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STATE OF MINNESOTA

Office Memorandum

DEPARTMENT : Health

DATE : October 22, 1992

TO : Legislative Commission to Review Administrative Rules
55 State Office Building

FROM : Jane A. Nelson, rules coordinator
Division of Environmental Health JN

PHONE : 627–5038

SUBJECT :

Submission of Statement of Need and Reasonableness pursuant to Minnesota Statutes, sections 14.131 and 14.23

In accordance with the above statute, the Minnesota Department of Health is submitting to you the Statement of Need and Reasonableness on proposed rules relating to Infectious Waste, Minnesota Rules, parts 4610.2300, 4622.0100 to 4622.1200, 4655.9070 and 4675.2205. These rules are scheduled for publication in the State Register October 26, 1992.

JAN:lk

Enclosure

The Legislative Commision to Review Administrative Rules

OCT 23 1992

Sept 22, 1992 (REV)

STATE OF MINNESOTA
MINNESOTA DEPARTMENT OF HEALTH

In the Matter of Proposed Permanent Rules of the Minnesota Department Health Relating to Infectious Waste, Minnesota Rules, parts 4610.2300, 4622.0100 to 4622.1200, 4655.9070 and 4675.2205.

Statement of Need and Reasonableness

The amendments to and new rule parts contained in the above entitled rules are proposed by the Minnesota Department of Health (MDH) to implement Minnesota Statutes, sections 116.76 to 116.83, titled the Infectious Waste Control Act. The Minnesota Infectious Waste Control Act was initially adopted in 1989 in Laws of Minnesota 1989, chapter 337. The 1989 law was subsequently amended by the legislature in 1990 (Laws of Minnesota 1990, chapter 568, article 2) and again by the 1991 legislature (Laws of Minnesota 1991, chapter 344).

The proposed rules establish criteria and procedures for the: 1) on-site management of infectious waste and pathological waste by the generators of such waste; and 2) development and submission of generator management plans. Parts 4622.0100 to 4622.1200 directly implement the Infectious Waste Control Act. Amendments to part 4610.2300 (relating to mortuaries and funeral establishments), part 4655.9070 (relating to nursing homes), and part 4675.2205 (relating to free standing surgical centers) are proposed to bring those existing standards into compliance with the proposed state standards for the management of infectious waste and submission of generator management plans.

The Infectious Waste Control Act is jointly administered by the Minnesota Pollution Control Agency (MPCA) and the Commissioner of Health. The MPCA regulates all aspects of off-site management of infectious waste, including off-site transport, storage, decontamination and disposal. Rules have been adopted by the MPCA as parts 7035.9100 to 7035.9150 to regulate these off-site activities.

The Minnesota Department of Labor and Industry has responsibility for the administration of regulations governing occupational safety and health. Federal Occupational Safety and Health Administration (OSHA) laws and regulations are adopted by the state Department of Labor and Industry and the health standards of those regulations in turn are administered through a unit of the Minnesota Department of

Health. Proposed federal OSHA standards on bloodborne pathogens were adopted by the state on June 1, 1992. There are also existing federal and state OSHA standards on protective equipment, containers, and work practices that impact worker safety with respect to the handling of sharp or potentially injurious objects. OSHA laws and regulations apply only to employers; they are not enforced on sole proprietors or the general public.

Federal and state standards on hazardous and radioactive waste are regulated and implemented by the Minnesota Pollution Control Agency.

Statutory Authority

Authority to adopt rules to implement Minnesota Statutes, sections 116.76 to 116.82, the Infectious Waste Control Act, is contained in section 116.81, subdivision 2 which states:

> the commissioner of health after consulting with the agency may adopt rules to implement sections 116.76 to 116.82. The commissioner of health has primary responsibility for rules relating to facilities generating infectious waste. The commissioner of health, before adopting rules affecting animals or research animal waste, must consult the commissioner of agriculture and the board of animal health.

Within the general regulatory powers of the commissioner, authority to oversee sanitary conditions in hospitals, mortuaries and other public places is found in Minnesota Statutes, section 144.12, subdivision 1, clauses (1), (2), (3), (6), (7) and (10) and section 149.05, subdivision 1 (3).

Procedure

The MDH published three Notices of Solicitation of Public Comment in the State Register on this matter. A notice was initially published August 7, 1989 at 14 S.R. 292; a second published January 22, 1990 at 14 S.R.1879; and a third published July 22, 1991 at 16 S.R.137 subsequent to 1991 legislative revision of the Infectious Waste Control Act.

The MDH convened an Infectious Waste Work Group to review and discuss draft rule provisions to implement the existing Infectious Waste Control Act. Membership on the work group, in addition to representatives from the MPCA and the Board of Animal Health, included the Minnesota Medical Association, Minnesota Dental Association, Minnesota Veterinary Association, Minnesota Hospital Association, Minnesota Home Care Association, Minnesota Podiatric Association, Minnesota Chiropractic Association, Minnesota Medical Technology Association (laboratories), Minnesota High Technology Council, Occupational Health Nurses Association, Mayo Clinic, University of Minnesota, Minnesota Association of Homes for the Aged, and Care Providers of Minnesota. The work group met three times in 1990 and once in 1991. They reviewed numerous rule drafts and the Statement of Need and Reasonableness.

As required by Minnesota Statutes, section 116.81, subdivision 2, the department consulted with the commissioner of agriculture and the board of animal health during the development of the proposed rules. A copy of letters requesting review of the proposed rules by those agencies and their replies department of agriculture have been entered into the record on this matter.

Need for Proposed Rules

In 1988 a federal Medical Waste Tracking Act was adopted by Congress. It owed its passage, according to the report "Perspectives on Medical Waste" by the State University of New York Nelson Rockefeller Institute of Government (p.2) to a "series of highly visible and widely reported incidents involving medically related wastes that culminated in the notorious 'washups' along northeast beaches throughout the summer of 1988." The resulting federal Medical Waste Tracking Act legislation was modeled on the Resource Conservation and Recovery Act (RCRA) tracking system established by Congress in 1975 to deal with hazardous waste. Final RCRA rules adopted in 1980 by the United States Environmental Protection Agency expressly excluded infectious waste from tracking control. No further infectious waste regulations have come from the USEPA though that federal agency did issue a "Guide for Infectious Waste Management" in 1986. Further washups occurred during the summers of 1986 and 1987 prompting passage by Congress in 1988 of the Medical Waste Tracking Act. The act was limited in its application to a two-year demonstration and applied directly to only three states: New York, New Jersey, and Connecticut. The Great Lakes States, including Minnesota, were named in the federal statute, but their governors were allowed to remove them from the waste tracking program with a letter. All Great Lakes States petitioned out of the program before the statutory deadline in May 1989. Emergency rules were adopted by the USEPA in March 1989 to implement the Medical Waste Tracking Act and the tracking program began in June 1989. The federal tracking act sunsetted two years later in June 1991. The USEPA is expected to issue a final report in 1992 on the effect of medical waste on the environment and public health and evaluate the cost and benefit of the two year tracking effort.

The federal waste tracking system was not adopted by Minnesota. The state's Infectious Waste Control Act initially adopted in 1989 instead specified the basic elements for the establishment of the state's infectious waste management program. The state law was based on a "Report and Recommendations on the Regulation of Infectious Waste" prepared by the Office of the Attorney General, August 10, 1988. This report noted that waste disposal haulers and handlers had become 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.

The Attorney General report noted at that time that existing state regulations were not helpful in determining which biomedical wastes presented a significant infection hazard. Those regulations based their definition of infectious waste on the infection status of the source (i.e., whether the patient had a contagious disease) rather than the potential of the waste itself serving as a vehicle of disease transmission.

The Infectious Waste Control Act prescribes handling and management practices for generators; requires the development and submission of generator infectious waste management plans; and mandates the payment of management plan fees.

The regulatory areas governed by the proposed rules of the MDH relate to and further clarify the practices for the on-site management of infectious waste and pathological waste of generators. The proposed rules apply to regulated generators of infectious waste or pathological waste on the site of the generating facility.

While the Infectious Waste Control Act is explicit in its definition of many terms and in the prescribed requirements for the submission and content of generator management plans, there remain specific requirements governing the on-site management of infectious waste and pathological waste that are addressed in rule. These include the criteria for plan and fee submission, plan review and on-site waste management.

MDH has responsibility to ensure that infectious waste and pathological waste is segregated, packaged, labeled, stored, decontaminated and disposed of properly on-site in a manner that minimizes the potential for transmission of infectious agents to employees and the public.

Statement of Reasonableness

4610.2300, SANITARY CONDITIONS OF FUNERAL ESTABLISHMENTS.

It is necessary to amend this existing rule so the management standards applicable to all regulated generators of infectious waste and pathological waste are consistently applied. According to the statutory definitions of "infectious waste", "regulated human body fluids", "person", "pathological waste" and "generator", funeral establishments and mortuaries are subject to the provisions of the Infectious Waste Act and proposed parts 4622.0100 to 4622.1200. The proposed amendments to subpart 3 of part 4610.2300 are necessary to clarify the applicability of the proposed infectious waste rules and the infectious waste act to funeral establishments and mortuaries. Part 4610.2300 is amended for consistency with Minnesota Statutes, sections 116.76 to 116.83 and proposed parts 4622.0100 to 4622.1200. The provisions of the rule pertain to waste. Instruments and appliances that are used in these practices but are not discarded as waste do not fall within the scope of the proposed rules.

4622.0100 APPLICABILITY.

This part specifies who and what is regulated by parts 4622.0100 to 4622.1200. Proposed part 4622.0100 is necessary to inform the public to whom the rules apply.

Subpart 1. General. Minnesota Statutes, section 116.77 delineates what is covered by the waste management practices prescribed by sections 116.75 to 116.83. Section 116.802 indicates that the commissioner of health "may adopt rules to implement sections 116.76 to 116.82" and that the commissioner of health has "primary responsibility for rules relating to "facilities generating infectious waste." Section 116.79 requires the preparation of management plans and requires submission of the plans to the commissioner of health. The statute does not make any provision for exclusion from the act on the basis of quantity of waste generated. Exclusions, as specified in subparts 2 and 3, are based on type of waste and the generator.

Subp. 2. Excluded waste. The Infectious Waste Act exempts from regulation under the act and rules adopted thereunder certain kinds of infectious waste or pathological waste that may carry bacteria, pathogens and infectious agents. According to Minnesota Statutes, section 116.77 "Coverage" the act covers:

> any person who generates, treats, stores, transports, or disposes of infectious or pathological waste **except infectious or pathological waste generated by households, farm operations, or agricultural businesses.**

The proposed rules apply to the management of infectious waste and pathological waste unless the waste is expressly excluded by law.

Subp. 3. Excluded generators. The proposed rules apply to any "person" as defined in Minnesota Statutes, section 116.76, subdivision 15 who generates infectious waste or pathological waste without regard to quantity. The state's Infectious Waste Control Act is not restricted to hospitals or large generators of waste though as noted in subpart 2, household waste, farm operation waste and agricultural business waste is excluded. Nor does the law apply to all "persons" who generate infectious waste or pathological waste. According to Minnesota Statutes, section 116.76, subdivision 9 which defines "generator", certain entities and the infectious waste generated by them, are exempt from regulation as a generator. Within the definition of "generator" it states that a generator does not include:

> an ambulance service licensed under section 144.802, an eligible board of health, community health board, or public health nursing agency as defined in section 116.778, subdivision 10, or a program providing school health service under section 123.35, subdivision 17.

In discussion on the proposed rules, advisory committee member Jeanne Pfeiffer of Hennepin County Medical Center requested clarification on the status of volunteer rescue workers as generators. The question of unpaid first responders to an

emergency situation was also raised by staff. The Infectious Waste Control Act specifically excludes licensed ambulance services as regulated generators. For the most part, their waste is handled by the hospital to which they may take a person and any infectious waste is mandated by law to be accepted by the receiving facility. It does not seem reasonable to extend coverage of the rules to volunteer emergency responders if ambulance services are excluded by law. It is true that emergency responders may in some fashion generate waste. (The department notes that exposure of employees to infectious waste and agents is addressed by OSHA laws and regulations governing bloodborne pathogens and personal protection equipment.) Persons acting within the context of the Good Samaritan law, Minnesota Statutes, section 604.05, likely would be difficult to identify and regulate. It is likely that the next step in any voluntary first response or emergency situation involving injury would be to call an ambulance licensed under Minnesota Statutes, section 144.802. To clarify that Good Samaritan and volunteer rescue persons are not regulated generators, the department proposes the language in item D which states:

> D. any person acting as a "good samaritan" within the context of Minnesota Statutes, section 604.05.

Minnesota Statutes, section 604.05 addresses the aid provided by volunteer firefighters, volunteer police officers, volunteer ambulance attendants, a volunteer first provider of emergency medical services, volunteer ski patrollers, and any partnership, corporation, association, or other entity that is responding to another person exposed to or suffering grave physical harm at the scene of an emergency in a voluntary manner.

Any person rendering emergency care, advice, or assistance during the course of regular employment and receiving compensation or expecting to receive compensation for rendering such care, advice, or assistance is excluded from section 604.05. Paid professional emergency response personnel are subject to the protections and precautions afforded to occupations exposed to bloodborne pathogens.

Subp. 4. Other practices. This subpart is necessary to clarify that the proposed rules do not apply to the "operation of on-site incinerators" and the "off-site management of practices regulated by the MPCA including persons who transport infectious waste or pathological waste." This limitation of applicability is consistent with the statutory delineation of state agency responsibility by the Infectious Waste Control Act.

Section 116.79, subdivision 4 as amended by Laws of Minnesota 1991, chapter 344, section 6, requires submission of management plans to the commissioner of the MPCA if the person "incinerates or disposes of infectious or pathological waste." Minnesota Statutes, sections 116.84 and 116.85 administered by the MPCA govern the operation of incinerators and do not limit the authority of the MPCA to "regulate incinerator operations under any other law" (Section 116.85, subdivision 4). Minnesota Rules, chapter 7005 set performance standards for incinerators. While Minnesota Statutes,

section 116.79, subdivision 3 (d) indicates the need to detail the use of incineration within a generator management plan submitted to MDH, section 116.79, subdivision 4 (a) requires that the plan for incineration be submitted to the MPCA for review and approval. A copy of the MPCA-approved plan submitted as an attachment to the generator management plan submitted to MDH fulfills MDH needs.

Minnesota Statutes, section 116.83, subdivision 1 gives the commissioner of health primary responsibility for the enforcement of the act as it applies to generators of waste. Section 116.79 states "to the extent applicable to the facility, a person in charge of a facility that generates, stores, decontaminates, incinerates, or disposes of infectious or pathological waste must prepare a management plan...." These plans then, under subdivision 3, are submitted to the commissioner of health for review. Parts 7035.9100 to 7035.9150 have been promulgated by the MPCA to regulate commercial transporters and off-site facility practices.

