 Attachment 3

STATE OF MINNESOTA

MINNESOTA POLLUTION CONTROL AGENCY

IN THE MATTER OF PROPOSED AMENDMENTS
TO MINNESOTA RULES CHAPTER 7035
RELATING TO INFECTIOUS WASTE MANAGEMENT

STATEMENT OF NEED
AND REASONABLENESS

I. INTRODUCTION

The proposed rules in this rulemaking effort all relate to the management of infectious waste once it leaves a generator's facility. The proposed rules establish standards for the offsite management of infectious waste, including packaging and labeling, transport, offsite storage, offsite treatment, and disposal. The proposed rules do not apply to infectious waste management activities occurring onsite, within the generating facility. Minn. Stat. § 116.81, subd. 1 and 2 divided the rulemaking responsibilities for infectious waste management between the Minnesota Pollution Control Agency (MPCA) and the Minnesota Department of Health. Rules that apply to generators of infectious waste may be developed in the future by the (MDH).

The Agency proposed rules are to be codified in chapter 7035. The proposed rules establish required practices for facilities and commercial transporters. These required practices include specific packaging and labeling, storage, treatment, transportation, and spill response requirements. The proposed rules also establish information that must be submitted to the MPCA in an infectious waste management plan, in addition to the information required by Minn. Stat. § 116.79, subd. 3 and Minn. Stat. § 116.80, subd. 2. The rules also require the owner and operator of storage facilities to provide financial assurance to ensure the proper management of infectious waste that is in storage. The rules are proposed for adoption pursuant to the Agency's authority under Minn. Stat. §§ 115.03, subd. 1, 116.07, subds. 2, 4, 4g and 4h and 116.81 (1988).

This statement is divided into ten parts. After this introduction, Part II provides an overview of the proposed rules. Part III discusses the legal and historical background of the infectious waste management rules. Part IV contains the Agency's explanation of the need for the proposed rules as a whole. Part V constitutes the Agency's explanation, part by part, of the reasonableness of the proposed rules. Pursuant to Minn. Stat. § 14.115 (1986), Small Business Considerations in Rulemaking, Part VI documents how the Agency has considered methods for reducing the impact of the proposed rules on small businesses. Pursuant to Minn. Stat. § 14.11 (1986), Agricultural Land, Part VIII documents how the Agency has considered methods for reducing any adverse impact the proposed rules might have on agricultural lands of the State. Part IX contains the Agency's conclusion regarding the adoption of the rules. Part X contains a

list of exhibits relied on by the Agency to support the proposed rules. The exhibits are available for review at the Agency's offices at 520 Lafayette Road, St. Paul, Minnesota 55155.

II. OVERVIEW OF PROPOSED RULES

In general, the proposed infectious waste rules establish required practices for the management of infectious waste. The rules provide standards for packaging, labeling, transport, offsite storage, offsite treatment, and disposal. The rules also list elements that need to be included in the infectious waste management plan and set out the Agency's procedure for reviewing these plans.

Part 7035.9100 sets out the scope of the infectious waste rules (7035.9100 to 7035.9150). This part explains that the proposed rules apply to owners and operators of facilities, to commercial transporters, and to all infectious waste without regard to quantity. The term "facility" is defined in the proposed rules to mean "a site where infectious waste is decontaminated, stored, or disposed". The term "offsite" precedes the term "facility" throughout the draft to specify that these rules apply to infectious waste management activities that occur away from the point of generation. The proposed rules therefore do not apply to infectious waste management activities performed within a generating facility. This part also explains that the proposed rules do not apply to waste generated by households, farms, or agricultural businesses. These entities were exempted by Minn. Stat. § 116.77.

Part 7035.9110 contains the definitions used throughout the proposed rules. Several statutory definitions are included to provide clarity to the proposed rules (Minn. Stat. § 116.76) and to provide one document that can be used by the regulated community when complying with the rules.

Part 7035.9120 contains the packaging and labeling requirements for infectious waste. This part establishes different packaging standards for sharps and for infectious waste. Any infectious waste container that includes sharps must be labeled with the word "Sharps" and with either the international biohazard symbol or with the words "Infectious Waste". Required methods to store, decontaminate, and transport infectious waste are also included in this part. The storage requirements apply only to offsite facilities, not to generators that store their own waste on the site where the waste is generated.

