatient chronic care and specialty clinics, dental clinics, clinical and biological laboratories, plasma blood banks, funeral homes, some physician, chiropractor and dental offices, and home health care services. The existing state rules do not directly address blood or body fluids. However, under the rules blood and blood products from patients in isolation would be considered infectious along with other isolation patient waste.

RECOMMENDATION: Blood, blood products and body fluids should be classified as infectious. The term human blood and blood products should include serum, plasma and other blood components. The term body fluid should include cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid and amniotic fluid.

Contaminated Animal Waste

Contaminated animal waste can potentially represent an infectious agent reservoir if it is derived from animals which have been infected with organisms transmissible to humans (zoonotic agents). According to Dr. Paul Landis, former president of the American Veterinary Medical Association, the vast majority of the waste emanating from veterinary facilities is free of any significant level of infectious bacteria and does not pose any more of a risk to people or the environment than does ordinary household waste. He states that

> Since the infectious nature of disease became known, we have not in this country experienced an

> outbreak of disease from the improper disposal of veterinary hospital wastes. A search in March of 1983 of the literature indexed in the computer system of the National Library of Medicine discovered no references related to problems arising from waste generated by veterinary hospitals or clinics."(18).

However, though there are no reports of disease outbreak from the handling of contaminated animal waste, there is one small segment of the animal waste stream which may, in the interests of eliminating all wastes with a significant infection potential from the solid waste stream, warrant special consideration. This segment of the waste stream could be characterized as emanating from animals who either naturally or purposefully have become infected with agents which are infectious to humans. These animal wastes could serve as a vehicle for transmission of disease.

Of the diseases contracted by animals, zoonotic diseases (i.e. anthrax, brucellosis, rabies, toxoplasmosis, etc.), are the only diseases which are directly transmissible from infected animals to humans. Since the occurrence of zoonotic versus non-zoonotic disease is relatively infrequent, the size of the waste stream derived from this source is quite limited.

Waste generated from research animals which are intentionally exposed to agents infectious to humans may also constitute a source of disease transmission to humans.

A comprehensive definition of infectious waste should include portions of the animal waste stream which present an infection potential. Carcasses, bedding, and diagnostic laboratory waste derived from animals afflicted with zoonotic disease are the animal waste stream components typically designated as infectious.

Potentially infectious animal waste is generated by veterinary medical care and diagnostic facilities, and research laboratories that use infectious agents in their animal testing procedures. The current Minnesota MPCA rules provide that waste is infectious if it emanates from an animal "that has been or may have been exposed to a contagious or infectious disease." "Contagious" could mean contagious to humans or animals.

RECOMMENDATION: Animal waste derived from animals afflicted with zoonotic disease or purposely infected with agents infective to humans should be classified as infectious waste. Infectious animal waste should include carcasses, body parts, excrement, and bedding of animals that were intentionally exposed to pathogens or which are suspected of being infected with a disease communicable to humans.

Sharps Waste

The diseases which are potentially transmissible by infectious waste are the blood-borne diseases (Hepatitis B, non A non B hepatitis, AIDS, malaria and syphilis) tuberculosis and enteric diseases (12). Disease could potentially be transmitted from infectious waste via exposures which occur through the skin (percutaneous route) via needle sticks and spills, by inhalation of aerosols, dust and spills, and by ingestion of infectious agents (from contaminated hands). Of these, the percutaneous route of transmission presents the single greatest concern. Though the number of reports of trauma-associated injury among waste handlers (e.g., cuts from ordinary solid waste) far exceeds that of needlestick injury and to date there are no reports of infection or disease arising from a reported needlestick injury, the threat of such an occurrence is real. This threat of disease transmission warrants sensible precautions.

Sharps such as discarded hypodermic needles, scalpel blades and glass vials containing infections material or residues ought to be removed from the general waste stream as they present a potential inoculation hazard if they have been in contact with infectious agents. Though the majority of blood-borne pathogens (hepatitis B virus being one exception) would probably not survive long in minute quantities of blood outside the human body, the inoculation hazard posed by contaminated sharps would appear to provide sufficient justification for removing them from the general waste stream. Discarded sharps present a physical as well as biological safety hazard which further supports their segregation from the municipal waste stream.

Sharps are generated by general acute care hospitals, nursing homes, urgent care clinics, outpatient and specialty clinics, dental clinics, veterinary facilities, physician and chiropractor offices, dentist offices, clinical and biological laboratories, plasma blood banks, chemical detox centers, funeral homes and home health care services. The MDH rule that governs waste disposal in outpatient surgical centers references sharps only under the general infectious waste category. The rule specifies that "except when suspected or identified to be of a hazardous infectious nature," sharps are to be considered general infectious waste and can be disposed of in a landfill.

The MDH nursing home rule specifies that "needles and similar medical single-use items shall be destroyed before disposal, unless incinerated."

The current MPCA rule does not specifically refer to sharps. However, according to that rule, sharps might be considered infectious if they were used for patients treated in isolation or if they had been in contact with wounds, burns, or surgical incisions that "are suspect or have been medically identified as hazardous." The proposed MPCA solid waste rules designate sharps and needles "originating from the diagnosis, care, or treatment of a person or animal that has been or may have been exposed to a contagious or infectious disease" as infectious waste.

RECOMMENDATION: All discarded sharps (not just those "originating from the diagnosis, care, or treatment of a person or animal that has been or may have been exposed to a contagious or infectious disease") should be considered infectious waste. Infectious sharps waste should be defined as all discarded items derived from patient care in medical, research or industrial facilities which could potentially transmit disease via direct subdermal (beneath the skin) inoculation. Included are: hypodermic needles, scalpels, and glass vials containing materials defined within the infectious waste rules to be infectious.

For various reasons, biomedical wastes other than laboratory microbiological waste, blood and body fluids, zoonotic animal wastes and contaminated sharps are sometimes classified as infectious wastes. Careful consideration, however, must be given to expanding the infectious waste stream to include wastes which do not present any true infection hazard. Once a waste is designated as infectious, it will have to undergo special handling, treatment and disposal procedures that are generally more labor intensive and substantially more costly than routine solid waste disposal. According to Dr. John McVicar, Director of Bio-safety at the Centers for Disease Control, "while any waste item may be potentially infective, it is not usually considered practical or necessary to treat all such waste as infective (5)."

Anatomical/Pathological Waste

Anatomical/Pathological waste including tissues, organs, body parts and some body fluids that are removed during surgery and autopsy, do not possess a significant infection potential w(7,22). These wastes, however, are often segregated from the general waste stream and disposed of with infectious waste for aesthetic and other reasons.[4]

4/ Fetal remains are specifically covered by state law that requires the remains to be buried or cremated. A preliminary injuncture precluding enforcement of the law has been granted by a Federal District Court. A hearing on a permanent injunction is scheduled for late in 1988.

Pathological/anatomical waste is generated by hospitals, urgent care clinics, clinical laboratories and some funeral homes. Both the MDH and the MPCA rules define all anatomical waste and pathological waste which is "of an infectious nature" as infectious waste.

RECOMMENDATION: Since human pathological/anatomical waste does not generally constitute a vehicle of disease transmission, it would be more accurate to cover its disposal under a separate category within the infectious waste rule. Nevertheless, pathological/anatomical waste should continue to be segregated from the general waste stream because of the aesthetic and other concerns with disposal of these wastes. Human pathological/anatomical waste should include tissues and body parts which are discarded from surgical, obstetrical, autopsy and laboratory procedures.