4622.0300 DEFINITIONS.

The terms "agency," "blood," "decontamination," "generator," "infectious agent," "infectious waste," "laboratory waste," "pathological waste," "person," "regulated human body fluids," "research animal waste," and "sharps," are defined in the Infectious Waste Control Act. Subparts 2, 4, 6, 11, 15, 16, 18, 21, 22, 24, 25, and 27, refer to the definitions given in statute. It is reasonable to refer to the statutory definition of a term to ensure consistent use of terms between the Infectious Waste Control Act and the proposed rules that implement the law.

Subpart 1. Scope. Part 4622.0300 defines terms used in parts 4622.0100 to 4622.1200. The definitions are needed to provide persons subject to the proposed rules with a common meaning. This subpart is necessary to clarify that the terms defined are applicable to the proposed rules.

Subpart 3. Agricultural business waste. Minnesota Statutes, section 116.77 exempts agricultural business waste from infectious waste regulation. The statute does not define the term "agricultural business" or "agricultural business waste". It is necessary to define the term "agricultural business waste" so persons know to what waste the rules do not apply. The definition of "agricultural business waste" is similar to the description of "Agricultural Services" published by the Executive Office of the United States Office of Management and Budget (USOMB) in its Standard Industrial Classification Manual 1987. This federal office describes the agricultural services industry as including soil preparation services, crop services, veterinary services, animal services except veterinary, farm labor and management services, and landscape and horticultural services. The proposed definition of "agricultural business waste" is consistent with the OMB description of those industries with the exception that veterinary services for animal specialties are excluded. All generators of infectious waste and pathological waste are regulated unless specifically exempted. Veterinarians are listed by Minnesota Statutes, section 116.77 as a covered generator. Laws of Minnesota 1991, chapter 344, section 1 codified as Minnesota

Statutes, section 116.77 states:

> Sections 116.75 to 116.83 and 609.671, subdivision 10, cover any person, including a veterinarian, who generates, treats, stores, transports, or disposes of infectious of pathological waste but not including infectious or pathological waste generated by households, farm operations or agricultural businesses....

The provision in item C to specify that the waste produced by a "slaughtering or rendering operation" is agricultural business waste, was added on the advice of Dr. Keith Friendshuh of the Board of Animal Health and Dr. Stan Diesch of the University of Minnesota College of Veterinary Medicine representing the Veterinary Medical Association, after discussion with other members of the rule advisory work group on August 12, 1991 (MDH Advisory Work Group Minutes). The additional clarification is reasonable because slaughtering and rendering operations are routinely part of the farming and agribusiness industry. The Department of Agriculture regulates the meat, fish, poultry and retail food industry.

Subpart 5. Commissioner. This subpart defines the term commissioner to be "the commissioner of health." The definition of "commissioner" in the Infectious Waste Control Act is the Commissioner of the MPCA. It is necessary to define commissioner for purposes of the proposed rules as the commissioner of health because Minnesota Statutes, section 116.79, subdivision 3 identifies the commissioner of health as the party responsible for reviewing generator management plans and approving or denying methods proposed to decontaminate infectious waste and pathological waste on-site by generators.

Subpart 7. Disinfection. This term is necessary to define to distinguish between "decontamination," a term meaning "rendering infectious waste safe for routine handling as a solid waste" and "disinfection" which is a method that cleans a surface only. The MDH proposes to use the definition of "disinfection" used in rules adopted by the MPCA. The definition in part 7035.9100, subpart 7 of MPCA rules states:

> "Disinfection" means the use of chemical solutions to substantially reduce the number of microorganisms present on surfaces of inanimate objects.

MDH believes it necessary to coordinate regulatory provisions used by agencies when possible to ensure consistent enforcement between agencies and ease compliance by those regulated. The term proposed is consistent with Taber's Cyclopedic Medical Dictionary, edition 16, edited by Clayton L. Thomas, M.D., M.P.H., consultant to the Harvard School of Public Health, F.S. Davis Company, Philadelphia, which defines "disinfectant" as:

> A substance that prevents infection by killing bacteria. Most disinfectants are used on equipment or surfaces rather than in or upon the body. Common disinfectants are the halogens: chlorine, fluorine, iodine; salts of heavy metals: mercuric chloride (bichloride of mercury),

silver nitrate; acids: boric acid; alkalines: chloride of lime; organic compounds: formaldehyde, alcohol 70 percent iodoform, organic acids, phenol (carbolic acid), cresols, benzoic and salicylic acids and their sodium salts; and miscellaneous substances; thymol, hydrogen peroxide, potassium permanganate, ethylene oxide.
An agent that frees from infection. This term is usually applied to a chemical or physical agent that kills vegetative forms of microorganisms. (MDH exhibit 8, Page 515)

Part 4622.0400, subpart 12 delineates acceptable disinfection agents for spill clean up.

Subp. 8. Facility. Minnesota Statutes, section 116.76, subdivision 8, states that a facility "means a site where infectious waste is generated, stored, decontaminated, incinerated, or disposed." In Laws of Minnesota 1991, chapter 344, section 4, the Legislature amended Minnesota Statutes, 1990, section 116.79, subdivision 1 to allow a person to prepare a common management plan to cover all generating facilities owned and operated by the person (as defined in section 116.76, subdivision 15) whose activities produce infectious waste. Laws of Minnesota 1991, chapter 344, section 5 which amended Minnesota Statutes, section 116.79, subdivision 3 further requires the person to submit a fee for each generating facility.

It is necessary to further clarify what a facility is to apply the statute and fee structure. It is reasonable to consider a mobile, self-contained generating unit individually as a facility because Minnesota Statutes, section 116.79, subdivision 3 (8) refers to mobile and satellite facilities with respect to fees.

The MDH will distinguish for purposes of plan submission and fees, between mobile facilities which are secondary satellite units of a generator and used for a short period of time [Laws of Minnesota, chapter 344, section 5 codified as Minnesota Statutes, section 116.79, subdivision 3, (b) (8)] and those which are mobile and are the primary site used by a generator. In the first case the generator would address the satellite within a single plan and if used for less than five hours per week on an annual basis, pay no additional fee.

Subp. 9. Farm operation waste. Minnesota Statutes, section 116.77 exempts farm operation waste from coverage by the Act. "Farm operations" and "farm operation waste" is not defined by statute. It is necessary to define farm operation waste to assure consistent interpretation. The definition of "farm operation waste" as that waste produced by an "operation involved in the growing or harvesting of crops, the raising of livestock or poultry, or related activities conducted on a site such as a farm, ranch, orchard, dairy farm, or similar farming operation," is consistent with the definition of "farming operation" used by the United States Department of Labor and Industry, Occupational Safety and Health Administration in Standard Directive 21.9571 for the implementation of appropriations guidelines. Infectious waste generated by a veterinarian in the course of practice at a farm

operation is regulated and must be covered by the veterinarian's generator management plan.

Subp. 10. Generating employee. Minnesota Statutes, section 116.79, subdivision 3, establishes fees a generator is required to submit with the generator management plan. Under the statute the fee for a laboratory or home care agency is based on the number of generating employees at the facility. The term "generating employees" is not defined in statute. Definition is necessary for consistent implementation of the law. It is reasonable that a generating employee be only those individuals directly engaged in the production of infectious waste or pathological waste and exclude employees whose activities do not directly produce infectious waste or pathological waste. Persons who may be volunteers are exempted from the definition of an employee for purposes of fee payment. An employee is a person who is compensated for work; a volunteer is not.

Subp. 12. Generator management plan. It is necessary to define this term to differentiate the plan for the management of infectious waste developed by a generator from other management plans required by Minnesota Statutes, section 116.79.

Subp. 13. Household. Minnesota Statutes, section 116.76, subdivision 10 defines "household" as "a single detached dwelling unit or a single unit of a multiple dwelling." The department has received questions that necessitate further clarification of the statutory definition. The department interprets a dwelling to also include private living quarters occupied by students in dormitories or nuns in convents. Such residential living facilities are reasonable to include within the meaning of a household because the residents are not patients and the purpose of a residential facility is not one of a medical or health care nature. If, in a household or residence, the resident administers his or her own medication, it is reasonable to view the occupancy as a household.

Within Minnesota Statutes, section 116.79, subdivision 3, (b) (3) the legislature specified fees that must be paid by various generators of infectious waste. Included in clause (3) are hospitals, nursing homes, boarding care facilities or intermediate care facilities. Such facilities are licensed to provide medical and health care services including the administration of medication to the persons residing there. Minnesota Statutes, section 116.76, subdivision 9 further exempts "a person who produces sharps as a result of administering medication to oneself" from being a regulated generator.

Subp. 14. Household waste. Minnesota Statutes, section 116.77 exempts "household waste" from regulation under the Infectious Waste Control Act. The definition of "household waste" is necessary to distinguish between the infectious and pathological waste generated by members of a "household" within that setting and persons who, as part of their employment come into the "household" to assist members, provide service and generate infectious or pathological waste.

While the statute defines "household" as a "place" it is not

reasonable to presume that the place itself generates waste. It is the occupants within the place that produce the waste. The occupants within the household and their waste generated in self care is excluded. Those persons who as part of their employment, generate waste, are not excluded even if they are generating the waste within a house.

Persons who provide professional health services rendered by a licensed home health care or hospice provider are not household members, do not reside within the home, and are not self-administering. The waste generated by home care or hospice care providers within the household may be infectious waste, including sharps. Licensed home care providers are not excluded generators. Minnesota Statutes, section 116.79 as amended by Laws of Minnesota 1991, in subdivision 3, (b) (9) requires a fee from licensed home care agencies. Infectious waste and pathological waste generated by a licensed home health care provider who is paid to come into a household and provide care must be covered and managed according to the licensed home health care provider's generator management plan. Infectious waste generated by any other person who is compensated for service provided to a member of a household, if that person is not a member of the household, such as a person working for an insurance company who is taking blood samples for testing for insurability, is a generator and is not excluded by the Act.

The policy of the MDH to require generator management plans to cover the infectious waste management practices of regulated home care providers or persons who sample blood and work for an insurer is consistent with the employee and environmental risk noted in studies on infectious waste and medical waste. The studies point out that the exclusion of small providers or household generated waste remains as a potential source of waste handling problems. In "Finding the Rx for Managing Medical Wastes" published in September 1990 by the United States Congress, the Office of Technology Assessment addresses the issue of managing household and small generator waste.

> The amount of medical waste generated nationally from non-hospital settings is not known (although EPA will reportedly be including such estimates in its first report to Congress). These small generators include such sources of medical wastes as: home health-care patients, doctor's offices (including dental and veterinarian), and rural health-care settings. Although some States are including some small generators of medical wastes, such as doctor and dental offices, in their regulatory programs for medical wastes, most exclude households.
>
> The equity of including some and not all generators of medical wastes under regulation is hotly debated. (Clearly, regulations are usually adopted not because they are perceived as "fair," but rather because they are necessary to achieve some social or economic goal of the greater public. That regulations be "reasonable" may be difficult to define, but a legitimate standard by which to judge them. In most areas of environmental policy, regulatory attention is first focused on the largest generators of the problem. Later, refinements are made

to the regulations and their scope broadened to include other significant sources.) It is widely recognized that the same types of controls are not feasible for both large and small generators. The focus of the debate is over where to draw the regulatory line between generators to be included or excluded from regulation and over how large the gulf should be between the level of scrutiny and degree of requirements for large versus small sources of medical wastes.

In the area of medical waste policy, the demand for a comprehensive scope for controls is being grappled with from the beginning of regulatory efforts. EPA issued guidelines for home health-care disposal shortly after it promulgated its standards for MWTA. Other guidelines are being developed and discussed in response to the increased attention to wastes from these sources and their infectious potential.

Subp. 16. Infectious waste. According to Stephan K. Hall, Ph.D, REP, writing on "Infectious Waste Management - A Multi-faceted Problem" in Pollution Engineering, the terms "medical waste" and "infectious waste" are often used interchangeably in laws, rules and other waste documents.

The term "medical waste" has been variously used in literature to refer to waste that includes not only infectious waste, pathological waste, laboratory waste, regulated human body fluids, research animal waste and sharps as defined in Minnesota Statutes, section 116.76, but also already regulated radioactive isotopes and hazardous wastes such as cytotoxic agents used in chemotherapy. Medical waste has been at times described by the kind of waste, and at other times by the source or location of the waste (Rutala 1989 p. 1637, 1991, p. 578; EPA Medical Waste Tracking Act; U.S. Department of Health and Human Services, ATSDR Report p. 3.6; Burkett, p. 29).

The term "infectious waste" has frequently been used to refer to that portion of medical waste that has the potential to transmit disease (Minnesota Office of the Attorney General Report, August 1988 p. I-3). Currently most hospital waste generators designate between 10-15 percent of their waste as infectious waste.

In Minnesota Statutes, section 116.76, subdivision 12 the term "infectious waste" is defined to mean "laboratory waste, blood, regulated body fluids, sharps and research animal waste that have not been decontaminated." "Blood" is further defined in subdivision 3, "laboratory waste" in subdivision 13, "regulated human body fluids" in subdivision 16, "research animal waste" in subdivision 17 and "sharps" in subdivision 18.

The question of infectious waste generated in the course of personal self care has been raised. Commentors and advisory committee members raised questions about the inclusion of feminine sanitary products within the definition of infectious waste. Minnesota Department of Health epidemiologist Craig Hedberg indicates feminine sanitary products by their nature do contain blood and infectious agents. However, feminine sanitary products

are designed to absorb and retain the blood. The definition of "blood" includes only "solid waste saturated and dripping human blood or blood products". Using the statutory definition of "blood", feminine sanitary products would routinely be excluded from the definition of infectious waste. This interpretation is consistent with a clarification by federal OSHA director of compliance, Patricia Clark who in an April 17, 1992 letter on the application the blood borne pathogen rules stated that:

> OSHA does not generally consider discarded feminine hygiene products, used to absorb menstrual flow, to fall within the (OSHA) definition of regulated waste. The intended function of these products such as sanitary napkins is to absorb and contain blood; the absorbent material of which they are comprised would, under most circumstances, prevent the release of liquid or semi-liquid blood or the flaking off of dried blood.

Ms. Clark noted that OSHA expects waste containers to be lined with plastic or waxed bags and employers to provide employees with suitable gloves for handling contents.

It is reasonable that other personal hygiene practices such as the disposal of bandages discarded by a person in the course of self care are excluded.

Minnesota Statutes, section 116.76, subdivision 9 excludes from generator activities the production of "sharps as a result of administering medication to oneself." This activity, whether performed in a house or elsewhere, is excluded from regulation primarily to address the issue of insulin injection by diabetics.