With the exception of incineration, methods used to decontaminate infectious waste apply only to offsite facilities. This part establishes a review process for technologies other than incineration and autoclaving. This part also contains requirements for spill cleanup, financial assurance, and annual reporting.

Part 7035.9130 lists the information that needs to be contained in the infectious waste management plan. This information is needed in addition to the information required by the statute (Minn. Stat. § 116.79, subd. 1 and Minn. Stat. § 116.80, subd. 2).

Part 7035.9140 establishes the procedures for management plan application, review and approval/denial. This part requires the submission of certification fees along with the management plan, and establishes the duration of the management plan to be two years. In general, these parts duplicate the statutory language (Minn. Stat. § 116.76).

Part 7035.9150 establishes the forms and information needed for a surety bond or letter of credit. These instruments are required of owners and operators of offsite storage facilities.

III. LEGAL AND HISTORICAL BACKGROUND OF THE RULE

This part provides the history of infectious waste regulation at the federal and state levels. In addition to discussing how infectious waste has been regulated in the past, this part discusses the events that led to the development of federal and state legislation that specifically addresses the management of infectious waste. The federal legislation resulted in the development of the Federal Medical Waste Tracking Program. The state legislation resulted in the current rulemaking.

A central theme in the history of both state and federal regulation of infectious waste is whether infectious waste should be classified as a hazardous waste or as a solid waste. On December 18, 1978, the United States Environmental Protection Agency (EPA) proposed regulations under the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, which would classify certain infectious wastes as hazardous waste. (See Exhibit 1). Infectious waste that would be classified as hazardous waste included wastes generated by healthcare facilities, veterinary hospitals, laboratories, and sewage treatment facilities.

The EPA proposed to list these wastes as hazardous because it was believed that the improper management of these wastes could pose a substantial hazard to human health and the environment. In addition, the federal statutory definition of hazardous waste specifically cited infectiousness as one of the properties that the EPA should consider in determining whether a waste is hazardous or not. Significant comments opposing the listing of infectious waste as a hazardous waste were received by EPA, resulting in infectious waste not being listed as hazardous when the hazardous waste regulations were made final on May 19, 1980. Instead, the EPA initiated information gathering activities to assess the problems posed by improper management of infectious waste. EPA used this information to issue a draft guidance document in 1982. (See Exhibit 2). The guidance document was made final in 1986 with the help of experts from the healthcare industry.

In November, 1987, as a result of several isolated incidents of improper management and disposal of infectious wastes and growing public concern about the potential threat of infectious waste to human health and the environment, the EPA called together a panel of experts to discuss the definition of, proper management, and risks posed by infectious waste. The EPA used the results of this meeting to develop and present issues for public comment in the Federal Register on June 2, 1988. The EPA solicited public comment on the definition of infectious waste, the implementation of a tracking system, the nature of the problem posed by infectious waste, and the role of the EPA in infectious waste management. (See Exhibit 3). (The EPA used the public input process to determine whether further guidance or infectious waste rules should be developed.)

During the summer of 1988, several incidences of improper disposal of medical wastes were reported. (See Exhibits 4-6). On the East Coast and in the Great Lakes region beach washups of medical waste resulted in significant economic losses for coastal communities. Additionally, reports of needles and other types of medical waste being disposed of in dumpsters also heightened public concern about the disposal of medical waste. The United States Congress responded by passing the Medical Waste Tracking Act on November 1, 1988. (See Exhibit 7).

The Medical Waste Tracking Act established a "cradle-to-grave" manifest system for the tracking of medical waste. The Act required the states of New York, New Jersey, and Connecticut to participate in a two year demonstration

program and granted the states contiguous to the Great Lakes the option of participating. The Act also established a definition of medical waste, listing thirteen categories of medical waste that would be regulated. Throughout the two year demonstration program, the EPA is required to evaluate the effectiveness of the program and to provide reports to Congress on whether a national program should be developed.