Isolation Wastes

Isolation wastes are generated by hospitalized patients who are cared for and treated in isolation. These wastes are not generally regarded as infectious by public health professionals. According to Dr. William Rutala, of the University of North Carolina School of Medicine there is no reason to suspect that isolation waste is more likely to cause infection during proper handling and disposal than residential waste (25). There is likewise no reason to believe that waste from a patient on respiratory precautions has a greater potential for being infectious than wastes from a critically ill person in an intensive care unit (12).[5]

"Healthy" infected individuals are a relatively more important source of infection than diseased bed-ridden individuals. Further, infected individuals frequently spread large quantities of virus either before the appearance of overt symptoms or during the prodromal (early onset) phase of disease (13,20).[6]

Isolation waste is generated primarily by hospitals. Both the current MPCA rules and the MDH rules for outpatient surgical centers define all wastes originating from persons or animals placed in isolation for control and treatment of an 'infectious disease' as infectious waste.

RECOMMENDATION: The waste generated by an isolation patient should not be identified as infectious unless it falls within the definitions of laboratory, blood and body fluid, or sharp waste.

5/ Though isolation waste is no more infectious than any other patient waste both inside or outside of the hospital setting, it is estimated that special handling and disposal of all isolation waste as if it were infectious waste could boost hospital waste management costs by as must as 20 to 25 percent (7).

6/ Recent clinical care guidelines issued by the Centers for Disease Control (CDC) recommend that health professionals exercise universal contagion precautions in their contact with all patients. According to the CDC recommendations, routine patient treatment practices should as a general rule incorporate handling precautions which recognize <u>every</u> patient as a potential source of infection. In their most recent report on disease prevention and health promotion, the CDC states "Universal precautions are not intended to change waste management programs previously recommended by CDC for health care settings (3)."

Miscellaneous Biomedical Waste

Miscellaneous biomedical waste includes a wide assortment of items such as soiled dressings, sponges, surgery drapes, lavage tubes, casts, catheters, disposable pads, disposable gloves, specimen containers, slides, coverslips, lab coats, aprons, and dialysis wastes such as tubing, filters, towels and disposable sheets. While any item that has had contact with blood exudates or secretions may be potentially infective, it is not usually considered practical or necessary to treat all such waste as infectious (4,10). There is no evidence that these materials pose an infection hazard any greater than that posed by residential waste (5,7,25,26). These types of waste materials do not generally provide the conditions that are required to support the growth and survival of infectious agents. For example, the CDC has shown that environmental drying has a 90-99 percent concentration reduction effect on the HIV virus which causes AIDS (4).

Even if one of these items when grossly contaminated with blood could maintain the moisture and nutrient conditions to support microbial growth, it is highly unlikely that it could also serve as a potential vehicle for disease transmission. Waste haulers and handlers should always be fully clothed and wearing gloves so that harmful agents -- whether physical, chemical, or infectious -- will be prevented from gaining access to open wounds, cuts or from absorption through the skin. It may, however, be prudent for health care facilities to dispose of heavily blood-soaked items along with their infectious waste stream.

Essentially all clinical health care facilities, mortuaries, veterinary facilities generate a variety of miscellaneous biomedical waste. The current Minnesota rules define different segments of this waste stream as infectious depending upon the particular rule. The MDH nursing home rule defines as infections waste, "materials or waste such as dressings or disposable pads which are infectious or suspected of presenting a potential health hazard". The MDH outpatient surgical center rules include as hazardous infectious waste "bandages, dressings, casts, catheters, tubing and the like, which have been in contact with wounds, burns, or surgical incisions of a suspected, known or medically identified hazardous infectious nature." The MPCA rule is essentially identical to the outpatient surgical center definition.

RECOMMENDATION: The types of waste materials described above do not generally provide the conditions which are required to support the growth and survival of infectious agents. As a result, this category of waste should not be defined as infectious.

Nevertheless, it is recognized that the presence of certain blood-contaminated wastes emanating from health care facilities has precipitated appreciable concern on the part of waste handlers. This issue should be addressed through educational efforts designed to aid waste handlers in understanding the process of disease transmission and the reasons why these types of waste materials would be no more likely to transmit disease than municipal waste. Waste handlers should be advised to exercise the same prudent handling precautions such as the use of gloves, in handling these wastes as they do in the general handling of municipal wastes.

OTHER CONSIDERATIONS IN DEFINING INFECTIOUS WASTE

The way in which infectious waste is defined will be reflected in a generating facility's waste disposal expenditure and ultimately in the cost of health care delivery. According to Dr. William Rutala, Research Associate, Professor and Director the University of North Carolina School of Medicine, the designation of waste as infectious requires special precautions and treatment practices which are roughly 20 times more costly than a hospital's general waste disposal costs (25).

Harvey Rogers, Chief of the Environmental Protection Branch at the National Institute of Health (NIH) reported to the U.S. House of Representatives Subcommittee on Transportation, Tourism and Hazardous Materials that an overly broad definition of infectious waste can have a drastic impact on a health care facility's operating budget. He said while it costs NIH 2.1 cents per pound to dispose of general waste in a county sanitary landfill it is not uncommon to hear of costs approaching 60 cents per pound for commercial infectious waste disposal (26).

In the interests of maintaining optimal workplace safety standards for waste handlers, biomedical waste which has the potential to transmit disease should be removed from the general waste stream and disposed of in a safe and efficacious manner. By the same token, it should not be required that biomedical waste which presents a threat of infection no greater than that of residential waste be handled as infectious waste. Failure to rationally define the infectious waste stream will likely result in unnecessary increases in the cost of health cares services.

The recommendations contained within this report will have three effects on the costs incurred by the regulated community. First, the recommendations for increased enforcement discussed in Section V of this report may translate into increased costs for the proper management of infectious waste for those infectious waste generators who until now have either ignored or have been unaware of the infectious waste regulations. Second, the recommendations on preparing management plans, packaging and transportation (reviewed in Section IV) could result in some increases in infectious waste management costs. Third, the adoption of a more precise definition of infectious waste which includes a smaller universe of materials should reduce the overall costs of infectious waste management.

INFECTIOUS WASTE MANAGEMENT

A sound infectious waste management program should have as its primary objective the safe, efficient and effective management of infectious waste from its point of generation to its ultimate disposal. Waste handling, storage, transport and disposal techniques should minimize the opportunities for exposure to untreated waste. An individual facility will generally select its waste management options on the basis of factors such as the nature and quantity of the infectious waste it generates; the availability of equipment for treatment on and off-site; the regulatory constraints to which it must adhere; and the costs of handling and disposal.

THE ESSENTIAL ELEMENTS OF AN EFFECTIVE INFECTIOUS WASTE MANAGEMENT PROGRAM

A program designed to insure the safe handling of infectious waste should effectively incorporate segregation, packaging, storage and transportation techniques that limit exposure to the waste. All persons directly involved in the management of infectious wastes should receive adequate training for the safe handling and disposal of this waste.

Segregation of Infectious Wastes

Wastes that present a potential threat of infection should be segregated from the general waste stream. The segregation of infectious waste from general waste serves the dual function of initiating the infectious waste treatment process and restricting the volume of the waste stream which must undergo treatment. This assures that the added costs of the special handling, treatment and disposal of infectious waste will not be unnecessarily applied to a larger non-infectious portion of a waste stream.

Infectious waste should be segregated at its point of generation. The bags and containers used to collect the waste should be clearly marked and readily identifiable. It has become commonplace for most facilities generating infectious waste to use brightly colored bags for disposing of their infectious waste. Hence, the term "red bag waste" is often used to denote infectious waste whether or not it is actually collected in red bags.

RECOMMENDATION: All infectious waste should be separated from the general waste stream and clearly identified as infectious if the waste is not immediately treated or disposed.

Packaging of Infectious Waste

The proper packaging of infectious waste is one of the primary means of preventing disease transmission. Proper packaging of infectious waste breaks the disease transmission chain at the third link - by denying infectious agents a mode of escape from their growth reservoir. If the infectious organisms cannot escape from their reservoir, then they cannot gain access to a susceptible host and induce disease.