In a question and answer document dated August 1989 the United States Environmental Protection Agency addressed the issue of the generation of sharp objects, in this case a razor used by a patient in a hospital for routine facial shaving by the patient, and whether a sanitary napkin discarded by a female patient waiting surgery should be handled as infectious waste. In both instances the USEPA indicated the discarded waste, while not expressly excluded because it was not generated in the home, should not be considered "medical waste" because it is not a "solid waste which is generated in the diagnosis, treatment, or immunization of human beings." The sharp object is part of routine personal care; the menstrual pad part of routine personal hygiene advised the EPA.

The regulation of all persons, all places of employment, and all public restrooms including restaurants, stores, factories and hotels or state rest stops, that provide for the disposal of personal waste would be excessive and not serve the public interest.

Finally it should be noted that the state's definition of "infectious waste" is not entirely consistent with some medical waste management practices, definitions or public perception. The MDH has not extended the definition beyond that statutorily authorized even though some medical and universal health care practices address and include as infectious waste all "isolation

waste" [all waste generated in the room of a patient specifically isolated because of an infectious condition which is often limited to patients isolated with a disease caused by a CDC Class 4 organism (State University of New York. Nelson Rockefeller Institute. "Perspectives on Medical Waste" p.III.23)]. Isolation waste is only regulated if it meets the state law's definition of infectious waste or pathological waste. Some practices and facilities provide special procedures for the management of dialysis machine fluids. The state definition of "infectious waste" while including "regulated body fluids" does not summarily include dialysis machine fluids, semen and vaginal secretions.

Subp. 17. Laboratory. Minnesota Statutes, section 116.76, subdivision 11 defines infectious waste as including "laboratory waste." The Act defines "laboratory waste" in section 116.76, subdivision 13 as:

> waste cultures and stocks of agents that are generated from a laboratory and are infectious to humans; discarded contaminated items used to inoculate, transfer, or otherwise manipulate cultures or stocks of agents that are infectious to humans; wastes from the production of biological agents that are infectious to humans; and discarded live or attenuated vaccines that are infectious to humans.

The term "laboratory" needs to be defined for a consistent interpretation of statute and rules. The definition proposed is reasonable in that it is the same as the USEPA definition of "laboratory" used in emergency rules adopted to implement the Medical Waste Tracking Act (page 12373).

Subp. 20. On-site. The MDH is authorized to regulate the on-site generation and handling of infectious waste, except for the operation of incinerators. A definition of the term "on-site" is necessary to ensure consistent application of the rule. It is reasonable that on-site mean those places including buildings and any mobile vehicles such as bloodmobiles where infectious waste is produced or decontaminated. It is reasonable that the place be owned by, leased to, or under contract to the party generating the waste. Defined in this manner, on-site includes a generator's satellite facilities.

Subp. 23. Point of generation. This definition is necessary to give a consistent meaning to the phrase as it is used in provisions specifying the segregation of waste. The point of generation is the starting point for infectious waste and pathological waste management. The definition proposed is consistent with the USEPA definition of "original generation point" published in emergency waste tracking rules (p.12373) which stated:

> "Original generation point" means the location where regulated medical waste is generated. Waste may be taken from original generation points to a central collection point prior to off-site transport or on-site treatment.

The proposed definition further adopts the clarification in the

USEPA's "Managing and Tracking Medical Wastes - A Guide to the Federal Program for Generators" which defines "Original Generation Point" as "Location where regulated medical waste first becomes waste (is 'generated')."

Subp. 26. Satellite facility. The MDH is authorized to regulate generators. This definition is necessary to determine responsibility for infectious waste or pathological waste generated at a site away from a generator's primary site. Satellite facilities are also on-site facilities where waste is generated.

Subp. 27. Sharps. The proposed rule definition of "sharps" refers to the definition in Minnesota Statutes, section 116.76, subdivision 18. Sharps are also addressed in Minnesota Statutes, section 116.78, subdivision 4. The MDH interprets the statutory definition to imply that sharp objects like glue injectors used in factory and industrial settings, or pipettes used to stir chemicals, are not "sharps" unless they contain or have the potential to contain infectious waste. Hypodermic needles and scalpel blades which meet the definition of a sharp under section 116.76, subdivision 18, clause (1) that are discarded by a generator must be managed as infectious waste until disposal. Even if the hypodermic needle does not currently contain infectious waste, it must be managed as a sharp until disposal. This policy is consistent with clause (1) which states "discarded items that can induce subdermal inoculation of infectious agents" and section 116.,78, subdivision 4, (2) which states that sharps may not be mixed with other waste material "whether or not the sharps are decontaminated unless it is part of an infectious waste decontamination process approved by the commissioner of health or the commissioner of the pollution control agency that will prevent exposure during transportation and disposal." Part 4622.0400, subpart 8 addresses the issue of discarded sharps that may be compacted or mixed with other waste.

Subp. 28. Spill. This term is necessary to define for consistent implementation of the proposed rules and statute. The MDH works with the MPCA to jointly implement the Act. It is reasonable for the agencies to be consistent in defining terms. The MPCA adopted rule part 7035.9110, subpart 22 defines "spill" as "the release of infectious waste to the environment." It is appropriate and reasonable to interpret environment as not only the area off the site of a generating facility or within an off-site waste disposal facility, but to apply to areas on-site of a generating facility as well. The environment is reasonably "a condition that surrounds one" (American Heritage Dictionary, Second College Edition).

Subp. 29. Storage. Minnesota Statutes, section 116.79 requires a generator to identify the procedures used for the on-site storage of infectious waste or pathological waste in the generator management plan. It is necessary to distinguish on-site storage which is addressed in MDH rules and the statute administered by MDH from off-site storage which is regulated by the MPCA. It is reasonable that "storage" include not only waste generated by the generator at a primary site, but also any generator-controlled secondary satellite facilities and any

infectious waste or pathological waste that may be stored by the generator on-site for another person. This makes it clear that the generator is responsible for all on-site waste management. Any waste stored on-site for an excluded generator as listed in part 4622.0100, subpart 3 is considered the responsibility of the regulated generator.

Subp. 30. Transportation. Minnesota Statutes, section 116.79, subdivision 1 states that "To the extent applicable to the facility" a generator must prepare a management plan which is submitted to the commissioner of health. MPCA regulates generators who transport waste in part 7035.9120, subpart 5 with respect to labeling, packaging and storage. MPCA rules address where and how a commercial transporter can deliver infectious waste for decontamination, storage or disposal in part 7035.9120, subpart 4. Minnesota Statutes, section 116.81 gives the MPCA "primary responsibility for rules relating to transportation of infectious waste and facilities storing, transporting, decontaminating...." and gives MDH "primary responsibility for rules relating to facilities generating infectious waste." The proposed definition of "transportation" is necessary to clarify applicability of the proposed rules. It is reasonable and consistent with statute that the MPCA regulate off-site storage, transporting and decontaminating practices. To the extent that the transportation of the waste is occurring on-site or within a mobile facility regulated by MDH it is MDH responsibility and regulated by the proposed rules.

Subp. 31. Universal biohazard symbol. Infectious waste must be labeled according to Minnesota Statutes, section 116.78, subdivision 2 which states:

> All bags, boxes, and other containers used to collect, transport or store infectious waste must be clearly labeled with a biohazard symbol or with the words "infectious waste" written in letters no less than one inch in height.

The universal biohazard symbol is one of two methods of labeling specified in Minnesota Statutes, section 116.78, subdivision 2. It is necessary to specify what this symbol is so a generator can comply with the statutory requirement.

Subp. 32. Waste. It is necessary to define this term so those persons who must implement and comply with the rule and statute know when an infectious material or contaminated material becomes waste. Only infectious waste and pathological waste are regulated. Infectious and pathological materials become a waste when they are discarded by the generator. Potentially infectious material does not become infectious waste if it is being retained for analysis. Infectious and pathological materials stored for future use or laboratory study are not waste until discarded. Reusable appliances contaminated with blood products are not infectious waste.

4622.0400 GENERAL MANAGEMENT STANDARDS

Subpart 1. Policies and procedures. This subpart specifies the general criteria which apply to the policies and procedures generators must develop and implement to assure compliance with Minnesota Statutes, sections 116.76 to 116.83. The plan should include discussion of designation of what constitutes infectious waste, segregation of waste, packaging and storage, transportation, treatment, disposal, contingency planning and staff training. It is reasonable that the generator's policies and procedures be consistent with adopted state standards governing the handling of infectious waste, and that they remain current. The development of infectious waste management policies and procedures is consistent with the practices recommended by the United States Environmental Protection Agency in "EPA Guide for Infectious Waste Management" (page viii) which recommends that a responsible person or committee at the facility prepare an infectious waste management plan outlining policies and procedures for the management of infectious waste.

Subp. 2. Employee training. Subpart 2 requires that training be provided for employees before they generate or handle infectious waste or pathological waste. The United States Department of Health and Human Services, Centers for Disease Control in "Guidelines For Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health Care and Public Safety Workers" page 6-11) recommend that all workers who handle infectious waste receive training that includes: (1) an explanation of the infectious waste management plan; and (2) an assignment of roles and responsibility for implementation of the plan.

The United States Environmental Protection Agency in "EPA Guide for Infectious Waste Management"(p. viii) recommends that a responsible person or committee at a facility prepare an infectious waste management plan outlining policies and procedures for the management of the infectious waste. The plan should include several elements - among them "staff training."

Minnesota Statutes, section 116.79, subdivision 1, paragraph (b)(5) requires a generator to identify the steps that will be taken to minimize the exposure of employees to infectious agents throughout the process of disposing of infectious and pathological waste.

In addition to ensuring employee safety, training must also include information on the proper separation of wastes. This ensures that infectious waste and pathological waste is handled properly and that other waste which might be hazardous waste, or routine solid waste, are handled in accordance with applicable state and federal policy. Source separation is also a key means to reduce the amount of waste that must be treated as infectious.

A generator must develop policies to provide refresher training as a means to correct and prevent violations. The Journal of the American Veterinary Medical Association in the monograph "AVMA guide for veterinary medical waste management" strongly endorses a routine review of procedures with employees (p. 449).

Subp. 3. Segregation at point of generation; mixing

wastes. Subpart 3 requires that infectious waste and pathological waste be segregated from other waste at the point of generation at the facility. This provision is consistent with Minnesota Statutes, section 116.78, subdivision 1 which states:

> All untreated infectious waste must be segregated from other waste material at its point of generation and maintained in separate packaging throughout collection, storage, and transport. Infectious waste must be packaged, contained, and transported in a manner that prevents release of the waste material.

The department received comment from advisory committee member Pfeiffer as to whether a container is a plastic bag and whether noninfectious and infectious waste in separate bags may be transported within the facility on the same cart. The department interprets a plastic bag to be a container and that waste once in the plastic bag has been segregated. Further separation by a separate cart is not necessary since the bag is designed to provide a barrier.

Solid waste mixed with infectious waste must be treated as infectious waste. Since infectious waste requires special handling, any solid waste contaminated with infectious waste must also receive special handling.

Subp. 4. No recycling. While recycling is a general societal goal, infectious waste or pathological waste must not be recycled until decontaminated. Recycling contaminated waste obviously poses a public health risk by recirculating pathogens. Hand sorting recyclable material may be practiced. Once waste is decontaminated, it is reasonable that material may be recycled provided it is done in a manner that protects employees from injury.

Subp. 5. Labeling waste. Subpart 5 requires the on-site labeling of infectious waste and pathological waste. The labeling standards specified are in accord with the requirements in Minnesota Statutes, section 116.78, subdivision 2 which states:

> All bags, boxes, and other containers used to collect, transport or store infectious waste must be clearly labeled with a biohazard symbol or with the words "infectious waste" written in letters no less than one inch in height.

The labeling of infectious waste simplifies waste identification without compromising the packaging. Minnesota Statutes, section 116.78 requires all bags, boxes and containers to be labeled with the words "Infectious Waste" or with the universal biohazard symbol. A problem identified during on-site inspections of generators by the MDH is a lack of labeling on internal bags and external containers. Some facilities have used red unlabeled bags that staff are trained to identify as infectious waste. According to section 116.78 of state law, bag color alone is not adequate; labeling is required. The State of Florida requires that the label or words "Infectious Waste" contrast with the color of the

background material. This requirement is reasonable to ensure the ready identification of the waste. Bags need to be properly labeled if they are removed from properly labeled storage containers. Containers must be labeled so anyone seeing them knows they contains infectious waste.

Subp. 6. Packaging waste. Subpart 6 addresses packaging requirements for the on-site handling of infectious and pathological waste. The requirements of this subpart are consistent with Minnesota Statutes, sections 116.78 and 116.79. Proper packaging is necessary to protect employees from infectious agents present in or on infectious waste and pathological waste. As long as the packaging remains intact, a protective barrier is provided. Proper packaging reduces the chance of injury and infection and deters vermin that can be disease vectors. Since infectious waste may contain sharp objects or be in a liquid or solid state, packaging requirements vary.

Subpart 6 requires infectious waste and pathological waste, with the exception of liquids and sharps, to be contained in plastic bags that are impervious to moisture and strong enough to preclude ripping, tearing, or bursting during use, storage, transportation and decontamination. The proper packaging of infectious waste is recommended by a number of federal agencies including the United States Department of Health and Human Services Agency for Toxic Substances and Disease Registry in their report "The Public Health Implications of Medical Waste: A Report to Congress" (p. 4.2). Adopted rules of the MPCA have established a standard for packaging infectious waste. This standard was established by the MPCA for infectious waste that leaves the generating site for decontamination or disposal.

Infectious waste in a fluid state must be contained to prevent leakage or release to the environment. It is reasonable to require containers with more than 20 cubic centimeters of fluid to be packaged as fluid infectious waste since this amount of fluid could be released during waste handling, contaminate other waste, or pose a hazard to employees. The application of provisions pertaining to fluids at 20 cubic centimeters is supported by comment from the USEPA in emergency rules governing medical waste tracking which required:

> Syringes and other containers such as vials and blood bags that contain fluids in quantities of greater than 20 cubic centimeters (cc) may be emptied prior to packaging. EPA has established a fluid residual level of up to 20 cc's that may remain in syringes, tubing, vessels, and containers and still allow the waste to be packaged under the requirements of section 259.51 (a) and (b) (1). This 20 cc level has been established based on the State of New Jersey's regulations, as a conservative estimate of the residual volume of fluid that will remain in a container after it has been emptied. The Agency is concerned that attempts to remove all remaining fluids may expose health care workers to additional risk, and such small volumes of fluid should not present any significant potential for contaminating other wastes or

waste handlers (page 12346).

Advisory committee members discussed the issue of prescribing a specific container for fluids. Members urged that discretion be allowed (MDH August 12, 1991 Minutes). The rule allows the generator to determine the nature of the container provided that the result is no spillage or routine breaking.

Subp. 7. Sharps. Segregation and containment of sharps is necessary to protect the public from injury as well as exposure to infectious agents.