To implement the Medical Waste Tracking Act, the EPA developed rules to provide the regulated community with more specific requirements than what was provided by the Act. During rule development, the EPA met with members of the scientific community and with regulatory officials, including the Great Lakes States Commission. A major topic of discussion was the broad definition of medical waste that was included in the Act. Opposition to the inclusion of medical waste items that do not pose a threat of infection resulted in EPA eliminating several of the categories of medical waste that were listed in the Act.

On March 24, 1989, the EPA published the interim final rule and request for comments in the Federal Register (vol.54 No. 56). (See Exhibit 8). Procedures for petitioning in and for opting out of the federal program were provided in this publication. The seven Great Lakes states, which includes Minnesota, were given until April 24, 1989, to notify the EPA that they were opting out of the program. If EPA did not receive a notice by April 24, the state failing to give notice was to be automatically included in the program. All seven Great Lakes states opted out of the demonstration program. The Governors of the States of Louisiana and Rhode Island and the Mayor of the District of Columbia, and Governor of the Commonwealth of Puerto Rico, petitioned the Administrator of the EPA to be included in the program. The Administrator reviewed the petitions for inclusion and determined that inclusion of the states would provide a broader range of experience and information and therefore, a more meaningful demonstration program. On June 22, the Medical Waste Tracking Program was implemented in the states of New York, New Jersey, and Connecticut. The four states petitioning in were given until July 24 to implement the program. (See Exhibit 9).

In Minnesota, the management of infectious waste was first regulated in 1973 by the MPCA Solid Waste Rules (Minn. Rules Chap. 7035.0300). (See Exhibit 10). The Solid Waste Rules prohibited the land disposal of infectious waste. The rules provided a broad definition of infectious waste to include isolation

wastes, and bandages, catheters, and tubing which have been in contact with wounds, and all pathological waste. Much of the waste that was prohibited from land disposal by these rules did not have the potential to cause infection.

In 1977, the MDH established rules for Freestanding Outpatient Surgical Centers (Minn. Rules Chap. 4675.2200). (See Exhibit 11). The MDH rules provided definitions of two types of infectious waste, hazardous infectious waste and contaminated infectious waste. Hazardous infectious waste included isolation waste, bandages, catheters, tubing, laboratory and pathology wastes of an infectious nature which has not been autoclaved. All of these waste types were considered as having a "suspected, known, or medically identified hazardous infectious nature". Contaminated infectious waste included these same waste items but were characterized as "not suspected or not medically identified to be of a hazardous infectious nature". The rules provided different management methods and standards for hazardous infectious waste and for contaminated infectious waste. The rules required the incineration of hazardous infectious waste and allowed the land disposal of contaminated infectious waste.

In 1987, the MDH established rules for Nursing Home Licensure (Minn. Rules Chap. 4655.9070). (See Exhibit 12). The Nursing Home Licensure rules required that materials or waste, such as dressings or disposable pads, which are infectious or suspected of presenting a potential health hazard should be collected in a manner which will prevent transmission of disease, and shall be incinerated. The rules required infectious waste that is not incinerated onsite to be packaged in special bags that indicate their content.

In 1988, the MPCA established rules for solid waste management Minn. Rules Chap. 7035). (See Exhibit 13). The rules defined infectious waste as "waste originating from the diagnosis, care, or treatment of a person or animal that has been or may have been exposed to a contagious or infectious disease". The rules stated that unless the materials have been rendered noninfectious by procedures approved by the state, infectious waste includes:

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

B. bandages, dressings, casts, catheters, tubing, and similar items which have been in contact with wounds, burns, anatomical tracts, or surgical

incisions and which are suspect of being or have been medically verified as infectious;

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

D. infectious sharps and needles;

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

F. any other waste, as defined by the state commissioner of health, which because of its infectious nature requires handling and disposal in a manner prescribed for items A to E. (Minn. Rules Chap. 7035.0300).

The solid waste rules also listed infectious waste, unless approved by the Agency, as a waste that is unacceptable for management at a solid waste management facility.

In November of 1987 the Attorney General's Office (AG) established a Task Force of healthcare professionals, waste haulers, public health officials, and state agencies. The Task Force examined current regulations and management practices for infectious waste. On May 7, 1988, the Task Force issued a set of recommendations which were supplemented with the AG's issuance of a report, in the fall of 1988, on the regulation of infectious waste. (See Exhibit 14). This report established the background material necessary for the development of legislation that was introduced in the 1989 legislative session.