A number of factors warrant consideration in the selection of appropriate infectious waste packaging materials including the waste management techniques and the treatment methods that will be utilized. While plastic bags (of varying density and durability) are suitable for the collection of most infectious waste, other methods of packaging must be used for liquids, heavy materials and sharps wastes. For example, it is generally recommended that discarded sharps be collected at their point of generation in puncture-resistant containers (12,31). Further, various treatment techniques have specific packaging requirements.

The integrity of all containers used to collect infectious waste should be maintained throughout the handling and disposal process. Waste which will be repeatedly handled and transferred may require additional packaging.

RECOMMENDATION: All infectious waste should be packaged and identified so that it is readily distinguishable throughout the handling and disposal process. The universal biohazard symbol could be used as the symbol of identification.

Sharps, such as discarded hypodermic needles, scalpel blades and glass vials containing infectious material or residues should be collected at their point of generation in puncture-resistant containers.

All infectious waste containers that are recycled and reused should be disinfected between each use.

Storage of Infectious Waste

Though an optimal waste treatment plan would involve the same-day collection and treatment of infectious waste, many generating facilities are unable to accommodate this management scheme. This means that the waste must be stored for some period of time. Special storage facilities are necessary for the storage of infectious waste. The temperature at which the storage area is maintained and the duration of time for which the waste is stored are the two key factors to be considered. Some states have established storage standards based upon these two factors in their infectious waste regulations. For example, Massachusetts' infectious waste requirements permit storage for a maximum of one day at room temperature (64 deg. to 70 deg. F.) and three days in a refrigerator (34 deg. to 35 deg. F.) (31).

RECOMMENDATION: Infectious waste should be stored only in separate rooms maintained at proper temperature. (Specific requirements are contained within the EPA Guide for Infectious Waste Management (31)). Further, limited rodent, vermin, insect and human access to infectious waste storage areas should be assured.

Compaction of Infectious Waste

Unless bags or containers of infectious waste can be re-packaged or treated as part of the compaction process, compaction is not advisable. The focal point of effective infectious waste management is the avoidance, if possible, or at least the minimization of opportunities for exposure. Compaction will frequently break the containers holding the infectious waste resulting in the generation of loose waste and therefore, increase the likelihood of waste haulers being exposed to the waste. Compaction of untreated infectious wastes can also aerosolize infectious agents producing an infection hazard for those in the vicinity of the compactor. Finally, compaction may destroy labels on containers making it difficult to determine whether a waste has been properly treated.

RECOMMENDATION: The compaction of untreated infectious waste should be prohibited.

Transportation of Infectious Waste

The maintenance of packaging that assures the containment of infectious waste is essential to all transportation processes, both within and outside of a facility. Within a facility, the use of mechanical waste collection devices is generally discouraged as it can result in the rupture of waste collection bags and the dispersal of their infectious contents. Gravity or pneumatic chute collection of infectious waste is often discouraged in medical care facilities since it can result in the forcing of contaminated air down the shaft and horizontally into nursing stations and other clinical areas (3,28). Carts, if routinely disinfected, are considered suitable for transportation of waste within a waste generating facility. The safe transportation of infectious waste between facilities is also important. Vehicles employed in the transport of infectious waste ought to be labeled in accordance with municipal, state and federal regulations. The waste should be contained in such a manner as to prevent scattering, spillage or leakage during transport.

RECOMMENDATION: Consideration should be given to requiring infectious waste transport vehicles (in or out of the generating facility) to be labeled with the universal biohazard symbol. Trucks used to transport infectious waste should not be left open and unattended.

THE TREATMENT AND DISPOSAL OF INFECTIOUS WASTE

Landfill Disposal

Nationally, landfill disposal of infectious waste is still used by many infectious waste generators. However, recently, there appears to be a trend for communities to exclude infectious waste from sanitary landfills. According to Allan Cochran, a solid waste consultant who was quoted in a recent edition of "Infectious Waste News" (a publication distributed to generators and haulers of biohazardous wastes): "There are several reasons why landfills have elected to reject infectious wastes: landfill employees are afraid of needle sticks; landfill operators are afraid of being held responsible for needle stick injuries; landfill space is dwindling; and the public is afraid of infectious waste (23)."

Some states have banned landfill disposal of infectious waste on the premise that it presents a public health problem. However, there is currently no scientific basis to support this conclusion. According to most experts, there is no threat to public health and safety associated with the disposal of infectious waste in a landfill that is properly sited and operated (2,7,8,26).

A landfill does not provide an environment that is conducive to the survival of human pathogens (8,26). Once waste has been deposited in a landfill, the temperature, pH, moisture and microbial conditions diminish the viability of the infectious agents. Initially, oxygen is present to support the microbial decomposition of the waste. But as the oxygen is depleted, the temperature of the landfill rises to 100-120 deg. F. or greater (8). The elevated temperatures in combination with the oxygen-depleted conditions further reduce the number of viable infectious organisms.

One significant question concerning landfill disposal of infectious waste is whether pathogens that survive the conditions in a landfill could travel through the underlying soil and reach the groundwater. Several factors make it unlikely that pathogens will reach the groundwater beneath a properly sited landfill.[7] As a leachate percolates through the soil, its pathogenic organism concentration in the leachate is reduced by "soil filtration" (22). A somewhat analogous situation is the process of sewage attentuation in a septic system. As the sewage effluent percolates down through the soil, it is purified and cleansed of its disease-causing properties. The infectious organisms cling to the edges of soil particles and, without the nutrients, quantity of oxygen and other conditions necessary to

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7/ According to Patricia Checko, an epidemeology consultant with the Connecticut Department of Health Services, "A properly constructed landfill site is at least 50 meters away from public access and fully secure in terms of fencing. It must be operated by skilled employees who cover the incoming waste immediately and keep careful records of where the waste is buried (7)."

their survival, eventually die off. One individual has explained the fate of infectious agents in a landfill as follows:

> In a manner similar to that of viruses, bacteria in the aerated zone above the water table rarely move downward through homogeneous soil more than five feet. If bacteria do enter the saturated zone, they will travel in a fairly narrow band a few feet wide and normally will completely disappear after travel of about 100 feet downstream from the point of entry in unconsolidated formation. Therefore, if solid wastes are deposited in a properly constructed sanitary landfill, there should be little chance of contamination of groundwater with pathogenic micro-organisms(8).

In response to complaints and the rising concerns of landfill workers, New Jersey conducted an investigation to study the problems related to the disposal of infectious wastes in public landfills (2). The study found that most landfill sites offer little opportunity for direct worker exposure to infectious waste and that that exposure can be further reduced through work procedures. Some of the exposure-minimizing techniques suggested include: the segregation of infectious waste loads from other loads; the visual inspection of infectious waste and the avoidance of the direct handling of open bags; the immediate burial of infectious waste so that it is not directly compacted on the landfill surface; and the proper safety attire for workers who work on the face of the landfill.

The current MPCA rules prohibit landfilling of infectious waste. However, the proposed rules would allow infectious waste to be landfilled if the landfill had a permit for the disposal of infectious waste.

RECOMMENDATION: Landfilling should be carefully considered as a potentially viable disposal option. The environmental hazards associated with landfilling of infectious waste should be assessed in light of the environmental hazards associated with the alternative treatment and disposal methods.

A landfill issued an infectious waste disposal permit should adopt specific waste handling procedures such as: segregating infectious waste from other waste for both handling and disposal purposes; avoiding of direct handling of uncontained infectious waste; immediate burial of uncompacted infectious waste; and requiring proper safety attire for all workers on-site.