Item A. Glass and rigid plastic vials that contain infectious waste must be managed as infectious waste. If they have never contained infectious waste or no longer contain infectious waste, glass and rigid plastic vials may be managed within the solid waste stream. This policy is consistent with the definition of a sharp in Minnesota Statutes, section 116.76, subdivision 17, clause (2) which states that discarded glass or rigid plastic vials are sharps "containing infectious agents."

Item B. Discarded sharps must be placed directly into leak-resistant, puncture-resistant containers. This requirement is consistent with Minnesota Statutes, section 116.78, subdivision 4, (1) which states "Sharps, except those generated from a household or from a farm operation or agricultural business: (1) must be placed in puncture-resistent containers;..." The United States Environmental Protection Agency did not define "puncture resistent" for purposes of medical waste tracking or infectious waste management. The United States Occupational Safety and Health Administration and the American Society for Testing Materials will be addressing this issue. Until a national authority establishes a specification for puncture resistance for sharps containers, the MDH will interpret "puncture resistent" for purposes of sharps containment to mean the container resists puncture by the materials within it.

Item C. Maintenance of the container to prevent spillage and tampering is necessary to prevent sharps containers from being placed in a manner so they are not easily tipped or tampered with by the public. Routine practice is to fix the container to a wall or counter and maintain containers in places with controlled access.

Subp. 8. On-site compaction of infectious waste; on-site compaction or mixing of sharps with other waste. Minnesota Statutes, section 116.78, subdivision 7 was amended in Laws of Minnesota 1991 to allow for the compaction of infectious waste.

> Compaction is acceptable if it is part of an infectious waste system, approved by the commissioner of health or the commissioner of the pollution control agency, that is designed to prevent exposure during storage, transportation, and disposal.

Minnesota Statutes, section 116.78, subdivision 4, (2) was also amended to state that sharps, except those generated from a

household or from a farm operation or agricultural business:

(2) may not be compacted or mixed with other waste material whether or not the sharps are decontaminated unless it is part of an infectious waste decontamination process approved by the commissioner of health or the commissioner of the pollution control agency that will prevent exposure during transportation and disposal;

The MDH will review on-site compaction and mixing processes. This will be done in consultation with the MPCA if the decontamination, or disposal process occurs off-site. (MDH memorandum of understanding). The MPCA is responsible for approving off-site storage, transportation, decontamination and disposal processes.

A compaction or mixing system may be part of an on-site process to decontaminate the waste or be disposed of on-site. Or the compacted material may be temporarily stored on-site and then transported to an off-site decontamination or disposal facility. The generator must be provided with discretion to determine what procedure works best in a particular setting. Some generators may only have a very small amount of waste and not want to have to deal with on-site decontamination. The important component is that whatever procedure is used, that it be an integral part of some approved decontamination or disposal process - whether on-site or off-site. The mechanism for mixing or compacting must be compatible with the decontamination process capabilities or approved disposal methods. (The department is aware that mobile facilities may be designed to handle infectious waste. The mobile facility would decontaminate waste. Compaction, mixing, or grinding waste may also occur within the mobile facility. The facility may be owned and operated by a party other than a generator. In this case the MPCA would review and evaluate the facility. The facility may also be owned by a generator who serves their own facility or facilities or other generator facilities. When it is owned and operated by a generator, the department would review and approve the mobile facility process.)

To evaluate a request for on-site compaction or mixing the generator must specify the reason for the request; describe the process proposed for use; and, if decontamination takes place on-site, present evidence to the commissioner that the method decontaminates the infectious waste, including sharps (item B). It is reasonable that the generator address the request in writing, so there is a record of the request. The commissioner needs to know why the request is needed; how the compaction or mixing process to be employed is part of an overall infectious waste management system; and how employees, the public and the environment are protected from exposure during mixing, compaction, storage, transportation, decontamination and disposal. The MDH interprets "exposure" to mean exposure not only to infectious agents, but also to subdermal injury from sharps.

Robert Emery et. al, writing in the May 1992 issue of the Journal of the American Industrial Hygiene Association, evaluated the release of bacterial aerosols during infectious waste compaction. They found that: 1) compaction greatly reduced the volume of waste at the site of generation; and when partially compacted may even

enhance incineration performance. However, the process may lead to the release of infectious aerosols which could pose a significant hazard to employees. The authors conducted a controlled compaction test using Bacillus subtilis spores adapting the nationally accepted standard for the testing of Class II (Laminar Flow) Biohazardous Cabinetry (Standard 49) of the National Sanitation Foundation. They found that viable bacteria were released during the compaction of infectious waste in their prototype compactor.

The compaction of infectious waste is such a new concept that no specific leakage criteria presently exist for compaction devices. The NSF standard for biosafety cabinetry could be a useful reference. Emery et al. made further suggestion for design and operation of such a system, including:

* securing compactor doors to prevent inadvertent contact.
* written worker instructions for operation, malfunction and disinfection.
* activation of an exhaust fan anytime the access door is opened.
* an exhaust period at the end of each compaction stroke.
* an interlock that precludes operation if the HEPA filter is not in place or the filtration system is disconnected.
* closure of the waste container inside the compactor to make use of capture velocity and negative pressure.
* air supply from both sides of the front of the chamber, into the chamber.
* a system of filter changing that reduces exposure to maintenance personnel.
* a spray system for periodic disinfection.
* a limit on collection container size.
* initial and periodic system certification and HEPA filter breakthrough monitoring.
* NSF certification of the compaction units.

The Rockefeller Institute in "Perspectives on Medical Waste" (pages IV.22 -IV 23) notes that:

> Compaction can reduce the volume of the infectious waste by four or five times. It has been discouraged or even prohibited by federal, state and local regulations because of its aerosolization and leakage potential....
>
> The major advantage of this technology is the volume reduction and improved public perception of the waste. The safety of dealing with infectious waste is also improved in the handling of the containers at a landfill or a municipal incinerator.
>
> The major disadvantage of this system is that during compaction there can be leakage of liquids from the unit. Another disadvantage of this system is that the smaller compacted cubes are difficult to burn at a regional infectious waste incinerator or at a municipal incinerator. There may not be time for the burnout of the compacted material to be completed without special precautions in compacting or in the design of the incinerator....
>
> As the compaction process does not sterilize the

material then it is necessary to sterilize the material prior to compaction or to sterilize or incinerate it after compaction. Sending unsterilized waste off-site for processing is not a good practice and has large potential liability problems.

The Council of State Governments in "Model Guidelines for State Medical Waste Management" (p. 11) recommends that "untreated medical wastes should only be compacted if the compaction takes place in a closed chamber which eliminates the possibility of exposure to infectious agents through aerosols."

The Rockefeller Institute evaluated a sterilization and compaction process which combined sterilization followed by compaction and concluded (pages IV.23 -IV.25) that:

> The major advantage of this system over either the sterilizer or the compactor is that the waste is disinfected in the sterilization compartment of the unit and goes into the compactor unit for volume reduction and/or further processing or disposal. A major disadvantage of this system is that it is very difficult to conduct microbiological testing on this system. Spore strips, such as those used in sterilization, are impossible to check as the waste goes from the sterilization cycle into the compactor.

Subp. 9. Waste from other regulated generators. Subpart 10 prohibits a generator from accepting infectious waste or pathological waste for storage, decontamination or incineration from another regulated generator unless the other generator has a card from the commissioner acknowledging receipt of a generator management plan. Generators of infectious and pathological waste are required by Minnesota Statutes, section 116.79, to develop and submit a generator management plan and fee to the MDH. An acknowledgement card from the MDH assures a generator, prior to the acceptance of infectious waste from another generator, that the other generator has developed a generator management plan.

Subp. 10. Record retention and access. This subpart requires a generator to maintain records for three years and make the records available in the event of an inspection by the Commissioner. Minnesota Statutes, section 116.83, subdivision 3 authorizes the Commissioner to review records and conduct investigations. Three years is a reasonable period to maintain records since Minnesota Statutes, section 116.79, subdivision 1 (e) requires the updating and resubmittal of a management plan at least once every two years. Three years was the retention period recommended by the U.S. Environmental Protection Agency in sections 259.54 and 259.61 of emergency rules implementing the medical waste tracking act (page 12351). Provision of record retention for three years and for retention beyond the three year period if there is unresolved enforcement action is consistent with part 7035.9120, subpart 8 of MPCA rules. Retention in the event of enforcement action is reasonable to ensure that necessary data are available for reference.

Subpart 11. Spill containment, cleanup kit. Subpart 11 addresses the containment of spills and leaks of infectious waste or pathological waste that take place at a generating facility. It is reasonable to require specific procedures for handling spills and leaks because of the potential for injury and infection to facility employees and the general public. Minnesota Statutes, section 116.79, subdivision 1(a)(5), requires that a generator's management plan identify the steps to be taken to minimize the exposure of employees to infectious agents during the disposal process for infectious waste and pathological waste.

If a spill occurs on-site, it is reasonable that a cleanup kit be readily available on-site to reduce the potential impact of the incident on employees, the general public and the environment. Christine Hendrickson of the Ebenezer Caroline Center commented to the department about the reasonableness of requiring a spill kit. The rule refers to a kit which is a collection of materials. The department prefers to retain the concept of a collection of materials. Ms. Hendrickson may erroneously presume that the kit must be purchased or developed by a party other than the generator. The department's intent is that the materials listed be collected by the generator and be readily available on-site.

The Council of State Governments in their 1992 Model Guidelines (p.13) recommend that:

> all medical waste management facilities should keep a spill containment kit within the vicinity of any area where medical wastes are managed, and the location of the kit shall provide for rapid and efficient cleanup of spills anywhere within the area.

Item A which specifies the requirements for a clean-up kit and item B which delineates response procedures are based on provisions in adopted rules, part 7035.9120, subpart 6, items A and B of the MPCA which some exceptions which will be explained. It is reasonable to require a generating facility to have a spill cleanup kit and develop spill response procedures so spills can be responded to in a timely manner to minimize exposure to infectious agents. In the monograph "Occupational Hazards and Incineration of Biomedical Wastes" by O.P. Malik, Ph.D. et.al. in conjunction with the Ontario Ministry of Labor recommend that hospitals have spill clean up procedures to prevent the spread of disease through biomedical waste.

> In addition, workers should be trained in these procedures and the potential hazards of handling such materials. These procedures should include containing and disinfecting the spill while using appropriate personal protective equipment (gloves, splash goggles, respirators, etc.) The spilled material should be removed and discarded in accordance with proper waste handling procedures, and the area of the spill disinfected. Tools, hands, and respirators should also be cleaned and disinfected [p.(ii)].

Absorbent material is necessary to maximize the recovery of liquid

waste. It is necessary to absorb as much spilled infectious liquid as possible to limit or minimize the impact to public health. Requiring a detergent is necessary because an initial cleansing with a detergent reduces visible solid and liquid waste that could provide a barrier to subsequent disinfection of the surface or material. The need for industrial grade detergent to initially remove soil was questioned in comment to the department. The department consulted with Oliver Ossana, director of Corporate Technical Services with Economics Laboratories about the need for industrial strength detergent. Dr. Ossana indicated that industrial strength was not necessary to specify.

Specification of a hospital grade disinfectant is reasonable to require since these chemicals are effective in reducing the number of viable microorganisms on surfaces once waste has been removed with a detergent. Because surfaces within the facility may become contaminated during a spill, it is reasonable to require that a spill containment kit include disinfectant. While MPCA rules require at least one gallon, members of the MDH rule's advisory work group did not think a specific quantity was necessary to prescribe for spills on-site (MDH Minutes of August 12, 1991). Many laboratories and facilities generate very small quantities of waste. Flexibility to have a smaller amount of detergent and disinfectant available at all times to clean up a spill is reasonable. A question was raised as to whether the disinfectant used must be registered with the USEPA as a tuberculocidal. Use of a tuberculocidal is currently recommended by the Centers for Disease Control. It was recommended by Dr. Ossana and is consistent with the "Model Guidelines for State Medical Waste Management" prepared by the Council for State Governments (1992) which recommend that:

> for infection control purposes, disinfectants are chemical germicides that are approved for use as hospital disinfectants and are tuberculocidal when used at recommended dilutions.

When an infectious waste spill occurs, the integrity of some packaging may not be maintained so spilled waste may require new packaging and labeling. It is reasonable to require that the spill containment kit include packaging and labeling material to accommodate the quantity of waste present and ensure prompt repackaging.

Provision of utensils for cleaning up an on-site spill is specified, though the MDH does not prescribe scoop shovels, push brooms and buckets as do MPCA regulations. The MDH rule advisory work group members recommended a broader description of cleanup devices (MDH August 12, 1991 minutes) to allow for the use of dust pans and brushes in small generator settings. Clean up utensils may be reused after they have been disinfected. They are necessary to pick up spilled material safely. However, given the small quantities of material some persons generate, it did not seem reasonable to prescribe a shovel when a whisk broom and dust pan would suffice.

The availability of personal protective equipment for those who may

have to clean up a spill is necessary to prevent injury and exposure. Latex and neoprene gloves, goggles and surgical facemasks are reasonable items to prescribe to ensure that those cleaning up a spill can protect themselves from skin exposure to potentially harmful objects and fluids. The Centers for Disease Control of the United States Department of Health and Human Services have issued guidelines for protection against exposure to bloodborne diseases. The guidelines recommend:

> 1. Use of gloves whenever blood, blood products, or body fluids will be handled. The use of gloves is essential if the worker has cuts, abraded skin, chapped hands, dermatitis, or the like;
> 2. Gloves must be of appropriate material, usually intact latex or intact vinyl, of appropriate quality for the procedures performed and of appropriate size for each worker....
> 4. General purpose utility (rubber) gloves worn by maintenance, housekeeping, laundry or other non-medical personnel may be decontaminated and reused.
> 5. No gloves shall be used if they are peeling, cracked or discolored, or if they have punctures, tears, or other evidence of deterioration....
> 7. Protective eyewear or face shields are required when contamination of mucosal membranes (eyes, mouth, or nose) with body fluids (such as splashes or aerosolization) is likely to occur, such as in surgery or dental procedures. They are <u>not</u> required for routine care.

The proposed requirements are consistent with recommendations of the Centers for Disease Control and United States Department of Labor OSHA regulations in Code of Federal Regulations, section 1910.1030 (d) (3) Bloodborne Pathogens - Personal protective equipment, issued December 6, 1991. Bruce Stainbrook and Robert Runkle writing on personal protective equipment in <u>Laboratory Safety: Principles and Practices</u> for the American Society for Microbiology, Washington D. C. 1986 (p.p. 166-170) also recommend the use of protective equipment.

Limiting access to the spill area by unauthorized personnel is necessary to prevent individuals from unnecessary exposure. Unauthorized personnel usually are not trained in methods to properly handle waste nor knowledgeable of the precautions to be taken when handling waste.