In April 1989, MPCA staff conducted informational meetings on the developing federal Medical Waste Tracking Rule and on the state Infectious Waste Control Act. The MPCA used these meetings to gather public input on how medical/infectious waste should be regulated. Appendix 1 contains a copy of the notices of these meetings. Five meetings were held with approximately 150 attending. At the time, Minnesota, as a Great Lakes state, had the option of participating in the federal Medical Waste Tracking program. The overwhelming public response at the informational meetings was to opt out of the federal program. As a result, on April 19, 1989, the MPCA and MDH recommended to Governor Rudy Perpich that the state of Minnesota opt out of the federal program. (See Exhibit 15). On April 21, 1989, Governor Rudy Perpich notified

William K. Reilly, EPA Administrator, of his decision to opt out of the federal Medical Waste Tracking Program. (See Exhibit 16). The governors of each of the Great Lakes states were notified of his decision. (See Exhibit 17).

During the 1989 legislative session, the Infectious Waste Control Act received supportive testimony from several professional organizations including the Minnesota Medical Association, the Minnesota Hospital Association, and the Minnesota Dental Association. On June 1, the Infectious Waste Control Act was signed into law. See Appendix 2.

During the summer of 1989, MPCA staff began rule development. On September 11, 1989, a Notice of Intent to Solicit Outside Information was published in the State Register. See Appendix 3. In October of 1989, a preliminary draft of the infectious waste rules, along with a schedule for informational meetings, was mailed to interested parties. (See Exhibit 18). A copy of the draft rules was also presented to the MPCA Ground Water and Solid Waste Committee in a memorandum dated October 16, 1989. (See Exhibit 19). Meetings were held on October 17 through October 31 to present the draft rules and to gather public input. Approximately 450 interested persons attended these meetings. See Appendix 4 for dates of meetings and list of attendees. MPCA staff also presented the draft rules at several seminars, including those held by the State Hospital Engineer's Association, the Arrowhead Engineer's Association, the Minnesota Environmental Health Association, the Community Health Conference, and the Minnesota Medical Association. MPCA staff also presented information on the draft rules to the District A Hospital Association and at meetings held by Abbott Northwestern Hospital. Several members of the regulated community requested meetings with MPCA staff to express their concerns. As a result of the comments received at these meetings and through written correspondence, MPCA staff made several changes to the draft rules. See Appendix 5 for comments on the rules.

In summary, Agency staff has put in a considerable effort to give full exposure to the concepts and the specific language in the proposed rules. All persons living in Minnesota have been given an opportunity for input into the rulemaking.

IV. NEED FOR THE PROPOSED RULES

Minn. Stat. § 14.14, subd. 2 (1986) requires an Agency to make an

affirmative presentation of facts establishing the need for and the reasonableness of the proposed rules. In general terms, this means that an Agency must set forth the reasons for proposing rules and the reasons must not be arbitrary or capricious. However, to the extent that need and reasonableness are separate, need has come to mean that a problem exists and requires administrative attention and reasonableness means that the solution proposed by the Agency is a proper one. The Agency will first address need. The need for these rules arises from the following sources:

1. The requirements of Minn. Stat. §§ 115.03, 116.07, 116.75, et seq.

2. The decision being made by hospitals and other healthcare facilities to shut down onsite incinerators due to air quality standards being developed at the state and federal levels. An infectious waste management program is needed to ensure that alternative management methods result in appropriate management.

3. The need to provide financial security for the cleanup of abandoned infectious waste in storage facilities.

4. The need to reinforce existing management practices to ensure appropriate management of infectious waste throughout the regulated community.

5. The need to establish a review process for offsite decontamination of infectious waste.

A. Requirements of Minn. Stat. §§ 115.03, 116.07, 116.75, et seq.

The Minnesota Legislature has "given and charged" the Agency with the power and duty:

> (e) To adopt, issue, reissue, modify, deny, or revoke, enter into or enforce reasonable orders, permits, variances, standards, rules . . . to prevent, control or abate water pollution, or for the installation or operation of disposal systems . . . .