Sewer Disposal

The disposal of bulk blood, suctioned fluids, excretions and secretions into the sanitary sewer system is, according to the Center for Disease Control, the EPA and other experts a safe and acceptable method of disposal for these waste types (3,4,5,8 10,22,31). Sewage, after all, is an infectious material. The sewage system is designed to attenuate sewage and is therefore is equally as effective in the attenuation of infectious agents harbored in bloods and body fluids.

The CDC and a number of the experts who advocate the sewering of liquid wastes also approve of the grinding and sewering of the pathological portion of the waste stream where feasible (5, 7). Grinding and sewering of wastes constitutes immediate removal of the infectious waste from the environment thus eliminating storage, transport and handling costs. However, the grinding and sewering of biomedical waste solids may not be advisable for other reasons. One potentially undesirable aspect of grinding and sewering waste is the generation of an infectious aerosol.

An additional concern is the clogging of sewer lines with a rope-like material that can form as a result increased organic matter loading into the system.

RECOMMENDATION: Sewering of infectious waste such as blood and body fluids should be considered an acceptable method of treatment. Local governments should have the option of limiting the introduction of ground waste into their systems to prevent clogging of sewers. Prudent disposal practices and potential aerosolization hazards should be addressed through educational materials.

Incineration of Infectious Waste

Incineration is a process which converts combustible materials into non-combustible residue or ash. The incineration of infectious waste will effectively reduce its volume by 90% or more (24,31). In some cases a substantial portion of the energy generated by incineration can be retrieved and reused.

Incineration has traditionally been selected by hospitals as the primary method of pathological and infectious waste disposal. Small-capacity, intermittently operated pathological waste incinerators were at one time suitable and adequate for the treatment of the hospitals' incinerated wastes. However, with the relatively recent upsurge in the use of disposables in biomedical facilities, both the size and composition of the infectious waste stream has undergone a major transition. The waste stream is far more variable in its overall composition and in its plastic content has increased substantially. The plastic content of the biomedical waste stream - estimated to be about five times that of the municipal solid waste stream - presents some major concerns with regard to incineration (9).

In order for waste materials to be safely, efficiently and effectively combusted, they must be maintained for an adequate period of time under proper temperature and oxygen conditions. The "three T's" - time, temperature and turbulence - are critical to the achievement of complete combustion and the minimization of toxic emissions (15,19,22,24,31). Primary combustion temperatures of at least 1600 degrees F and secondary temperatures of at least 1800 degrees F with good mixing and a gaseous residence time of about two seconds should provide for good burnout of infectious and pathological waste (5,14,19, 22,24). Incomplete burnout can result from overfeeding, decreased temperatures or a failure to adequately disperse and oxygenate the waste in the incinerator chambers. Incomplete burnout can result in smoke, odors, toxic emissions and uncombusted materials in ash.

The destruction of pathogenic (disease-causing) micro-organisms is easily accomplished at temperatures well below those which have been described as necessary for the combustion of organic and chlorinated organic compounds (15,19,22). The Canadian Ministry of the Environment recommends that a minimum of thirty minutes be allotted as a pre-heat period for the secondary chamber before any waste is fed into the incinerator. They also suggest that with any incinerator not operated on a continuous basis, only non-infectious waste be initially incinerated at the beginning of each burn session (15).

Types of Incinerators

Of the three types of incinerators (multiple-chamber, rotary kiln and controlled-air) that are currently available for the incineration of infectious waste, the controlled-air incinerator is most commonly selected (15,19,24). Though multiple-chamber incinerators are suitable for the destruction of a slow heat release pathological waste stream, they are unable to meet the complex physical and thermal demands characteristic of a modern day infectious waste stream. An incineration process which can accommodate these demands must have a higher heat release rate and greater oxygen fluctuation capacity.

The rotary kiln incinerator, though widely and successfully employed in various industrial operations, has had a somewhat restricted application in the area of biomedical waste disposal (15,24). Though the rotary kiln does offer some promise as an incineration process which could be modified and adapted for biomedical waste disposal, it does have the significant drawback of generating unusually high particulate loadings and is also more costly than other incineration processes. (15,24).

The controlled-air incinerator has become the most widely selected hospital waste incinerator technology during the last 10 to 15 years and now dominates the market among hospitals and similar medical facilities (15,24) The "starved air" type of controlled-air incinerator is generally preferred over the "excess-air" type because of its ability to substantially reduce the entrainment of particulate matter in the flue gas. The air which flows into the primary chamber at sub-stochiometric ratios (lower than normal air-fuel ratio) reduces the velocity and turbulence of the flue gas, ultimately yielding a decrease in the amount of particulate formed. As a result, most controlled-air incinerators can meet state and local particulate matter emission limits without the use of special cleaning devices (15,24).

Since it is equipped to respond to sporadic fluctuations in temperature, the starved-air incinerator is especially suitable for the incineration of wastes which have a wide variation in composition (15,24). Starved-air incineration is such that the unusually high levels of unburned hydrocarbons generated in the primary chamber are directly funneled into the secondary chamber which has the effect of increasing the incinerator's overall rate of combustion efficiency (15,24). This means that a starved-air incinerator has an additional energy-economizing feature since it is able to internally utilize the unburned hydrocarbons which it generates in order to achieve maximum operating efficiency. Therefore, less auxiliary fuel is required when burning wastes by starved-air as opposed to other types of incineration.

Incinerator Emissions

Particulate Matter

The particulates emitted as a byproduct of incineration are small, solid particles or aerosols that can range in size from less than one micron to hundreds of microns (19). The particulates can arise from inorganic substances contained in the waste feed that are carried into the flue gas rather than deposited in the ash; organometallic substances formed as part of the incineration process; and uncombusted fuel molecules. Particulate emissions have been shown to be potentially harmful to human health. The ultrafine submicron particles which can adsorb toxic substances and penetrate deep into the alveoli of the lungs present the greatest concern.

In general, good combustion conditions (i.e., optimal time, temperature and turbulence) will minimize particulate emissions. Scrubbers and baghouses can be used to further reduce particle emissions.

Acid Gases

Several acid gases may be generated during incineration including sulfuric, nitric and hydrochloric acids. Hydrochloric acid (HCl) is by far the most predominant (19,24). Due to their high plastic content, biomedical wastes provide a ready source of chlorine for the synthesis of HCl. A hospital incinerator burning 1000 lbs/hr. of waste with 1% of chlorinated PVC-type plastic would exceed the U.S. EPA HCl standard of 4 lbs/hr. under the Resource Conservation and Recovery Act (RCRA)(19). U.S. EPA RCRA standards which require that HCl be controlled by 99% or to 4 lbs per hour apply only to hazardous waste incinerators and therefore do not include biomedical waste incinerators (19). Many states are, however, now requiring 90% control for HCl emissions from new commercial biomedical waste incinerators (19).

Acid gases are highly corrosive and can cause human health as well as environmental problems. In the human body, acid gases can act directly as primary irritants to the eyes and upper respiratory system. They can also be adsorbed on to particulate matter and carried down into the deep lung and induce long-term effects in the respiratory system. The solubilization of heavy metals in the body fluids making them far more toxic is an additional concern with acid gas exposure. Environmentally, acid gases can produce direct corrosive effects or contribute to regional acid precipitation problems.

Scrubbers are typically employed for acid gas removal. An HCl removal efficiency of 93 - 96% has been obtained with wet scrubbers which contain calcium hydroxide (24). The scrubber design and the type of liquid solution used in large part determine the contaminant removal efficiency. Dry scrubbers have also exhibited efficient acid gas removal (24).

Trace Metals

The level of trace metals in flue gas is proportional to the quantity of trace metals contained in the waste being burned. Some of the likely sources of trace metals in biomedical waste include surgical blades, foil wrappers, plastics and printing inks (19). Trace metal emissions may pose a variety of systemic as well as localized health effects. Acid gases can react with trace metals to create an exacerbated toxicological effect. A number of trace metals (e.g., arsenic, cadinium, nickel, selenium, and zinc) tend to collect and adsorb onto the respirable fraction of particulate matter (24).