Repackaging broken containers and spillage is reasonable to provide a barrier between the waste and handlers or others who may come in contact with waste.

Application of absorbent material to surface areas contaminated with waste is reasonable because not all surfaces are nonporous, liquid waste may penetrate or be absorbed by equipment or other items, and disinfection may be difficult. Absorbent material draws infectious waste out of porous surfaces, reduces the number of microorganisms present on or within a contaminated item, and allows subsequent disinfection of the surface to be more effective because the microbial load and amount of organic material present is

reduced.

Cleaning with a detergent and the disinfection of reusable items is necessary and reasonable to lower the risk of infection for workers or others in contact with it.

Subp. 12. Spill cleanup procedures. Subpart 12 requires disinfectant procedures for surfaces contaminated by spills or leaks of infectious or pathological waste at a generating facility. The procedure includes the initial application of a detergent to remove visible soil. It is reasonable to require the removal of visible soil with a detergent from the contaminated surface prior to the use of the disinfectant. Visible soil and waste spillage may provide a protective barrier to the microorganisms present and could therefore lessen the efficacy of the disinfectant. The USEPA registers intermediate level disinfectants with a label claim for tuberculocidal activity. The intermediate disinfectants destroy mycobacterium tuberculosis, vegetative bacteria, most viruses and most fungi, but do not kill bacterial spores. The manufacturer's specified application time must be followed to give the disinfectant enough time to destroy the microorganisms present on the surface.

The procedures and solutions specified in this subpart are consistent with those required in the OSHA standard Bloodborne Pathogens - Housekeeping, adopted December 6, 1991 at 29 CFR, section 1910.1030 (d) (4) and with the recommendations of Rutala in "Disinfection, Sterilization and Waste Disposal".

Subp. 13. Cleaning of decontamination devices. Devices such as autoclaves used to steam sterilize infectious waste may be used for other sterilization procedures. Work and loading areas may become contaminated during treatment of the waste. It is necessary that devices used for decontamination and adjacent work and loading areas be maintained in a clean condition to prevent the spread of infectious agents.

4622.0600 ON-SITE STORAGE.

Subpart 1. General. This subpart specifies on-site storage requirements for generators of infectious and pathological waste. The storage requirements are designed to prevent unauthorized access to storage areas as well as maintain proper sanitary conditions. The requirements are consistent with Minnesota Statutes, section 116.78, subdivision 6 which states:

> Infectious and pathological waste must be stored in a specially designated area that is designed to prevent the entry of vermin and prevents access by unauthorized persons.

Storage of small quantities of infectious or pathological waste in a service area or laboratory station for a short period of time is permitted as long as the waste is stored according to the requirements in subpart 3 of this part in a separate compartment or container and properly labeled.

Subp. 2. Area. Subpart 2 requires all areas used for the storage of infectious or pathological waste other than the point of generation to be constructed of smooth, easily cleanable materials capable of being maintained in a sanitary condition. It is reasonable to require the area to be constructed of easily cleanable materials in the event there is a leak or spill to assure that the area can be maintained in a sanitary manner. The area should not provide a breeding place or food source for vermin. Vermin can be vectors for human disease.

The central storage area must be conspicuously marked with a biohazard symbol or with the words "Infectious Waste" on or attached to the exterior of any entry door or access gate to notify employees and the general public that the area contains infectious waste. These requirements are reasonable to protect employees and the general public from unnecessary exposure to infectious agents.

Subp. 3. Storage of plastic bags. This subpart requires plastic bags to be placed in a rigid container during storage. Although a plastic bag usually can withstand the stress of handling and collection within the facility, it is reasonable to require that during stationary storage an additional rigid container be used to maintain the integrity of the plastic packaging. To increase the options available to the generator, the rule provides for reusable containers, such as bins and drums, provided a liner is used or the container is decontaminated prior to reuse. It is reasonable to require that the containers be closed or covered to maintain the integrity of the packaging and avoid leakage or spills. All external containers must be labeled with the words "Infectious Waste" or the international biohazard symbol.

4622.0700 ON-SITE DECONTAMINATION, INCINERATION, DISPOSAL.

Subpart 1. General. This subpart applies the provisions in part 4622.0700 to any generator who decontaminates, incinerates or disposes of infectious or pathological waste on-site. Mobile decontamination units used by the generator on-site must be addressed in the generator's waste management plan. It is reasonable that safety and health provisions applicable to stationary devices also apply to those which move. Mobile devices may require additional precautions of calibration to ensure effective and consistent operation.

Subp. 2. Procedures. It is necessary to require development of and compliance with written procedures so a record is available to review and there is an increased likelihood of consistent application of approved practices and methods. A procedure must be developed for each decontamination, incineration and disposal method used on-site. The generator is responsible to ensure that procedures, once established, are followed so decontamination, incineration and disposal effectively takes place.

If a generator decontaminates infectious or pathological waste on-site it is reasonable to expect that the person overseeing the process understand the factors affecting the effectiveness of the decontamination method used and establish a program to ensure that the decontamination objectives are met. EPA recommends:

(1) using standard operating procedures for each process employed for treating regulated infectious waste;

(2) monitoring all treatment processes to ensure efficient and effective treatment;

(3) using indicators to monitor treatment; and

(4) selecting treatment methods appropriate for the waste type being treated (USEPA Emergency Waste Tracking rules, p. 12343).

The development of procedures gives each generator the flexibility to gear the method of decontamination, incineration and disposal to the type of infectious waste and pathological waste present.

Subp. 3. Loading. A number of variables must be considered to properly decontaminate infectious or pathological waste. Load size is one of them. How quickly and completely waste is decontaminated depends on the amount and density of the waste as well as the method of decontamination or incineration. It is reasonable that infectious waste and pathological waste be properly decontaminated or incinerated and that the device be used in accordance with its design capacity. According to Chen, during the operation process of equipment, load standardization is essential to ensure effective treatment (p. 6).

Subp. 4. Maintenance. A record of calibration and maintenance is necessary to show that the device and equipment used has been maintained in accordance with the manufacturer's instructions.

Subp. 5. Load decontamination verification. In comment to the department in response to the Notice of Solicitation, Deborah J. Osgood, Government Affairs Coordinator for Waste Management of Minnesota indicated that regardless of the treatment system used, a performance standard should be indicated. She further recommended that the performance indicated be - the destruction of all pathogenic organisms to the point where the waste is biologically benign (p. 4). Ms. Osgood stated that a treatment method that "simply reduces the number of organisms" is not acceptable since the potential for disease transmission to health care and waste management workers is still present. She indicates that proposed regulation should include appropriate testing procedures and protocols for the treatment technology. "Establishment of standards will go a long way towards providing assurance to generators, waste handlers, and final disposal facilities that the waste has been properly treated and is safe to handle and manage," she states.

Monitoring to verify the effectiveness of the treatment process used is employed by other states that regulate the management of infectious and pathological waste. The regulatory method used is one that calls for chemical or biological indicators if continuous monitoring of time, temperature and pressure is not available. In addition, there is regular verification (Subpart 7) that whatever procedure and device is used, it is capable of the complete destruction of infectious agents.

The standards proposed are consistent with those used by other states. Wisconsin requires the treatment of infectious waste by steam sterilization at a temperature of not less than 250 F for 90 minutes at 15 pounds per square inch of gauge pressure or not less than 272 F for 45 minutes at 27 pounds per square inch of gauge pressure. Other combinations of operational temperatures, pressure and time may be used "if the installed equipment has been proved to achieve a reliable and complete kill of all microorganisms in the waste at design capacity." Wisconsin recommends documentation of all testing, including tests of the capacity to kill Bacillus stearothermophilus.

The State of Florida [Regulation 10D-104.007 (4) (c)] allows procedure treatment methods that employ chemical or gas sterilization or microwaving. Equivalent tests include bacteria, virus, protozoa and fungi and stipulate that "the spore-forming bacteria Bacillus species shall be included as part of the testing regimen."

In West Virginia generators must check recording or indicating thermometers after and during each complete cycle to ensure the attainment of a temperature of 250 degrees Fahrenheit for approximately one hour (depending on quantity and dispersal of load) in order to achieve sterilization of the entire load. West Virginia provides a number of options to verify decontamination and the performance of the decontamination method including the use of heat sensitive tape or other device for each container that is processed to indicate "the attainment of adequate sterilization conditions." The tape or other device must accompany the container to the landfill or other final disposal site.

The following is required by the state of Ohio.

> All autoclaves shall operate at a minimum temperature of one hundred twenty-one degrees centigrade or two hundred fifty degrees Fahrenheit at a minimum of fifteen pounds per square inch pressure;
>
> All autoclaves shall operate at the specified temperature and pressure of one-half hour or longer, depending on quantity and density of the load, sufficient to render the waste non-infectious;
>
> All autoclaves shall be operated with a maximum registering thermometer, except for fast exhaust loads; and
>
> Other combinations of operational temperature, pressure, and time may be approved by the director if installed equipment has been proven to achieve a reliable and complete kill of all infectious agents in the waste at design capacity. Complete and thorough testing shall be fully documented, including tests of the capacity to kill spores of B. Stearothermophilus.

In Mississippi generators are required to:

* Check recording and/or indicating thermometers during each complete cycle to ensure the attainment of a temperature of 121 C (250F) for one-half hour or longer, depending on quantity and density of the load, in order

to achieve sterilization of the entire load.
* Thermometers shall be checked for calibration at least annually.
* Use of heat sensitive tape or other device for each container that is processed to indicate the attainment of adequate sterilization conditions.

In Florida "biohazardous waste must be subjected to sufficient temperature, pressure and time to kill Bacillus stearothermophilus spores in the center of the waste load being decontaminated."

In Connecticut a steam sterilizer used to decontaminate biomedical waste must be operated in accordance with the following requirements:

A. In a gravity flow sterilizer, biomedical waste shall be subjected to a temperature of not less than 250 degrees F (121C) at 15 pounds per square inch of gauge pressure for no less than 60 minutes.

B. In a vacuum type sterilizer, biomedical waste shall be subjected to a temperature of not less than 270 degrees F (132 Degrees C) at 27 pounds per square inch gauge pressure for no less than 45 minutes.

C. Notwithstanding subparagraphs A and B of this subdivision, a different combination of operational time, temperature and pressure may be utilized for steam sterilization of biomedical waste if such combination is first described in writing to the commissioner and approved in writing by the commissioner. The commissioner will not grant approval unless such combination is proven on the basis of thorough tests, including tests of its capacity to kill bacillus stearothermophilus, to completely and reliably kill all microorganisms in waste at design capacity.

In California, standard written operating procedures must be established for biological indicators, or for other indicators of adequate sterilization approved by the California Department of Health, for each steam sterilizer, including time, temperature, pressure, type of waste, type of container, closure on container, pattern of loading, water content, and maximum load quantity. California requires recording or indicating thermometers to be checked during each complete cycle to ensure the attainment of 121 degrees Centigrade (250 degrees Fahrenheit) for at least one-half hour, depending on the quantity and density of the load, in order to achieve sterilization of the entire load. Heat sensitive tape, or another method acceptable to the Health Department must be used on each container processed to indicate the attainment of adequate sterilization conditions. Similar procedures using a monitoring and validation device are required by the State of New York and by Canada.

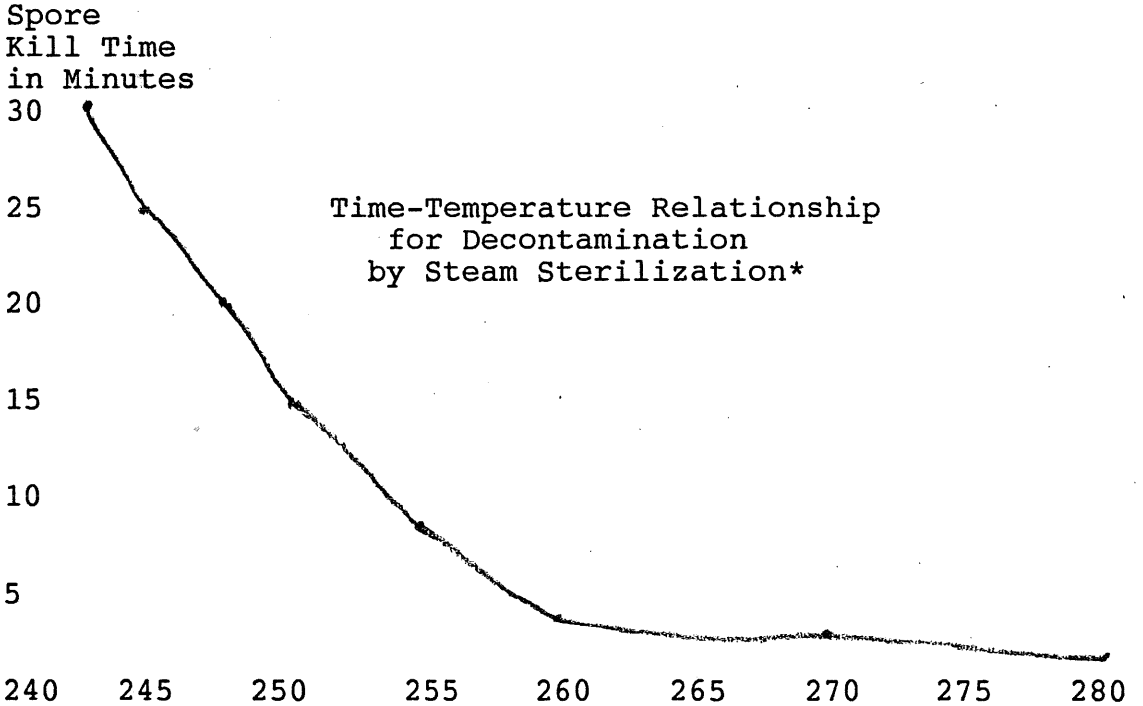
Item A. Discussion of the issue of decontamination with advisory work group members and the prescription of a single specific temperature and pressure proved difficult. The recommendation of work group members Gruninger of the Hennepin County Medical Center representing the Minnesota Medical Association and Lauer of the University of Minnesota was that a

validation system be used instead of specifying a single temperature, pressure and time. The amount of temperature, time and pressure depends on the device or equipment used, the amount and type of waste to be decontaminated, and the specific method employed. Lauer suggested use of a chemical indicator to verify that the generator's prescribed time and temperature had been reached. He recommended that the rule put the responsibility on the generator to verify that temperature, time and pressure were reached inside the waste container depending on load size and autoclave operating standards (MDH Minutes September 24, 1990 p.7).

The State University of New York Rockefeller Institute in Perspectives on Medical Waste evaluated various decontamination methods. The Institute notes (p. IV.17) that killing spore forming bacteria is achieved at temperatures up to 121 degrees C in steam for 15 minutes. If dry heat is used it requires temperatures at 160 to 170 degrees C for two hours.