Minn. Stat. § 115.03, subd. 1 (1986)

The Minnesota Legislature has authorized the Agency to "adopt standards for the control of the collection, transportation, storage, processing, and disposal of solid waste . . . for the prevention and abatement of water, air, and land pollution . . . ." Minn. Stat. § 116.07, subd. 2 (1986). The Legislature has supplemented that basic authority and made it more specific with the following:

> Subd. 4. Rules and standards. . . . Pursuant and subject to the provisions of chapter 14, and the provisions hereof, the pollution control agency may adopt, amend, and rescind rules and standards having the force of law relating to any purpose within the provisions of Laws 1969, chapter 1046, for the collection, transportation, storage, processing, and disposal of solid waste and the prevention, abatement, or control of water, air, and land pollution which may be related thereto, and the deposit in or on land of any other material that may tend to cause pollution . . . . Without limitation, rules or standards may relate to collection, procedures, methods, systems or techniques or to any other matter relevant to the prevention, abatement or control of water, air, and land pollution which may be advised through the control of collection, transportation, processing, and disposal of solid waste . . . and the deposit in or on land of any other material that may tend to cause pollution. . . .

Minn. Stat. § 116.07, subd. 4 (1986).

The proposed rules are needed to provide a comprehensive program that ensures the protection of human health and the environment during collection, transportation, storage, processing and disposal of infectious waste. The rules for infectious waste management facilities and commercial transporters will establish a system that minimizes the potential for transmission of infectious agents through appropriate packaging, labeling, and handling procedures.

Authority to adopt rules was granted by the following:

> The Agency has primary responsibility for rules relating to transportation of infectious waste and facilities storing, decontaminating, incinerating, and disposing of infectious waste.

Minn. Stat. § 116.81, subd. 1.

B. The Decision Being Made by Hospitals and Other Healthcare Facilities to Shut Down Onsite Incinerators.

The Air Quality Division of the MPCA estimates that ninety percent of the existing hospital incinerators will decide to shut down by 1993. Most healthcare facilities that have been incinerating onsite will be managing their wastes offsite. These facilities will be transporting medical waste to offsite facilities to be incinerated or treated in some other manner, or landfilled. An infectious waste management program is needed to ensure that infectious waste is managed to protect human health and the environment.

Minn. Stat. § 116.76 requires the segregation of infectious waste from other types of waste, including municipal solid waste. By segregating and managing the infectious portion separately from the general solid waste stream, infectious waste will not be entering the municipal solid waste stream where it has been a problem at solid waste processing facilities where garbage is hand sorted. And, although there is no epidemiological evidence suggesting that infectious waste poses a public health problem if directly landfilled, the state of Minnesota and most other states do not allow direct land disposal of infectious waste. Generally, infectious waste must be decontaminated prior to disposal at a municipal solid waste landfill. If Minnesota were to become one of the few states to allow the land disposal of infectious waste, the state may experience a huge influx of infectious waste from other states. The proposed rules provide a safe and effective alternative for infectious waste that will no longer be managed by onsite incineration.

C. The Need to Provide Financial Security for the Cleanup of Abandoned Infectious Waste in Storage Facilities.

In the Waste Management Act of 1980, the Minnesota Legislature stated its goals for solid and hazardous waste management. The 1980 Act states that it is the goal of the State to improve waste management in the State to serve the following purposes:

a. Reduction in waste generated;
b. Separation and recovery of materials and energy from waste;
c. Reduction in indiscriminate dependence on disposal of waste;

d. Coordination of solid waste management among political subdivisions;
e. Orderly and deliberate development and financial security of waste facilities including disposal facilities.

Minn. Stat. § 115A.02

Financial security for infectious waste management is needed in the proposed infectious waste rules to ensure that funds are available to clean up abandoned infectious waste storage facilities. A funding mechanism needs to be established by the owner and/or operator of infectious waste storage facilities that can be used in the event that the owner/operator is either unable or unwilling to transport the waste offsite for treatment and disposal. The funding mechanism is needed to ensure that waste that is warehoused can be packaged, labeled, transported and disposed of properly. Financial security will eliminate the possibility of abandonment that has occurred in the past. (See Exhibit 20).