The maintenance of proper flue gas temperatures and minimization of particulate matter levels can help to greatly reduce trace metal air emissions. Since incinerators operated with extremely high temperatures in fuel-rich zones generate a greater amount of respirable particulate matter, the use of controlled air or two-stage incineration, with its lower primary combustion temperatures, should reduce or minimize trace metal emissions (24).

Organic Emissions

Organic emissions from incineration can be in the form of low molecular weight organic compounds such as ethane, propylene and trichloroethylene or polychlorinated compounds such as dioxins and furans. The chlorinated compounds are of greatest concern. The high quantities of chlorine derived from the combustion of the plastic-dense biomedical waste stream can serve as precursors for dioxin and furan formation. There are actually a number of theories regarding dioxin and furan formation from biomedical waste incineration. They include: a lack of combustion of trace quantities of the polychlorinated compounds which are present in the waste fuel; in-situ combination of precursor compounds which are released during incineration; spontaneous synthesis from a variety of organics compounds, and the chlorine emitted during the incineration process and; catalyzed reactions on fly ash at low temperatures (19,24). Chlorinated dibenzodioxin and dibenzofurans may exist in both the vapor phase and as fine particulates in incinerator emissions. At temperatures below 300 degrees F. they condense onto fine particulates (24).

Select isomers (chemical configurations) of dibenzodioxin and dibenzofuran are extremely toxic to animals and humans. These compounds are not readily detoxified in the body and are extraordinarily potent at very low levels. At low doses, the 2,3,7,8-tetra-isomers have been found to induce carcinogenisis and reproductive failure in laboratory animals.

The generation of dioxins and furans can be most efficiently and effectively minimized via the maintenance of a high combustion efficiency which assures the complete breakdown of organic molecules. Add-on pollution control devices should be considered as only a back-up to the maintenance of proper temperature and turbulance conditions in the combustion chambers. Periodic combustion upsets and transient puffs should also be avoided. Since dioxins and furans will condense onto fine particles at temperatures 300 degrees F. and below, scrubber collecting devices operated in the 200-300 degrees F. range will also aid in effectively controling their emission (24). And, since starved-air incineration generates lower levels of in-situ chlorine than other incineration processes, it is optimal for biomedical waste disposal (24).

Incinerator Ash

Incinerator ash residue will have to be properly disposed of in a landfill provided that it does not exhibit characteristics of a hazardous or was derived from the incineration of a listed hazardous waste. Biomedical waste incinerator ash may be even less intrinsically harmful than municipal waste ash because it is unlikely to include ash from processed tires, batteries, discarded paint and other household wastes (14). Recent studies seem to confirm that the ash from a properly operated biomedical waste incinerator contains no disease-producing microorganisms (14). Ash resulting from the incineration of biomedical waste may, however, contain a significant quantity of sharps such as needles and glass. Therefore, care should be exercised in the removal and disposal of infectious waste incinerator ash. It is suggested by the Canadian Ministry of the Environment that this ash also be wetted prior to handling to minimize the potential for generating airborne dust (15). All personnel handling the ash should wear or use dust masks, gloves and protective clothing as a safety precaution.

RECOMMENDATION: Since incineration will continue to be one of the principal methods for treating infectious waste, the MPCA should be provided with the funds necessary to conduct a thorough study of the impacts of incinerating infectious wastes in light of the changing composition of the biomedical waste stream.

THE TREATMENT OF INFECTIOUS WASTE

The purpose of treating infectious waste is to alter its biological character so as to reduce or eliminate its potential for causing disease. No single treatment technique is ideal for all types of infectious waste. Therefore, the selection of a particular treatment method should be based upon the type of waste generated and the suitability of the options which are available.

Steam Decontamination (Autoclaving)

Steam decontamination (autoclaving) utilizes saturated steam within a pressurized vessel to achieve temperatures high enough to kill infectious agents. Autoclaves are commonly found in laboratories, dental offices, and surgical clinics. There are two types of autoclaves - the gravity displacement type in which the displaced air flows out the drain through a steam-activated exhaust valve and the prevacuum type, in which a vacuum is pulled to remove the air before steam is introduced into the chamber (31).

All autoclaving procedures are time and temperature dependent. In order to be rendered non-infectious, materials must be maintained within the autoclave vessel at a high enough temperature and for a long enough period of time. The decontamination of infectious materials is therefore a function of the degree of steam penetration as determined by the treatment time and temperature. Standard autoclave operating conditions for infectious waste decontamination are approximately 121 deg. C at 15 lbs/in^2 of pressure for greater than 60 minutes (22,29). Low density wastes such as disposable laboratory items are best suited for autoclaving. High density wastes that insulate the contaminants from heat and steam penetration generally should be treated using another method.

The packaging and containment of infectious waste to be autoclaved is crucial to effective autoclave treatment. Metal pans, bottles, flasks and plastic bags are among the containers commonly used. To facilitate steam penetration, bags should be opened and bottle caps and stoppers loosened immediately before placement in the steam sterilizer. Special attention must be paid to the type of plastic bags which are used because some types of bags, such as those constructed of high density polypropylene or temperature-resistant polymorphs, will impede steam penetration. Since bags made of plastic polymers which will allow steam penetration have sometimes been found to crumble and melt during treatment, it is commonly recommended that they be placed in rigid containers when autoclaved (31).

The volume and configuration of the waste load placed in an autoclave is an important factor in the attainment of temperatures sufficient to achieve effective decontamination. Waste volume limits the suitability of the steam sterilization treatment method. For example, it may be more effective to autoclave a large quantity of wastes in two small loads rather than one large load.

Autoclave Monitoring

There is some divergence of opinion as to how to effectively monitor and verify the autoclaving process. Since autoclaving is dependent upon time as well as temperature - chemical indicators, which demonstrate only the attainment and not the maintenance of temperature, are generally not recommended. Biological indicators such as Bacillus stearothermophilus are typically found to be more reliable. (20,31).

However, some experts believe that sterility testing or testing for the survival of an indicator micro-organism is not suitable nor practical in verifying effective infectious waste treatment. According to a National Research Council Committee which is currently examining the issue . . .

> Sterility is not an objective of waste decontamination method, and indicator microorganisms do not simulate typical waste load conditions. The adoption of arbitrary standards (e.g., biological indicator) may also preclude the importance of ensuring strict adherence to process and operational control. Process controls must be relied upon to validate adequate treatment of the waste.

Labeling Autoclaved Waste

Infectious waste which has been autoclaved is often not readily distinguishable from infectious waste which has not been autoclaved. It is usually difficult for those off-site to visibly determine whether a particular batch of waste has been treated even though once treated the infectious capacity of the waste is markedly altered. For this reason, bags of infectious waste which have been autoclaved should be clearly labeled as such throughout the disposal process.

RECOMMENDATIONS: Process controls should be used as the principal method of monitoring the process of autoclaving infectious waste. All facilities which utilize autoclaves to treat infectious waste should be required to maintain a log of the operating parameters for each load of infectious waste.

Identification of Autoclaved Waste:

Two options should be considered for the disposal of waste which has been autoclaved:

Option 1: Require separate handling of autoclaved waste and prohibit compacting. Waste disposal personnel would then receive intact, "autoclaved"-labeled packages and would be able to readily identify the waste as having been treated.

Option 2: Permit autoclaved waste to be mixed and compacted with the general waste stream. However, generators would be required to provide a written statement to the waste haulers that the waste has been properly autoclaved. The hauler would be required to provide a copy of the notice to any disposal facility to which the waste is taken.

Options 1 or Option 2 would serve as a means to provide assurance to the waste handlers that the infectious waste that has been autoclaved has been properly treated.