Items B and C. Biological indicators provide a method of verifying the effectiveness of treatment procedures. They consist of ampules or strips enclosed in glassine envelopes that contain a known quantity of Bacillus stearothermophilus and/or B. subtilis spores. Because these bacterial spores are more resistent than viruses or vegetative bacteria, destruction of these spores infers that decontamination has occurred.

The use of decontamination performance indicators is recommended by other parties involved in the management of infectious waste. Nelson S. Slavik, PhD., notes that decontamination by steam sterilization is a time and temperature dependent process illustrated by the curve in the following figure.



* July/August 1985 Journal HSPD (p. 33)

The curve is based on the minimum times necessary to kill Bacillus stearothermophillus spores exposed to saturated steam (wet heat) as a function of temperature.

According to Slavik, infectious waste materials most suited for decontamination by a steam sterilization process are those with a relatively low density and low-to-moderate water content. Conversely, materials such as body tissue, parts, and fluids exhibit a relatively high density and water content which inhibit the amount of heat directly transferred by steam contact. Slavik indicates that monitoring is required to ensure the effectiveness of the process. Because of the multiple variables, relying on common treatment times may not be long enough. The use of graded biological indicators can be a reliable indicator of effectiveness when certain criteria are adhered to. The biological indicator must be challenged within the interior of the worst-case load and done on a routine basis. Taping the indicator to the outside of a bag or laying it on top of the waste load will not adequately demonstrate decontamination of the waste (p. 33).

Richard Hastreiter et al, writing in the October 1991 Journal of the American Dental Association notes that to evaluate instrument sterilization procedures in Minnesota dental offices, biological indicators were used to monitor 406 sterilizers at 381 sites. His findings suggest a general improvement in instrument performance over that of a decade ago, but that there still are sterilization failures. Biological indicators are useful in monitoring sterilization performance when sterilization procedures are performed consistently and competently by well-trained staff using adequately maintained equipment (p.51). The CDC recommends that biological indicators be used weekly in most dental practices to verify the sterilization performance of each sterilizer (p.52)

Item D. There may be other treatment procedures or methods that a generator may want to use. Though autoclaving is the most common, consideration will be given to the use of other methods and devices provided there is comparable verification that the method will kill the infectious agents present.

Subp. 6. Decontamination records. A generator who decontaminates infectious waste or pathological waste on-site must keep a record of each load decontaminated. It is reasonable to require a generator to maintain a record of waste decontaminated to assure that the waste is treated and monitored properly. The record provides written data if there is a question about the proper decontamination of the waste. The record documents the amount of infectious waste and pathological waste decontaminated on-site. The amount decontaminated on-site is required to be included in the generator's management plan pursuant to Minnesota Statutes, section 116.79, subdivision 1(d).

Subp. 7. Decontaminator process verification. Decontamination process monitoring is consistent with standards and guidelines adopted by other states and Canada. North Carolina mandates "monitoring under conditions of full loading for effectiveness of treatment...no less than once per week through the use of biological indicators or other methods approved by the Division"

(p. 5). Canada recommends "regular monitoring of the effectiveness of the treatment process." Alabama requires that "each sterilizer shall be evaluated for effectiveness under full loading by an approved method at least once for each 40 hours of combined operation. Biological indicators such as spores of 'Bacillus stearothermophilus' may be utilized with Departmental approval." In Connecticut the requirement is that "at least once during every forty hours of operation, a sterilization unit shall be evaluated to determine whether it is operating properly with respect to temperature and pressure." Mississippi requires "use of the biological indicator Bacillus stearothermophilus placed at the center of a load processed under standard operating conditions at least monthly to confirm the attainment of adequate sterilization conditions." Missouri requires weekly testing with a biological indicator. And West Virginia requires weekly confirmation using a bacteriological spore test culture to "confirm the attainment of adequate treatment conditions."

The Rockefeller Institute notes that:

> Biological indicators are more reliable than chemical indicators (U.S. EPA, 1986) in that they actually verify destruction of a large number of most resistant spores. Bacillus stearothermophilus is recommended by U.S. Pharmacopeia as the biological indicator of choice for steam autoclaves (U.S. Pharmacopeial Convention, 1975).

Rutala writing on "Disinfection, Sterilization and Waste Disposal" in Prevention and Control of Nosocomial Infections states that "Bacillus stearothermophilus spores are used to monitor the efficacy of the steam sterilization.... "

The use of bacillus spore indicators to verify that a process will decontaminate infectious waste and pathological waste is recommended by various medical and professional associations. The Council on Dental Materials, Instruments, and Equipment and Council on Dental Therapeutics states that "the routine use of biological or spore tests to verify the adequacy of sterilization cycles is recommended by the American Dental Association and the Centers for Disease Control.

> Biological indicators for monitoring steam autoclave or chemical vapor (alcohol-formaldehyde-water) sterilization contain spores of Bacillus stearothermophilus. Biological indicators for monitoring dry heat or ethylene oxide sterilization contain spores of Bacillus subtilis. Both of these nonpathogenic spores are highly resistent and difficult to kill. When results from spore testing indicate the destruction of known concentrations of these spores after the sterilization cycle, this provides verification of sterilization.

A major operator of medical waste decontamination devices, Browning-Ferris Industries Medical Waste Systems, in a public statement on the opening of a new infectious waste facility in St. Paul, indicated "High-temperature resistent bacteria are run through the autoclave and tested to ensure the complete system is

operating properly." David Manarin a spokesperson for BFI indicated that the "high-temperature resistent bacteria" referred to are stearothermophilus bacillus spores. Ramsey County in permitting requirements for the facility specified verification using bacillus stearothermophilus spores.

Verification by periodic monitoring permits refinement of the operating procedures so excess processing can be avoided while savings are realized in expenditures of time, energy or materials. Monitoring demonstrates decontamination and confirms that proper procedures were used and equipment is functioning properly (USEPA Guide for Infectious Waste Management, 1986, p. 4-3).

Subp. 8. Autoclaving. According to the Agency for Toxic Substances and Disease Registry in "The Public Health Implications of Medical Waste-A Report to Congress":

> steam sterilization can be used for most medical waste. The technology can handle large volumes of waste; it has sufficiently reliable indicators, both biological and chemical, to measure its effectiveness; the process can be easily verified and validated; and almost any load can be decontaminated if exposed to saturated steam for the proper length of time (ATSDR p. 7.3).

The Rockefeller Institute (Perspectives, p. IV.22) evaluated various decontamination methods. With respect to steam sterilizers the Institute stated:

> The major advantage of the sterilization system is that this process has been used for many years in hospitals for small quantities of waste and sterilization of instruments and containers. Hospitals are familiar with the operation of the units and this is a big advantage. The second advantage to this system is that waste can be properly sterilized if it is processed correctly.
>
> The major disadvantages of this technique are that the waste does not change in appearance (this can be a possible public perception problem) and that it may be difficult to insure that the time/temperature relationship has been met in the unit. Normally microbiological testing is done on the system using spore strips or other techniques to insure that sterilization has taken place...

Hall in "Infectious Waste Management - A Multi-faceted problem (p.76) states:

> With the exception of incineration, autoclaving or steam sterilization is the most highly recommended method for sterilizing infectious wastes prior to disposal in a landfill. Typically, for autoclaving, bags of infectious waste are placed in a chamber which is sometimes pressurized. Steam is introduced into the container for 20 to 90 minutes, depending on the temperature of the steam which may range from 250 to 270 F. Higher

temperatures sterilize waste more quickly and allow shorter cycle times. In addition, other factors such as the type of waste container, the addition of water, and the volume and density of material have important influence on the effectiveness of the autoclaving process. Each of these factors influences the penetration of steam to the entire load, and consequently the extent of pathogen destruction.

One method of assuring that pathogen destruction has taken place during autoclaving is the use of a biological indicator such as Bacillus Stearothermophilus, a spore forming bacterium.

Steam autoclaving has a proven record of being an effective method of decontamination and sterilization. It has been used in hospitals and other medical, dental and veterinary offices as a standard method of sterilizing instruments and to sterilize microbiological laboratory cultures. The use of autoclaves as a decontamination method is one of two methods recommended by the Centers for Disease Control.

Subp. 9. Incineration. Incineration of medical waste is the prevalent treatment method in the United States as well as other Western Countries. It reduces the volume of waste (by about 90 percent), assures destruction, weight reduction, and has the ability to handle most waste with little preprocessing. As a disposal method it has a proven record for handling medical waste but it can require costly air emission control systems and costly ash disposal according to Malik, Lee and Hall. According to the United States Department of Health and Human Services Agency for Toxic Substances and Disease Registry in its 1990 Report to Congress:

> Incineration sterilizes any material kept at the proper temperature for an adequate period of time. In addition to decontaminating sharps, incineration can melt sharps so they are no longer usable (p. 5.2).

Patricia Burkett, hazardous materials compliance director for the Kaiser Foundation Health Plan of Northern California writes in the October 1991 issue of Environmental Protection that:

> steam sterilization of needles and sharps is recognized by health departments and related agencies throughout the country as an acceptable means of treatment and disposal of sharps. With proper packaging to minimize accidental exposure, they pose little or no risk.
>
> However, acceptance of sterilizing and landfilling needles by city, county and landfill operators in the United States will vary. Northern California facilities, for example, decided to incinerate all needle sharps to control any possible public access to sharps as well as to assure the safety of waste haulers and landfill personnel.
>
> Incineration must be used to dispose of some hospital waste. Residual amounts of chemotherapy drugs and pathology specimens containing trace formaldehyde,

for example, cannot be rendered non-hazardous by any steam sterilization, microwave or disinfection process known to date. Incineration of these and other special hospital materials are still appropriate and necessary (p. 30).

For microbiologic wastes the CDC recommends steam autoclaving or incineration. Autoclaving alone of large specimens of pathological waste is not recommended for aesthetic reasons. In "Disinfection, Sterilization, and Waste Disposal" (MDH Exhibit 20, p. 277) Rutala notes that while the Centers for Disease Control and the EPA do not totally agree on the appropriate method of disposal for each different kind of infectious waste, there is agreement among those agencies that pathological waste including waste from autopsies, should not solely be steam sterilized. Incineration is recommended by CDC and incineration, steam autoclaving with incineration or grinding, cremation or burial are recommended by the EPA.

The Rockefeller Institute notes that incineration temperatures of between 1500 and 2000 degrees will guarantee sterility not only of virtually all growing bacteria, viruses (including AIDS and scabies) as well as fungi. The safety factor present in these conditions would more than assure that all pathogenic organisms would be destroyed (p. 11.19).

The MPCA is responsible for permitting the operation of incinerators and oversees emission standards (Minnesota Statutes, sections 116.84 and 116.85 and Minnesota Rules, chapter 7005 and 7035). The state fire marshal is responsible for the prevention of fire hazard (Life Safety Code incorporated into the Minnesota Uniform Fire Code, chapter 7510, sections 7-5, 12-5.4 and 13-5.4).

While Laws of Minnesota, 1991 require submission of incinerator plans to the MDH as part of the generator's management plan if the incinerator is on-site, [Minnesota Statutes, section 116.79, subdivision 3 (d)], a memorandum of understanding between MPCA and MDH states that the MPCA will be responsible for overseeing the content of on-site incinerator management plans. A generator who incinerates on-site must submit a copy of the MPCA incinerator management plan as an appendix to the generator's management plan to the MDH. MPCA will send a list of approved on-site incinerator management plans to the MDH in December of each odd numbered year beginning in December, 1991. Such an agreement is consistent with Minnesota Statutes, section 116.85, subdivision 4 which provides that the authority of the MPCA to monitor incinerators does not limit the authority of the MPCA to regulate incinerator operations under any other law.

Subp. 10. Other methods. This subpart specifies the criteria and procedures to be used by the department to evaluate the effectiveness of on-site decontamination methods other than autoclaving infectious or pathological waste.

Alternative technologies are emerging and being evaluated nationally and by individual states. The technologies under development include mechanical chemical disinfection; microwaving;

irradiation and others (Malik, Lee and Hall). The EPA is conducting research projects to evaluate waste treatment technologies but has made no recommendations. The Agency for Toxic Substances and Disease Registry in its September 1990 Report to Congress on the Public Health Implications of Medical Waste notes that:

> The development of new technologies for medical waste management should be encouraged. New treatment technologies should effectively disinfect medical waste with minimal negative impact on the environment. These new treatment technologies should be developed for situations where incineration may not be the preferred treatment method. In addition, technology development in the areas of medical waste reduction, recycling, reuse and reclamation should be undertaken.

Minnesota Statutes section 116.76, subdivision 6 states that decontamination means "rendering infectious waste safe for routine handling as solid waste." The statute did not determine what methods render infectious waste safe for routine handling. For the commissioner to determine if a method effectively decontaminates infectious waste or pathological waste, there must be evidence that the method does not cause adverse public health effects and environmental concerns. The commissioner needs specific information to make a determination. It is reasonable and prudent for the commissioner to require evidence that the method effectively decontaminates waste and that the method further does not pose a threat to the health and safety of employees or to the public.

Since a decontamination method may not be effective for all types of infectious or pathological waste, it is reasonable that the applicant specify the type of waste for which the method is appropriate.

Chemical decontamination is generally not as effective as steam but may be necessary under some circumstances, according to the Rockefeller Institute.

> ...it may be used for personnel protection prior to steam autoclaving, for emergency decontamination in the event of spillage or leakage of wastes during transport, or when steam autoclaves are not available. It may also be appropriate for some mixed waste situations where steam autoclaving is precluded because of the potential release of chemicals or radioactive materials.
>
> Chlorine bleach or formalin are high level disinfectants which may be suitable for such tasks. Chlorine has also been used as a decontaminant for wastes to be subjected to hammermill grinders where the effluent is to be sewered and solid residues landfilled (Eitzen and French, 1985). Ethylene oxide gas has also been used for decontamination processes as a substitute for steam. However, this gas has been identified as a carcinogen (USEPA, 1980) and the current OSHA standard of 1.0 ppm PEL (0.5 ppm. action limit) results in it not being

> recommended for waste decontamination (USEPA, 1986). Similarly, formaldehyde gas has also been identified as a carcinogen (U.S. EPA, 1980), and thus is contraindicated for waste decontamination.(Perspectives on Medical Waste, p. III.12).

Chemical decontamination appears to be most effective in the decontamination of surfaces. However decontamination throughout the regulated waste may not occur. The U. S. Environmental Protection Agency in its December 20, 1991 MMWR newsletter notes that it has begun testing antimicrobial products registered for use as sterilants and sporicides to determine their effectiveness. The product Sporicidin Cold Sterilizing Solution (SCSS) (EPA Reg. No. 83835), registered as a sterilant to reprocess medical instruments that are reused, has failed standard registration efficacy tests. On December 13, 1991, EPA issued a "Stop Sale, Use or Removal Order" against the registrant.