D. The Need to Reinforce Existing Management Practices to Ensure Appropriate Management of Infectious Waste Throughout the Regulated Community.

Much of the regulated community, including generators and commercial transporters are already managing infectious waste in a manner that protects human health and the environment. In particular, hospitals that have made the decision to shut down their incinerators, have demonstrated a need to transport waste for offsite management and that need has been responded to by the waste industry. Many infectious waste collection and transport services have been providing services that are protective of human health and the environment. The packaging and labeling already used by most infectious waste transporters is similar to the requirements of the proposed rules. However, with increasing numbers of healthcare facilities making the decision to shut down their incinerators, an increase in the number of entrepreneurial infectious waste management businesses is expected. The rules are needed to ensure that these new businesses implement management practices that are consistent and effective in protecting human health and the environment. Although most of the regulated community has been managing infectious waste appropriately, there have been incidences where infectious wastes have not been managed appropriately and have

raised public concern. (See Exhibit 21). With the increase in innovative solid waste management practices that involve a high degree of human contact with municipal solid waste, and with the increasing public concern with AIDS and other infectious diseases, standards are needed to reinforce and ensure that healthcare and waste management professionals appropriately manage infectious waste. The infectious waste management rules provide greater assurance that infectious waste will be managed appropriately throughout the regulated community.

E. The Need to Establish a Review Process for Offsite Decontamination of Infectious Waste.

Both incineration and autoclaving of infectious waste have a history of use for the decontamination of infectious waste. (See Exhibit 22). Viable microorganisms do not survive at the temperatures required to properly incinerate or autoclave infectious waste. These two methods are considered effective and are proven technologies for the decontamination of infectious waste.

Several new methods for decontaminating infectious waste are being developed by the waste management industry. These methods include microwaving, chemical disinfection, laser technology, and other methods that are claimed to be more cost effective and may have lesser environmental impacts. These new technologies must be reviewed to determine whether the microorganisms present in the waste are reduced to a level that renders the waste safe for routine handling. The infectious waste rules are needed to establish a review process for new decontamination technologies. Through the review of information and data, Agency staff will be able to determine whether the proposed method effectively decontaminates infectious waste and can then either approve or deny a proposed decontamination method.

V. STATEMENT OF REASONABLENESS

A. Reasonableness of Proposed Part 7035.9100 SCOPE

The scope section establishes the community regulated by these rules. It indicates that the proposed rules apply to owners and operators of facilities,

commercial transporters, and to all infectious waste without regard to quantity. This part also states that households, farms, agricultural businesses, and generators, except where specified, are exempt from these rules.

B. Reasonableness of Proposed Part 7035.9110 DEFINITIONS

Subpart 1. Scope. This subpart establishes definitions of terms that are used in Parts 7035.9100 through 7035.9150. It is necessary to establish definitions to ensure the consistent and intended interpretation of the management requirements for infectious waste.

Subparts 2, 3, 4, 6, 9, 10, 11, 16, 17, 19, 20, 21. Incorporate the statutory definitions in Minn. Stat. § 116.76.

Subpart 5. Commissioner. This subpart defines the term "Commissioner" to mean the Commissioner of the Minnesota Pollution Control Agency. This definition is included to identify the entity responsibility for review and approval/denial of management plans and proposed methods to decontaminate infectious waste.

Subpart 7. Disinfection. This subpart defines the term "disinfection" to mean the use of chemical solutions to substantially reduce the number of microorganisms present on surfaces of inanimate objects. It is necessary to define this term to specify the methods that must be used to decontaminate inanimate objects and surfaces. It is also necessary to define "disinfection" so that the terms "decontamination" and "disinfection" are differentiated and not used interchangeably. The term "decontamination" is used in reference to the treatment of infectious waste; whereas, "disinfection" is used in reference to the use of chemical solutions to treat surfaces of inanimate objects.

Subpart 8. Facility. This subpart defines the term "facility" to mean a site where infectious waste is treated, stored, or disposed. It is necessary to define this term to identify the type of facility that will be covered by these parts. The statutory definition includes "generators" of infectious waste. The Agency does not have the statutory authority to regulate generators; therefore, they have been excluded from the definition.