Gas/Vapor Sterilization

Gas/vapor sterilization involves the use of a sterilizing agent which is a gaseous or vaporized chemical. The two most commonly employed chemicals, ethylene oxide and formaldehyde, are both recognized as probable human carcinogens (cancer-causing agents). Ethylene oxide, though widely used in the sterilization of temperature-sensitive (thermolabile) supplies, is not recommended in the treatment of infectious waste. Formaldehyde frequently forms a residue on the materials sterilized thereby providing an opportunity for additional exposure. These reasons, among others, do not make gas/vapor sterilization a desirable method of treatment.

Chemical Disinfection

Chemical treatment is most appropriate for liquid waste. However, it also can be used in treating solid infectious wastes (31). There are a number of parameters that must be considered in chemical disinfection including the type of microorganisms present, the degree of contamination, the type of disinfectant and the length of contact time necessary to effectively treat microbially contaminated materials. The disposal of chemically-treated waste must be in accordance with state and local requirements.

Decontamination by Irradiation

Decontamination by irradiation is an emerging technology for treating infectious waste that involves the use of ionizing radiation. When properly used and monitored, ionizing radiation may provide an effective method of treating infectious waste. The high capital cost, requirement for highly trained operating and support personnel, and problems associated with the ultimate disposal of the decayed radiation source may prevent this treatment method from ever being widely adopted even if it were proven to be effective.

RECOMMENDATION: Infectious waste rules should be written in such a manner as to allow for incorporation of new, effective treatment technologies.

V. ENFORCEMENT

In order to be successful, any good regulatory system must include an effective enforcement program. If rules are not enforced, those who are willing to comply only because of the threat of enforcement will likely not comply with the rules. Those who initially are willing to comply with the rules, may stop complying if they feel that non-complying competitors achieve a significant cost advantage as a result of their noncompliance. It is therefore important that any new infectious waste rules be supported by an effective enforcement program.

In addition, to facilitate an effective enforcement program, the agency rules must clearly set out the duties of the regulated entities. Finally, the regulated entities must be informed of their obligations under the state infectious waste management rules.

RECOMMENDATIONS:

Regulated Community

The existing state rules governing infectious waste should be revised to clarify the responsibility of generators, haulers and disposal facilities.

Generators should be responsible for segregating infectious waste, properly containing and identifying the waste, and insuring that it is not disposed of with general refuse. To help generators in meeting the infectious waste management requirements and to assist in conducting compliance inspections, it is recommended that each infectious waste generator prepare and maintain an infectious waste management plan. The plan should include a description of the infectious waste generated by the facility; the segregation, packaging and labeling and storage procedures that will be implemented; the treatment/disposal methods for each waste; and the name of the person(s) responsible for infectious waste management at the facility.

Solid waste haulers should be responsible for taking waste that has been identified by the generator as infectious or is known by the hauler to be infectious to only those facilities authorized to treat or dispose of the waste. Haulers of infectious waste should be responsible for insuring the safe and secure transport of infectious waste to a legal treatment or disposal site. Haulers should also prepare and maintain an infectious waste management plan.

Solid waste treatment and disposal facilities should be responsible for accepting only those wastes that their facility is permitted to handle. Infectious waste treatment and disposal facilities should be responsible for the proper treatment, storage and disposal of the infectious waste they receive. Treatment and disposal facilities, too, should prepare and maintain an infectious waste management plan.

Agency Responsibility

Once the revised infectious waste rules are in place, the enforcement efforts of responsible state, and local governments should be increased and coordinated to ensure compliance, and to increase the confidence of waste handlers and the general public in the infectious waste regulatory system. This will require increased funding and staffing for the enforcing agencies.

Minnesota Pollution Control Agency

The MPCA should assume the primary enforcement responsibility in the management and implementation of any newly adopted infectious waste roles once the waste has left the generating facility.

Waste haulers and waste treatment or disposal facilities should be required by the MPCA to maintain on file an infectious waste management plan. In addition, the MPCA should consider requiring infectious waste haulers and disposal facilities to notify the agency that they engage in the business and certify that they have prepared a management plan.

The Minnesota Health Department

The MDH should adopt and enforce rules that govern the in-house waste management operations of an infectious waste generating facility. MDH should require all generators of infectious waste to maintain on file a waste management plan. In addition, MDH should consider requiring generators to notify MDH that they produce infectious waste and to certify that they have prepared a management plan.

Minnesota Occupation, Safety and Health Administration

Since the infectious waste issue has an important worker safety component, the Minnesota Occupational Safety and Health Administration (MN OSHA) should also play a key role in the state's infectious waste program. The MPCA and MDH should inform MN OSHA of any worker safety problems that the agencies become aware of. Under the current Minnesota Employee Right-to-Know requirements, only clinics and hospitals are required to provide their employees with training on potential workplace hazards associated with infectious agents. The requirements should be extended to cover all facilities involved in the handling of waste which may present an infection hazard.

Under Employee Right-to-Know rules, waste management facilities have a general responsibility to provide a safe workplace and adequate training for their employees. OSHA could assist the infectious waste enforcement program by reviewing compliance with these two general requirements.

Local Government

As local governments develop waste management systems to protect public health and the environment, infectious waste issues are likely to arise. Since there are a variety of solutions to the solid waste problem, the concerns about infectious waste are likely to vary from one local unit to another. Thus, local governments should have the authority to resolve infectious waste issues unique to their particular solid waste management system.

Compliance and Penalties

Since infectious waste is generated by a relatively large number of facilities, a situation somewhat analogous to the large number of hazardous waste generators in the state, it is recommended that the MPCA and the MDH be authorized to impose administrative penalties for violation of their infectious waste rules.

To augment the enforcement effort, it is important that the regulated facilities are aware of what they are required to do and the penalties for noncompliance. Therefore, the MPCA, the MDH and interested counties should identify those persons who will be affected by the new program and provide them with information on how to comply with the rules.

VI. EDUCATION

Recently,the level of concern regarding biomedical waste handling and disposal has increased dramatically among waste management personnel. Some of this concern is very legitimately based upon a recognition of the potential of select segments of the biomedical waste stream to transmit disease. However, it is apparent that much of the preoccupation with the infectious waste issue has arisen from confusion of the perceived with the actual risks associated with the management of biomedical wastes. Unfortunately, a modification of the infectious waste rules designed to properly and thoroughly address the first concern will not automatically alleviate the second. The perceived risks associated with general biomedical waste will likely persist. Therefore, educational efforts, both interim (until the new infectious waste rules are adopted) and ongoing must augment any regulatory initiatives.

The "actual risks" associated with infectious waste should be addressed through educational materials designed to inform infectious waste generators of the safe and proper method of disposing of the infectious waste which they generate. Waste handlers should be informed of the biological wastes that present an infection hazard and the responsibility of the infectious waste generator to properly manage the infectious waste stream.

In addition, waste handlers should be instructed on which biomedical wastes DO NOT present an infection hazard beyond that of general municipal waste in an effort to allay concerns associated with "perceived risk. Educational efforts, such as the distribution of pamphlets and the administration of on-site training programs designed to assist waste handlers in identifying infectious waste as a limited subset of the composite biomedical waste stream, are pivitol to the successful implementation of any modified infectious waste rules.

RECOMMENDATION: The Agencies with responsibility for overseeing infectious waste management should coordinate the development and distribution of informational and educational materials. Those agencies participating in the effort (i.e., MPCA, MDH, OSHA and the Attorney General's Office) should work with the Minnesota Waste Education Coalition and the Minnesota Technical Assistance Program (MN TAP) in preparing these materials.