ATSDR in its 1990 Report to Congress on the issue of liquid and gaseous chemical decontamination states:

> Current chemical disinfectant technology should be viewed as an adjunct to the prime waste disinfection method, autoclaving. The organic content of waste and the corrosive nature of most chemical disinfectants limit the usefulness of chemical disinfection. However, it should be considered the alternate method of choice if waste should not be volatilized (e.g. antineoplastic, radioisotopes, or hazardous chemicals). It may also be the choice in situations where autoclaves are not available or when spills or leaks occur during transport.
>
> Currently, the two liquid chemicals of choice are hypochlorite, in the form of bleach, and iodophors. Bleach is one of the most effective decontaminants, especially for local applications such as surface decontamination and spill clean-up. A more general application of chlorine is in decontaminating wastes destined for hammermill grinders where the effluent is discharged to the sanitary sewer and the solid residues are placed in a landfill.
>
> Ethylene oxide gas is occasionally used as a decontaminant, but its effectiveness on different types of waste varies considerably. It is sometimes used as a substitute for steam and also requires a pressure vessel....
>
> Recently, a chemical decontamination system with the potential for more widespread application has been developed. The system processes infectious waste using an electrocatalytic oxidation system. The system purportedly will destroy any known living organism by the oxidizing solution's temperature, acidity, and chemical activity. The system requires no pressure vessels and only normal amounts of electric power (p. 7.3).

On the use of radiation as a decontamination method, the ATSDR report states:

> Although gamma radiation will inactivate microorganisms, and its possible use for decontamination has been reviewed, irradiation is not widely used for routine medical waste decontamination. Irradiation will certainly decontaminate medical waste, but it is also a very expensive technology requiring highly trained operators. The radioactive source, usually cobalt-60, produces radiation decays just as any other isotope. Because decontamination by this method requires exposure to a minimum dose in rads, the source must be replaced on a regular basis or decontamination time will become longer than acceptable. Replacing the source may nearly equal the system purchase price.
>
> Advantages to the irradiation process include nominal electricity use, no steam requirements, and no residual heat in the treated waste. But its disadvantages -- high capital cost, the need for highly trained operators and support personnel, large space requirements, and the problem of timely disposal of the decayed radiation source -- virtually preclude its use as a decontamination system for medical waste.

Other treatment methods being developed, but not frequently used include hydro-pulping, grinding, microwave technology, and recycling and reclamation. The ATSDR notes that:

> Hydro-pulping is a process in which medical waste is pulverized by a hammermill and submerged in a disinfecting solution. Disinfected solids are dewatered and sent to a landfill for final disposal. Disinfected liquids are discharged to the sanitary sewer. This process must be conducted under negative pressure to avoid producing aerosols. This treatment method disinfects any material that can be pulverized.
>
> Wet grinding of medical waste has been used in the United States on a very limited scale. This process grinds the waste material and discharges it into the sanitary sewer, where it is then treated by that system. As discussed previously in this section, secondary treatment methods and disinfection used by sewage treatment plants will effectively treat medical waste discharged to the sanitary sewer. The major drawback of this treatment method is that it increases the amount of solids sewage treatment plants receive. Some sanitary sewer systems are unable to handle this increase in solids.
>
> Microwave technology is one of the most recently developed medical waste decontamination systems being marketed in the United States. It is designed to treat waste containing blood secretions, bandages, and hypodermic needles with syringes. Waste material is crushed before entering the microwave chamber and then

exposed to microwaves until decontamination temperatures are achieved. The decontamination process is controlled by an automatic temperature control system. As with hydro-pulping and grinding, this treatment must be conducted under negative pressure to avoid producing aerosols. The manufacturer does not recommend treating pathological wastes or animal carcasses in this system.

Recycling or reclamation have been suggested as alternative methods of medical waste management. The American health care industry has been using disposable material (e.g., needles and syringes) for many years, primarily to prevent cross-infection between patients and because disposable items are currently more economical than reusable ones. A wide variety of plastics are used in the medical industry, and a single process is not available to reclaim them all. However, as recycling technologies improve, and as research and development on plastics progress, the current situation may change. Additionally, certain items are already segregated within the hospital environment (e.g., needles). Recycling need not solely mean reuse; reclaiming these items should be considered as a viable waste management option (pp. 7.9-7.10).

Subp. 11. Disposal by sanitary sewer. Generators may dispose of blood and blood products and regulated body fluids in a sanitary sewer unless prohibited by local ordinance. Vesley et al. writing for the Rockefeller Institute in Perspectives on Medical Waste (p. III.16) states that CDC, USEPA and others indicate the disposal of bulk blood, suctioned fluids, excretions, and secretions into the sanitary sewer system is safe and acceptable. The USEPA condones this practice "provided that secondary sewage treatment is available." The Council of State Governments recommends the bulk blood and blood products can be discharged to a sanitary sewer system or approved on-site septic system provided the system is not a combined sanitary storm sewer system. Untreated waste should not be placed in a combined sanitary/storm sewer system. The United States Department of Health and Human Services Agency for Toxic Substances and Disease Registry in its 1990 Report to Congress, does not recommend treatment prior to sewer in a sanitary sewer system. According to the ATSDR:

A sanitary sewer system collects and treats waste material generated by humans. This waste material, sewage, contains microbiological organism. Studies conducted on the microbiological content of residential sewage have isolated many infectious agents (including fungi, bacteria, and viruses). These agents are the result of human excretions, and if residential sewage is not properly treated, disease transmission (of water-borne diseases) can occur.

Most sewage from hospitals, clinics, laboratories, and blood banks originates from patients who do not have communicable diseases, from staff, and from process waters (e.g., heating and cooling). Medical wastes

typically discharged to the sanitary sewer system by these facilities include blood and blood products and pathological and animal wastes. These medical waste materials constitute a small portion of the sanitary sewer discharged from those sources. Any blood and blood products discharged to the sanitary sewer are diluted by the large amount of residential sewage to well below the concentration needed for bloodborne disease transmission.

Secondary treatment methods (trickling filters, activated sludge, anaerobic digestion, and stabilization ponds) are very effective in reducing the microbiological content of sewage. More than 90 percent of sewage microbiological content, including infectious agents, can be removed by secondary treatment followed by disinfection. Effective treatment of medical waste can also be accomplished by septic tank systems because the anaerobic conditions of septic tanks are hostile to human pathogens (p. 7.9).

An epidemiological study of wastewater workers showed that these workers have no increased potential of becoming infected by bloodborne infectious agents. Therefore, medical waste discarded into the sanitary sewer is not likely to present any additional public health effects to wastewater workers or to the general public.

Wastewater workers could be injured by medical waste sharps discarded into the sanitary sewer. The frequency of medical waste sharp injuries to wastewater workers is anticipated to be less than the rate for refuse workers because wastewater workers do not physically contact waste material as do refuse workers. Wastewater is conveyed and treated by mechanical means to prevent frequent human contact (p. 7.13).

Sanitary sewage systems are designed primarily to carry liquid waste. From an infectious agent transmission perspective, sanitary sewage systems are designed to carry and treat infectious material. However, the sewerage of waste is contingent on the potential of particulate matter obstructing the system and backflow in the even of a storm. Sewerage of ground up waste may place an additional particulate burden on community waste water treatment facilities and must be done in accordance with local restrictions and conditions.

Subp. 12. Body tissue. The question of the infectious nature of body tissues that is histologically fixed for study has been raised. This subpart is necessary to clarify that such material, if fixed in accordance with standard procedures, is considered decontaminated. Body tissues which are histologically fixed are small pieces of tissue that are microscopically studied. Histological fixation is the rapid killing of tissue elements so their normal living form is preserved for study. Hoskins and Bevelander in Essentials of Histology state that histology is the science which deals with the detailed structure of animal and plant cells.

> Our knowledge about cells is obtained by a study of "fixed" or dead cells and by other methods developed to study living cells. The method of fixing cells consists of treating cells of tissues with a "fixing" medium such as formalin or any of several other chemical agents which has as its chief purpose the setting of the cells so they may be further processed without undue change in configuration. Subsequent treatment consists of dehydration and then infiltration with a substance such as paraffin or collodion that will solidify. A block of this material containing the tissue is affixed to a machine known as a microtome which is designed to permit the cutting of the tissue in extremely thin sections. These slices are affixed to glass slides and selectively stained with dyes. Certain parts of the cell, such as the chromatin of the nucleus, have an affinity for basic dyes like hematoxylin. Other parts of the cell, particularly the cytoplasm, have an affinity for acid dyes such as eosin. The preparations are made transparent with clearing agents. Finally, they are covered with a drop of transparent mounting medium and a thin cover slip.

Freezing cells to immobilize them does not necessarily kill or decontaminate them.

4622.0900 GENERATOR MANAGEMENT PLAN SUBMISSION

Minnesota Statutes, section 116.79, subpart 3 requires that a person in charge of a facility that generates infectious or pathological waste prepare a management plan for all infectious waste and pathological waste handled by the facility.

It is reasonable that the plan be dated and signed so the MDH knows who is responsible for its implementation. Management of waste must be in accordance with statute and adopted rules.

A generator who begins to generate infectious or pathological waste after adoption of parts 4622.0100 to 4622.1200 must submit to the commissioner a copy of a generator management plan before initiating the handling of infectious waste or pathological waste. This requirement is reasonable and consistent with Minnesota Statutes, section 116.79, subdivision 3(b). The department must have a management plan from the party responsible for the operation and management of waste. If that party changes, the new generator must submit a plan and fee to the department.

4622.1000 GENERATOR MANAGEMENT PLAN

Subpart 1. General. This part requires a generator of infectious waste or pathological waste to develop and submit a generator management plan pursuant to Minnesota Statutes, section 116.79. It is reasonable that the plan address all facilities generating waste operated by the generator. It is reasonable that the plan submitted be the plan implemented.

Subp. 2. Plan contents. The content of a generator

management plan is specifically prescribed in statute. For purposes of these rules, the content of the plan is reiterated for clarification and completeness.

Item A requires the plan to specify the name, address and phone number of the facility as well as the name of the person responsible for the management of the infectious or pathological waste. The person responsible for the facility(ies) must sign and date the plan. By signing the plan the person acknowledges ownership of the plan and the generator's intent to implement the plan as written. Item A is consistent with Minnesota Statutes section 116.79, subdivision 1 which requires a person in charge of a facility that generates, stores, decontaminates, incinerates or disposes of infectious or pathological waste to prepare a management plan for the infectious and pathological waste handled by each facility. Minnesota Statutes, section 116.79 was amended during the 1991 legislative session to allow a generator to prepare a common management plan covering all generating facilities. If this procedure is used, the Act requires that the management plan list each generating facility covered by the plan.

Except for hospitals and laboratories, the Minnesota Statutes, section 116.79, subdivision 1 (a) requires that the generator management plan list all physicians, dentists, chiropractors, podiatrists, veterinarians, certified nurse practitioners, certified nurse midwives, or physician assistants, employed by, under contract to, or working at each generating facility (Item B). Although one plan is required from each generator, pursuant to Minnesota Statutes section 116.79, subdivision 3, the fee is based on each facility and the number of practitioners, listed above, using each facility. In the case of hospitals, long term care facilities, laboratories, and the practitioners specified in part 4622.1100, item C, the fee is based on the number of beds or number of generating employees.

(1) A management plan from a hospital or long-term care facility, including a nursing home, boarding care facilities, or intermediate care facility must list the number of licensed beds. This requirement is consistent with Minnesota Statutes, section 116.79.

(2) A laboratory plan must list the number of generating employees. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1 (a).

Item C requires a generator to identify the types of infectious or pathological waste generated at each facility. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1 (B)(2).

It is reasonable that all infectious and pathological waste generated by a practitioner at a hospital or nursing home be covered by the hospital or nursing home generator management plan, since the mission of the hospital or nursing home is to provide health services under the direction of specific practitioners (Item D).

Item E is reasonable because Minnesota Statutes, section 116.77

exempts household waste from the requirements of the Infectious Waste Control Act. It is reasonable to require a home care provider, registered and licensed under Minnesota Statutes sections, 144A.43 to 144A.49, to develop and implement a generator management plan for the infectious waste generated by the provider in a household, since the provider is not an exempt generator under Minnesota Statutes, section 116.76, subdivision 9. The home care provider's waste is not excluded under Minnesota Statutes, section 116.77 and home care providers are considered generators for purposes of fee payment and generator management plan submission under Minnesota Statutes, section 116.79, subdivision 3 (b) (9) and (10).

Item F requires all information in a generator management plan to be consistent with the policies and procedures established in parts 4622.0100 to 4622.1200 and include the information required in Minnesota Statutes, section 116.79.

Item G requires a generator to describe the activities, programs and locations at the facility that generate infectious or pathological waste. It is reasonable to require a review of the generating areas of each facility to assure that all areas of generation in a facility are covered. A generator may manage infectious waste by type or by the area the waste is generated in and may use more then one method of treatment or disposal.

Item H requires a generator to estimate the average monthly quantity of infectious or pathological waste generated at each facility. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(d).

Item I requires a generator to describe the procedures for segregating untreated infectious or pathological waste from other waste materials at the point of generation. The segregation requirement raises institutional awareness of the types and quantities of infectious waste generated and promotes development of appropriate management strategies. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(b)(2).

Item J requires a generator to describe each facility's procedure for packaging infectious or pathological waste. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(b)(2).

Item K requires a generator to describe each facility's procedure for labeling all bags, boxes, and other containers used to collect, transport, or store infectious or pathological waste on-site. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(b)(2) and Minnesota Statutes, section 116.78, subdivision 2.

Item L requires a generator to describe each facility's procedures for collecting the infectious and pathological waste from the point of generation to the central collection point, prior to treatment or incineration on-site or its transport off-site. This requirement is consistent with Minnesota Statutes, section 116.79,

subdivision. 1(b)(2).

Item M requires a generator to describe each facility's procedure for storing infectious waste and pathological waste at temporary collection points and at central collection points. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(b)(2). If a generator stores infectious waste or pathological waste from a satellite facility or another generator the plan must identify the type of waste stored and the generating facility. This item is consistent with Minnesota Statutes, section 116.79, subdivision 1(d). It should be noted that if infectious or pathological waste is stored for more than 48 hours for another regulated generator other than those excluded generators listed in part 4622.0100, subpart 3, the generator providing the storage becomes an off-site storage facility subject to the rules of the MPCA (Rule part 7095,9110, subpart 23).

Item N requires a generator to describe the methods and procedures used for on-site decontamination of infectious waste or pathological waste including the estimated total volume in gallons and pounds. The requirement to describe methods and procedures used for decontamination of infectious waste and pathological waste is consistent with Minnesota Statutes, section 116.79, subdivision 1(b)(3). The requirement for the estimated volume of infectious waste and pathological waste decontaminated on-site is consistent with Minnesota Statutes, section 116.79, subdivision 1(d).