Subpart 12. Management plan. This subpart defines the term "management plan" to mean a written and implemented system for the safe handling of infectious waste throughout the process of generation, segregation, packaging, storage, collection, transportation, treatment, and disposal as described in

parts 7035.9130 and 7035.9140. It is necessary to define this term to identify what a management plan is. The definition is reasonable because it ensures that the contents of the plan specify infectious waste management practices that are consistent with the goals of Minn. Stat. § 116.75.

Subpart 13. Offsite. This subpart defines the term "offsite" to mean the land area and appurtenances for the storage, treatment, or disposal of infectious waste that is not on the generator's site. Minn. Stat. § 116.81, subd. 1 states that the Agency has responsibility for rules relating to transportation of infectious waste and to facilities storing, transporting, decontaminating, incinerating, and disposing of infectious waste. The statute therefore vests the Agency with the responsibility to make rules that apply to activities that occur away from the point of generation, or away from the generator's site. It is necessary to define the term "offsite" because it is used throughout these parts to clarify the regulatory scope of the Agency in the infectious waste management program and to identify the activities that are covered by these parts.

Subpart 14. Operator. This subpart defines "operator" to mean the person or persons responsible for the operation of the facility. It is necessary to define this term because responsibilities for infectious waste management are assigned to the operator.

Subpart 15. Owner or facility owner. This subpart defines "owner or facility owner" to mean the person or persons who own a facility or part of a facility. It is necessary to define this term because responsibilities for infectious waste management are assigned to the owner or facility owner throughout these parts.

Subpart 18. Putrefaction. This subpart defines the term "putrefaction" to mean the decomposition of organic matter by microorganisms, producing foul-smelling matter. Rules require that infectious waste be stored in a manner that prevents putrefaction. It is therefore necessary to define this term (so that transporters and facilities know what is prohibited by the rules) because it is used to describe the condition that infectious waste must not be allowed to reach before treatment or disposal.

Subpart 22. Spill. This subpart defines the term "spill" to mean the release of infectious waste to the environment. It is necessary to define this term to specify what constitutes a spill and to identify an incident that requires spill response and clean up procedures.

Subpart 23. Storage. This subpart defines the term "storage" to mean the offsite holding of infectious waste for more than 48 hours. Agency responsibilities are limited to infectious waste management activities that occur offsite, away from the point of generation. It is therefore necessary to define "storage" so that the requirements do not apply to generators that store their own waste at their place of business. The 48 hour time limit is included in the definition to allow generators to provide storage area for waste generated offsite, by other generators in the community, without having to file a storage management plan. It is necessary to define this term because the definition specifies the activities that constitute storage.

C. Reasonableness of Proposed Part 7035.9120 REQUIRED PRACTICES FOR FACILITY OWNERS AND OPERATORS AND COMMERCIAL TRANSPORTERS

Subpart 1. Packaging and Labeling Requirements. This subpart provides packaging and labeling requirements for infectious waste that is managed offsite. These requirements are limited to waste that is transported, stored, treated, or disposed of offsite because the statute (Minn. Stat. § 116.76) limits the responsibilities of the Agency to these activities. Onsite waste management practices must be in compliance with the statute (Minn. Stat. § 116.76), unless the MDH develops rules that expand upon the requirements of the statute.

The packaging requirements are necessary to protect workers who collect, transport, store, treat, or dispose of infectious waste, from coming in direct contact with infectious waste. With the exception of accidents, where packages are under excessive stress, the packaging standards in this part provide a reasonable barrier between the infectious waste being managed and the waste handler. The packaging standards are reasonable because they provide worker protection under normal waste handling conditions and limit the potential for direct human contact in the event of an accident.

The labeling requirements of this section expand upon the requirements of the statute (Minn. Stat. § 116.78, subd. 2). It is reasonable to expand upon the statutory labeling standards because the additional standards are more descriptive, and inform persons who must label infectious waste of the specific type of label that will be acceptable. The labeling standards required by this

part are reasonable because they result in easily identifiable, standardized labels for infectious waste.