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APPENDICES

APPENDIX A - RULES

4675.2300 <u>**FREESTANDING OUTPATIENT SURGICAL CENTERS**</u>

HANDLING AND DISPOSAL OF SOLID WASTE

4675.2200 INFECTIOUS WASTE.

Subpart 1. **Defined.** Infectious waste is defined as waste which originates from the diagnosis, care, or treatment of a person that has been or may have been exposed to a contagious or infectious disease. Such waste includes but may not be limited to the wastes listed in subparts 2 and 3.

Subp. 2. **Hazardous infectious waste.** Hazardous infectious waste includes:

A. all wastes originating from persons placed in isolation for control and treatment of an infectious disease;

B. bandages, dressings, casts, catheters, tubing, and the like, which have been in contact with wounds, burns, or surgical incisions of a suspected, known,or medically identified hazardous infectious nature;

C. laboratory and pathology waste of an infectious nature which has not been autoclaved;

D. all anatomical waste, including human parts or tissues removed surgically or at autopsy;

E. any other waste as defined by the commissioner of health which because of its potential infectious characteristics or hazardous nature requires handling and disposal in a manner prescribed for (a) through (d).

Subp. 3. **General infectious waste (contaminated waste).** General infectious waste (contaminated waste) includes:

A. bandages, dressings, casts, catheters, tubing, and the like, which have been in contact with wounds, burns, or surgical incisions, but are not suspected or have not been medically identified as being of a hazardous infectious nature;

B. discarded hypodermic needles and syringes, scalpel blades, and similar materials, except when suspected or identified to be of a hazardous infectious nature; and

C. incinerator ashes from infectious waste.

4675.2300 ORDINARY WASTE.

All household-type trash is defined as ordinary waste. It includes uncontaminated dietary garbage, autoclaved laboratory specimens and cultures, and incinerator ashes from ordinary waste. Autoclaved laboratory waste shall be labeled "autoclaved."

4675.2400 COLLECTION AND HANDLING OF WASTE.

Subpart 1. **Collection of hazardous infectious waste.** Hazardous infectious waste as defined shall be collected separately in containers provided with moisture-proof heavy-duty or double plastic or paper bag liners for safe storage and disposal. Bags or containers shall be kept positively closed or sealed at all times, and shall be color coded or otherwise marked for easy identification.

Subp. 2. **Collection of general infectious waste.** General infectious waste as defined shall be collected in containers provided with moisture-proof plastic or paper bag liners. Bags or containers shall be kept closed or sealed at all times and shall be color coded or otherwise be identifiable. Disposal of needles with the waste shall provide safety from puncture wounds to personnel. General infectious waste may be collected separately or it may be collected with the ordinary waste. Where separation of general infectious waste is not accomplished, all such mixed waste shall be considered and handled as general infectious waste.

4675.2500 **REMOVAL, STORAGE, AND DISPOSAL OF WASTE.**

Subpart 1. **Removal.** Removal of hazardous or general infectious waste from the originating points of collection shall be accomplished as needed, but at least daily in accordance with an established housekeeping program. Waste shall be removed in the original bag liners which must be positively sealed. Waste shall not be transported through dietary or medically sensitive areas.

Subp. 2. **Storage.** Storage of infectious waste in a central waste collection area shall be done in a sanitary manner. Space assignment shall clearly indicate separation of hazardous waste as well as general infectious or mixed waste from ordinary waste.

Waste accumulated in an inside storage area shall be stored in closed metal containers or in a pest-proof enclosed room. The room shall be provided with exhaust ventilation. If container storage is not provided for bagged waste or if a room serves a compactor unit, a floor drain must be provided for cleaning and flushing.

Hazardous infectious waste accumulated in an outside refuse area shall be stored inseparate metal containers with tight fitting covers. General infectious waste or mixed waste shall be stored in metal containers with tight-fitting covers; or it may be stored in a closed metal dumpster or in a compactor unit if such a method of waste handling is compatible with an approved system of waste disposal.

All containers shall be of noncorrodible watertight construction. Containers in patient areas must be of metal or other fireproof material. Appropriate facilities shall be provided to facilitate washing of waste containers and for cleaning of rooms used for refuse storage, compaction, or incineration.

Subp. 3. **Disposal.** Disposal of infectious waste shall be in accordance with the rules of the Department of Health and the Minnesota Pollution Control Agency.

Hazardous infectious waste shall be destroyed either by on-site incineration or by contracted incinerator service.

General infectious waste or mixed waste may be deposited in a sanitary landfill which has been approved by the Minnesota Pollution Control Agency without conditions. If the landfill operation does not comply with the requirements, general infectious and mixed waste must also be incinerated.

Ordinary waste shall be disposed of in accordance with state rules and local ordinances for such waste.

4655.9070 <u>**NURSING AND BORDING CARE HOMES; OPERATION**</u>

4655.9070 HOUSEKEEPING RULES APPLICABLE ONLY TO NURSING HOMES.

Subpart 1. **Scope.** Subparts 2 and 3 apply to nursing homes only.

Subp. 2. **Disposal of special waste.** Materials or waste such as dressings or disposable pads which are infectious or suspected of presenting a potential health hazard shall be collected in a manner which will prevent transmission of disease, and shall be incinerated. If regular waste or refuse is not incinerated, infectious waste shall be collected separately in special bags to indicate their content. Needles and similar medical single-use items shall be destroyed before disposal, unless incinerated.

7035.0300 **CURRENT SOLID WASTE RULES**

(CURRENT AND PROPOSED SOLID WASTE RULES PROHIBIT THE LANDFILLING OF INFECTIOUS WASTE.)

GG. "Special infectious waste" means waste originating from the diagnosis, care,or treatment of a person or animal that has been or may have been exposed to a contagious or infectious disease. Special infectious waste includes, but is not limited to,

(1) all waste originating from persons placed in isolation for control and treatment of an infectious disease;

(2) bandages, dressings, casts, catheters, tubing, and the like, which have been in contact with wounds, burns, or surgical incisions and which are suspect or have been medically identified as hazardous.

(3) All anatomical waste, including human and animal parts or tissues removed surgically or at autopsy;

(4) laboratory and pathology waste of an infectious nature which has not been autoclaved;

(5) any other waste, as defined by the state commissioner of health, which, because of its infectious nature, requires handling and disposal in a manner prescribed for subitems (1) to (4).

PROPOSED SOLID WASTE RULES

(DEVELOPED PRIOR TO FORMULATION OF INTERAGENCY TASK FORCE INFECTIOUS WASTE RECOMMENDATIONS SLATED FOR ADOPTION BY LATE SUMMER - EARLY FALL, 1988)

Subp. 48. **Infectious waste.** "Infectious waste" means waste originating from the diagnosis, care, or tretment of a person or animal that has been or may have been exposed to a contagious or infectious disease. Unless the materials have been rendered non-infectious by appropriate processing, infectious waste includes:

A. all wastes originating from persons or animals placed in isolation for control and treatment of an infectious disease;

B. bandages, dressings, casts, catheters, tubing, and similar disposable items which have been in contact with wounds, burns, anatomical tracts, or surgical incisions and which are suspect of being or have been medically verified as infectious;

C. all anatomical waste, including human and animal parts or tissues;

D. sharps and needles;

E. laboratory and pathology waste of an infectious nature; or

F. any other waste, as defined by the state commissioner of health, which, because of its infectious nature, requires handling and disposal in a manner prescribed for items A to D.

APPENDIX B - REGULATORY OVERVIEW

In 1976, Congress enacted the Resource Conservation and Recovery Act (RCRA) which required the Environmental Protection Agency (EPA) to develop and evaluate sound methods for the management of solid waste and establish "cradle-to-grave" management for solid waste which is identified as hazardous. RCRA defines a hazardous waste as:

> a solid waste or combination of solid wastes which, because of its quantity, concentration, or physical, chemical, or infectious characteristics may (A) cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or (B) pose substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.