Subitem (1) requires that if a generator decontaminates infectious waste or pathological waste for any other generator, the plan must identify all other generators, whether the waste is sharps or bagged waste, and the estimated quantity in pounds. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(b)(3) and (d).

Subitem (2) requires a generator who puts blood or other regulated human body fluids into an on-site sanitary sewer for disposal, to identify the types of regulated human body fluids disposed of in this manner and estimate the volume. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(b)(3) and (d).

Subitem (3) requires a generator, who incinerates infectious or pathological waste on-site, to estimate the volume of infectious waste and pathological waste incinerated on-site. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(d). The rule requires a generator to maintain a record for each load of infectious waste and pathological waste incinerated on-site. The record must be maintained for three years and specify for each load the date, operator and the approximate amount of waste incinerated. It is reasonable to require a generator to maintain a record of infectious or pathological waste incinerated on-site because the record provides written data if there is a question about the on-site incineration. The record will verify the estimated volume incinerated on-site required by Minnesota Statutes, section 116.79, subdivision 1(d).

Item O requires a generator, who incinerates infectious or

pathological waste for any other generator, to include in the plan the identity of the generators, whether sharps or bagged infectious waste is incinerated, and estimate the volume of the infectious or pathological waste incinerated. Since the MDH regulates generators, it is reasonable to require documentation of the infectious waste or pathological waste incinerated at a generating site. The waste incinerated on-site by a generator of another generator's infectious waste or pathological waste needs to be included in the estimated volume of waste incinerated on-site, pursuant to Minnesota Statutes, section 116.79, subdivision 1(d).

Item P requires a generator to identify the disposal facility, including the type of disposal facility and the method of disposal. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(b)(4). A generator who transports infectious waste or pathological waste off-site for storage, decontamination or disposal must identify each storage, decontamination or disposal facility used and the type and volume of infectious waste or pathological waste handled by each facility. This is consistent with Minnesota Statutes, section 116.79 which requires a generator management plan to address transportation procedures for the infectious waste and pathological waste, as well as the decontamination or disposal methods used and the identification of the disposal facility.

Item Q requires a generator to identify any intermediate facility or transporter used between initial transport and final disposition of infectious waste or pathological waste. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(b)(4).

Item R requires that a generator who transports his or her own waste or if that generator's waste is transported by another generator off-site, to identify all storage, decontamination and disposal facilities used throughout that process. This is necessary so both the department and MPCA have a means to track the disposal or decontamination or waste should a problem or complain arise. Also required is a record of each shipment of infectious waste or pathological waste transported off-site for decontamination or disposal. The record provides information on the volume shipped, the destination facility and the date of shipment. The record must be maintained on-site for three years and the following information must be noted for each shipment: the destination facility pursuant to Minnesota Statutes section 116.79, subdivision 1(b)(4); the weight or volume of infectious waste or pathological waste shipped; and the date the waste is shipped.

Item S requires a generator who mails sharps to specify to whom the sharps were mailed and estimate quantity. The Department notes that the United States Postal Service has amended its rules to govern the mailing of sharps (June 30, 1992, Federal Register, page 29028).

Item T requires a generator who transports infectious waste or pathological waste for another generator to list the name of each generator whose waste is transported. Minnesota Statutes, section 116.79, subdivision 1(b)(2) and (4) requires a generator management

plan to address how infectious waste and pathological waste is transported and by whom.

Item U requires a generator whose infectious waste or pathological waste is transported by any other generator to identify all generators transporting the waste. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(b)(4) which requires a generator to identify transporters in its management plan.

Item V requires a generator to describe the steps to be taken by the generator to minimize the exposure of employees to infectious agents throughout the process of handling infectious waste and pathological waste. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(b)(5) and (6). If a generator has no employees, item V does not apply.

Item W requires a generator to identify a contingency system to be used if the present infectious waste or pathological waste system breaks down or is unavailable. Since a generator is responsible for managing all the infectious waste and pathological waste generated at the facility and has responsibility for overseeing the disposal of all infectious waste and pathological waste in a manner that is protective to employees, the general public and the environment, it is reasonable to require the generator to identify a contingency method for handling the waste. By identifying a contingency system as part of the generator's management plan, the generator is prepared in the eventuality that the system breaks down or is unavailable. The identification, by the generator, of a contingency system assures the MDH that the generator is prepared to handle the waste appropriately. It is not necessary for the generator to have a contingency contract.

Subp. 3. Maintenance of plan on-site. Subpart 3 requires a generator to maintain a current copy of the generator's management plan on-site. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(c).

4622.1050 GENERATOR MANAGEMENT PLAN RENEWAL, RESUBMISSION.

A generator must update and resubmit a generator management plan on January 1 of each even numbered year. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 1(e).

A generator must submit an updated generator management plan at least 30 days before the expiration of the previous generator management plan. This requirement is reasonable to assure that the MDH receives the updated plan prior to the expiration of the previous plan. The requirement assures that the generator remains in compliance with state law.

A generator must notify the commissioner if the facility ceases operation; the generator opens a new satellite facility not previously identified in the generator management plan; or the generator materially changes the infectious waste management system, including changes in the method of waste decontamination.

It is reasonable to require a generator to notify the MDH if a facility ceases operation, since the MDH is responsible for overseeing all generating facilities. A facility may cease to be owned or operated by a particular generator and sold to or managed by another generator. To assure that the facility remains compliant with state law, it is necessary for a new owner or operator to develop and submit a generator management plan and fee for the facility. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 3(b).

It is reasonable to require a generator to notify the MDH if the generator opens a new satellite facility since the generator must amend the generator management plan to include the facility and must submit the fee for the facility before initiating the handling of infectious or pathological waste. This requirement is consistent with Minnesota Statutes, section 116.79, subdivision 3(b)and(c).

It is reasonable to require a generator to notify the commissioner, if a generator materially changes the infectious waste management system at the generator's facility. Examples of material changes would be the proposed use of a new or not previously identified decontamination method or a change from on-site incineration to off-site disposal. It is reasonable to require notice to assure that the management system of the generator continues to properly treat waste and employees and the public are protected.

4622.1100 FEES.

This part requires a generator to submit to the commissioner a fee in accordance with Minnesota Statutes, section 116.79, subdivision 3 with submission of the generator's management plan. The fee schedule for a facility that generates infectious or pathological waste is determined according to Minnesota Statutes section 116.79, subdivision 3(b). If a hospital and a nursing home are a single entity at a single site, then the plan must list the total number of licensed beds for the facility. This requirement is consistent with Minnesota Statutes, section 116.79. Since there are practitioners who staff facilities such a bloodmobiles, that are other than those listed in Minnesota Statutes, section 116.79, subdivision 3 (b) (1) and (2) it is necessary for clarification to indicate into what fee category these other generating sites fall. The clarification in items C and D is reasonable to avoid confusion and assure the consistent application of the statute.

The department notes that subdivision 3 (a) in section 116.79 also speaks to fees. This paragraph should have been deleted when subsequent amendments to the law were adopted in 1991. It was not, but the department is assuming that the later law supersedes the previous on this matter.

4622.1150 GENERATOR MANAGEMENT PLAN REVIEW

This part addresses the commissioner's review of a generator management plan pursuant to Minnesota Statutes, section 116.79, subdivision 3(f). Minnesota Statutes, section 116.79, subdivision 3, paragraph (e) requires the commissioner of health to establish

a procedures for randomly reviewing plans. The statute did not establish what percent of plans must be randomly reviewed. The Minnesota Department of Health has based its review on staffing resources available to review plans and on the total number of plans anticipated during each submittal period. The department has been reviewing about ten percent of the plans received. A record is maintained of all plans received. Random samples are drawn from the plans submitted more than once during the submittal period to assure late plans or new generator plans have an equal chance to be reviewed. The random sample is drawn from the universe of plans received. The information systems manager for the Environmental Health Division is responsible for drawing samples. Since plans are only randomly reviewed, generators are sent a card acknowledging receipt of a generator management plan and fee and a statement that the generator will be notified only if the plan is reviewed and needs modification. Generators are not routinely notified if their plan has been reviewed and approved. Minnesota Statutes, section 116.79, subdivision 3(e), states that the commissioner may require a generator management plan to be modified, if the commissioner determines that a plan is not consistent with state law or rule. On determination that the plan is not in compliance, the commissioner notifies the generator in writing of the determination and specifies the modifications necessary for compliance. It is reasonable to require a generator to modify the plan to comply with parts 4622.0100 to 4622.1200 within 20 working days after the receipt of the notice from the commissioner, since this time period should be sufficient to allow a generator to modify the handling of infectious and pathological waste at the facility so that it complies with state law and rule.

4622.1200 REMEDIES AND PENALTIES.

A generator who fails to submit a generator management plan, fee, or manage infectious waste or pathological waste in accordance with adopted statutes and rules is subject to the remedies and penalties specified in Minnesota Statutes, sections 115.071 and 116.072 as authorized by Minnesota Statutes, section 116.83. In Laws of Minnesota 1991, chapter 347, section 18 which was part of the new environmental enforcement act of 1991, the Revisor was ordered in an instruction to amend Minnesota Statutes, section 116.83, subdivision 2 to include section 116.072. This action applied the administrative penalties for hazardous waste violations used by the MPCA to the infectious waste control act adopted in 1989. In adopting this instruction, the commissioner of health was given the option to use the mechanisms in sections 115.071 and 116.072 to enforce provisions of the Infectious Waste Control Act and rules adopted thereunder for which MDH is responsible.

4655.9070 HOUSEKEEPING RULES APPLICABLE ONLY TO NURSING HOMES.

Part 4655.9070, subpart 2 regarding the management of special waste is amended. The amendment references the statutory definition of infectious waste and pathological waste pursuant to Minnesota Statutes, section 116.76 and the management of the waste according to Minnesota Statutes, chapter 116 and parts 4622.0100 to 4622.1200. This amendment is reasonable because nursing homes are subject to the provisions of the Infectious Waste Act if infectious

waste is generated at the facility. The commissioner has authority to establish standards for sanitation and safety under Minnesota Statutes, sections 144A.02, 144A.08 and 144.56.

Part 4675.2205 INFECTIOUS WASTE AND PATHOLOGICAL WASTE.

This rule part specifies the proper disposal of the waste. The rule is amended to be consistent with chapter 116, including Minnesota Statutes, sections 116.76 to 116.83, and parts 4622.0100 to 4622.1200.

SMALL BUSINESS CONSIDERATIONS

Minnesota Statutes, section 14.115 requires that an agency consider five factors for reducing the impact of proposed rules on small business. According to Minnesota Statutes, section 14.115, a small business is an entity, including its affiliates, that (a) is independently owned and operated; (b) is not dominant in its field; and (c) employs fewer than 50 full-time employees or has gross annual sales of less than $4 million. The proposed rules may impact small businesses run by private practitioners such as physicians, dentists, veterinarians and nurses. However, Minnesota Statutes, section 14.115 excludes many of these practitioners from the application of section 14.115 in subdivision 7, clause (3)

> (3) service businesses regulated by government bodies, for standards and costs, such as nursing homes, long-term care facilities, hospitals, providers of medical care, day care centers, group homes, and residential care facilities, but not including businesses regulated under chapter 216B or 237....

The methods delineated in Minnesota Statutes, section 14.115 for reducing the impact of the rule on small business include:

A. the establishment of less stringent compliance or reporting requirements for small businesses;

B. the establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

C. the consolidation or simplification of compliance or reporting for small businesses;

D. the establishment of performance standards for small businesses to replace design or operational standards required in rule; and

E. the exemption of small businesses from any or all the requirements of the proposed rules.

The proposed rules must balance the requirements and exclusions expressly specified in statute with the need to protect public health. Minnesota Statutes, section 116.76, subdivision 9, expressly excludes certain persons from regulation by the Infectious Waste Control Act. Section 116.77 excludes certain kinds of waste from control under the act. These exclusions were deliberately made and discussed. The department does not believe

it prudent to expand upon the statute which is clear in this case.

Further amendments to statute made during the 1991 legislative session consolidated plan development, and thus reporting and compliance requirements. This consolidated plan development and reporting process has been incorporated into the proposed rules and should make compliance with the intent of the Infectious Waste Control Act easier for those businesses with multiple sites.

The establishment of less stringent compliance and reporting requirements for small business other than those expressly excluded by subdivision 7 is not reasonable because the source of infectious waste and pathological waste management problems rest not only with large generators, such as hospitals, but also with small generators. Department monitoring of compliance with the act has shown that large businesses because they frequently have their own waste management personnel have a higher percent of compliance with the requirements of the act, particularly in the area of management plan generation, than do small businesses.

The Infectious Wastes Control Act did not establish less stringent schedules or deadlines for compliance for small business beyond the opportunity to consolidate generator management plans. The fee schedule stipulated in Minnesota Statutes, section 116.79 provides for a distinction between large firms and small firms on the basis of number of practitioners, generating employees, or beds.

Consolidation and simplification of the management plan development was addressed in the 1991 legislative session through amendments to section 116.79, subdivision 1. The proposed rules are consistent with the law.

The department, through the establishment of performance verification standards, provides flexibility to the small business to gear the procedures and methods used to manage waste to the size and type of business and amount and type of waste generated.

Effect on Agricultural land

The adoption of these rules will not have a direct adverse impact on agricultural land (Minnesota Statutes, section 14.11).

Fiscal Impact

The adoption of the proposed rules will not require the expenditure of public money by local public bodies of greater than $100,000 in the two years following promulgation. The Infectious Waste Act has been in effect and applicable to generators since adoption in 1989. The basic management provisions of the act including the submission of fees, the development of generator waste management plans and the application of most waste management practices are already prescribed by law. Using its authority under the act, the department has solicited the submission of and received generator management plans from persons the department identified as potential generators of infectious and pathological waste. The department does not anticipate that the proposed rules embody basic

requirements not already delineated by law. Wherever possible the department tried to clarify standards to specify a performance criteria that reflects current practice used by the regulated industry. The department believes most infectious wastes are managed in ways that meet the requirements of the proposed rules. The department has developed the rules with the use of representatives of regulated industries. Where initial compliance proved overly burdensome, as indicated by advisory work group discussions, legislative change was sought by regulated parties and approved. For example, the need for a plan for each generating site was amended by 1991 law to allow for a single generator plan that would encompass a number of generator sites. The schedule of generator fees was modified to reflect the generating practices of small entities.

REPEALER. Minnesota Rules parts 4675.2200, 4675.2300, 4675.2400, 4675.2500 and 4675.2600 are repealed. These parts are repealed because the persons to whom they apply are subject to the provisions of the Infectious Waste Act, and the infectious waste and pathological waste handling practices specified in proposed rules are applicable.

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