Infectious wastes are therefore designated by RCRA as a subset of hazardous wastes. In 1978, EPA's first set of proposed regulations for hazardous waste management included a proposed definition and proposed treatment methods for infectious waste. However, after receiving numerous responses from state health authorities, the Centers for Disease Control (CDC) and others knowledgeable on the subject of infectious waste, the EPA elected not to regulate infectious waste disposal. The decision was based upon what EPA believed was insufficient evidence of human or environmental health hazards to justify regulatory action. In lieu of regulations, the EPA published a draft manual for infectious waste management in 1982. The manual, revised in May 1986, was designed to serve as a guide and general resource for those states and municipalities that elected to develop their own infectious waste management policies.

While the general principles presented in the EPA manual (i.e., appropriate waste designation, segregation, packaging, etc.) are widely recognized as fundamental to the establishment of a reliable infectious waste management program, there is a some divergence of opinion among the authorities regarding a number of the specific suggestions put forth by the EPA. For example, while the EPA designates isolation waste as infectious waste and refers to the Center for Disease Control (CDC) guidelines in doing so, the CDC suggests that isolation waste be classified as infectious waste only if doing so will, from a practical standpoint, assist in the the management of waste within the generating facility. Further, though the EPA suggests that the landfill disposal of untreated infectious waste be prohibited, research indicates that landfilling should be acceptable from both an environmental and a public health standpoint.*

The lack of consensus on an appropriate definition of infectious waste and on acceptance treatment and disposal options has made the development of infectious waste programs somewhat difficult for the states. Previously, many states had chosen to simply incorporate the recommendations presented in the EPA

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*/ Task forces, such as the one formed by the New Jersey Public Employees Occupational Safety and Health Division, have formulated modified waste disposal plans which would alleviate occupational exposure hazards to the landfill workers.

guidelines into their own regulatory framework. However, the recent controversy surrounding the infectious waste issue has led a majority of the states who have had infectious waste disposal regulations in place to re-evaluate their efficacy. In addition, many of the states which, until now, have had no regulations have begun to consider adopting infectious waste regulation. A recent Council of State Governments (CSG)** survey indicated that, as of February 1988, forty-one states and the District of Columbia had some type of infectious waste regulations in place. Of the eleven states which have no infectious waste regulations, only six indicated that they had no immediate plans to develop any.

The majority of states with existing infectious waste programs placed the lead authority with their solid waste divisions. A far smaller number placed the authority with their health departments, and even fewer still granted joint lead authority to both agencies. Though most states have delegated lead authority to their solid waste divisions, that authority does not usually extend beyond regulation of off-site disposal. Regulation of internal waste management practices of waste generating facilities is typically within the purview of the state's health department. Frequently regulations that apply to infectious waste generators are not universally applied to all infectious waste generators. Rather, the infectious waste handling practices of select generator groups such as hospitals,

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**/ Council of State Government's "State Infectious Regulatory Programs, 1988."

outpatient surgical centers, and nursing homes are often regulated through the licensure requirements for the facilities. State health departments commonly rely on licensure suspension as their primary enforcement tool.

State health departments have relinquished their regulatory authority for at least two-thirds of the nation's hospitals to a third entity--the Joint Commission on Accreditation of Hospitals (JCAH). The JCAH has only a very general requirement regarding the establishment of an effective waste management system within accredited facilities. A general requirement was purposefully selected by the JCAH to allow for state-to-state variation in infectious waste disposal requirements promulgated by state environmental agencies.

The following discussion briefly addresses the principal approaches taken by states in dealing with several key issues related to infectious waste management.

1. <u>Definition of Infectious Waste</u>.

Most of the states regulating infectious waste management have incorporated those regulations into their special or nonhazardous waste programs. If infectious waste were to be designated a hazardous waste, then each individual segment of that waste stream - treated or untreated - would be subject to a cumbersome delisting process in order to be considered non-hazardous. This delisting process would make standard treatment and disposal operations unnecessarily difficult.

In defining infectious waste, most states have opted to list specific waste types rather than formulate a characteristic definition of infectious waste. In contrast to hazardous waste, it would be exceedingly difficult to define infectious waste on a characteristic basis since there is no definitive, quantitative analysis that can be used to determine whether or not a waste is "infectious". Many states have chosen at this point to simply incorporate the EPA definition into their own infectious waste regulations.

2. Infectious Waste Handling.

On-site handling of infectious waste is generally governed by state health department guidelines. Thirty-one states single out packaging/labeling requirements to be included in their infectious waste rules. The wastes most commonly subject to packaging/labeling requirements are sharps (hypodermic needles, glass vials, scalpels, etc.). Some states including California, Tennessee and New York, have general container integrity and labeling regulations while others, such as Maryland and Massachusetts, have specific requirements for bag thickness and color. Provisions regarding the decontamination of reusable and recyclable infectious waste collection containers are not an uncommon subsection of packaging requirements. California actually lists a series of decontaminants that can be used under various conditions. Compacting untreated, infectious waste is prohibited by a number of states.

Infectious waste storage requirements vary considerably from state to state. Massachusetts and California are examples of states which have very specific storage temperature and duration requirements. According to the CSG survey, only eight states require permits for infectious waste storage facilities.

3. Transportation Requirements

Infectious waste transportation requirements adopted by the states generally consist of truck design (e.g., closed, leakproof, noncompacting, etc.) and truck placarding requirements. According to the CSG survey, only 8 states currently have infectious waste transport regulations in place. At least two of those, Missouri and California, have 100 kg/month quantity exemptions.

4. Treatment and Disposal

According to the CSG survey, half of the states are considering or have already enacted regulations to ban the landfilling of infectious waste. Some states such as Tennessee have considered, but rejected, adopting a blanket prohibition of landfilling. Tennessee has determined that with the maintenance of safe disposal procedures, there is no identifiable public health or environmental health risk from placing infectious waste in a sanitary landfill. Michigan permits the disposal of certain segments of the patient-derived infectious waste stream in a landfill. This includes all paper and plastic waste provided it has not been contaminated with what the Center for Disease Control designates as high-risk agents (highly contagious organisms).

The CSG survey reports that approximately three-fourths of the state's name incineration as an appropriate treatment method under their existing or proposed regulations. However, only a few of these states actually require infectious waste to be incinerated.

Twenty-seven states recommend steam decontamination (autoclaving) for the treatment of infectious waste. Fourteen of the 27 states are considering specifying process operation standards such as time, temperature and pressure. Some states stipulate process monitoring controls and recordkeeping procedures.

Chemical treatment alternatives are, according to the CSG data, included in the regulations of 18 states. The report additionally briefly discusses some emerging treatment technologies.***

***/ The Canadian Interministry Task Force on Biomedical Waste Disposal recognizes an emerging treatment technology in their 1986 report. The report describes a device being developed to safely reduce and decontaminate the infectious waste without resorting to incineration. In one simultaneous operation, infectious waste would be reduced to grit by a hammermill and decontaminated by a chemical disinfectant. The Canadian report states that the device has been approved for use in hospitals in several states.

5. <u>Recordkeeping Requirements</u>

Very few states have required a cradle-to-grave tracking of infectious waste similar to that mandated for hazardous waste. The trend among the states which do require manifesting of infectious waste is to require only the generator to maintain copies of manifests rather than submit them to a regulatory agency. Missouri is one of the few states that requires the infectious waste generator, transporter, storage and treatment facilities to maintain manifest records for 3 years.

6. <u>Worker Safety Regulations</u>

California, unlike many other states, includes worker safety provisions in both its infectious waste transfer/transport and treatment/disposal regulations. For example, the operator of infectious waste treatment, storage, and disposal facilities must provide and require their employees to use clean gloves, coveralls, and other protective clothing, face masks, or respirators necessary to provide ample protection of employees against exposure to infectious waste.

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