Item A requires sharps to be placed in rigid, puncture resistant containers that have lids or caps that are designed to preclude loss or leakage of the contents. The requirement that sharps be placed in a rigid puncture resistant container is a statutory requirement (Minn. Stat.§ 116.78, subd. 4 (1)). It is reasonable to require that the containers have lids or caps so that the release of the sharps, under normal handling conditions, is prevented.

Item B requires that sharps remain packaged throughout collection, storage, decontamination, and any handling processes that precede disposal, unless the sharps have been treated by a process that renders them incapable of inducing subdermal inoculation. Minn. Stat. § 116.78, subd. 1 requires that infectious waste be packaged, contained, and transported in a manner that prevents release of the waste material. Minn. Stat. § 116.79, subd. 1.b.5 requires the contents of a management plan to include the steps that will be taken to minimize the exposure of employees to infectious agents throughout the process of disposing of infectious waste. It is reasonable to require that sharps remain packaged throughout any management processes to limit the waste handler's contact with potentially infectious waste. The potential to cause subdermal inoculation, or puncture wounds, is eliminated by treatment processes that grind, or in some other manner, alter the shape or form of the sharp. It is reasonable to exempt sharps that have undergone this type of treatment process from this packaging requirement.

In addition, item B does not prevent the use of sharps containers that are designed to be reusable if Parts 7035.9100 through 7035.9150 are met. It is reasonable to allow the use of reusable containers that contain the waste throughout transport, storage, treatment, and up to the point of disposal, because the reusable container also limits the waste handler's contact with the infectious waste. Although the use of reusable containers for sharps requires opening the container before the sharps are treated or disposed of, it achieves valuable waste reduction which is a high priority under Minn. Stat. ch. 116A. In addition, employees working with reusable containers will receive special training to reduce any risk associated with handling infectious waste and the reusable containers. Training and education programs are required in the infectious waste management plans which are reviewed by Agency staff.

Item C requires the outside of any container that has sharps being transported to an offsite facility, to be labeled, with the word "Sharps" in letters at least one inch high with a stroke width of one-eighth inch. The label must also have either the international biohazard symbol, at least three inches by three inches or the words "infectious waste" in letters at least one inch high with a one-eighth inch stroke width. The height of the letters is consistent with the letter size specified in the statute (Minn. Stat. § 116.78, subd. 2). It is reasonable to set a standard for stroke width of the letters so that the letters are visible, resulting in a package that is conspicuously labeled. A one-eighth inch stroke width is easily seen, whereas a stroke the width of a pen stroke would not be easily seen or conspicuously labeled. It is reasonable to require these containers to be labeled with the word "Sharps" to alert waste handlers to the potential hazards posed by the contents of the container. It is also reasonable to require either the international biohazard symbol or the words "infectious waste" in addition to the "Sharps" label because the biohazard symbol or the words "infectious waste" are more universally recognized than the term "Sharps".

Some individuals have commented that this item would require significant changes in sharp containers that are manufactured for use within the hospital or other generating facility. The requirement that the outer container be labeled allows several small puncture resistant containers of sharps to be placed in a larger, labeled container, such as a cardboard box or reusable container. Because the small, puncture resistant containers could potentially break open inside the larger, labeled container, the outer container needs to be labeled "Sharps" to alert waste handlers to the potential hazards of the container. This requirement is also reasonable because it does not result in changes to the types of sharps containers that are currently being used by generators. Because sharps are both a physical and biological safety hazard, workers need to recognize that special care needs to be taken when they are handled.

Item D requires infectious waste, except for sharps, to be contained in plastic bags that are impervious to moisture, and of sufficient strength to preclude ripping, tearing, or bursting under normal conditions of use and handling. It is reasonable to require that the bag be impervious to moisture to prevent leakage of liquids that are emitted from infectious solid waste items, such as blood soaked gauze. Both requirements are reasonable because they result in the integrity of the packaging being maintained throughout normal

handling processes, and thus, the barrier which prevents workers and the public from coming in contact with the infectious waste is maintained.

Item D also requires the infectious waste bag to meet the 165-gram dropped dart impact resistance test as prescribed by the American Society for Testing and Materials (ASTM) and requires the bags to be secured to prevent leakage of waste during handling, storage, treatment, transport, or disposal. The ASTM 165-gram dropped dart impact resistance test is a widely accepted industry standard. See Appendix 6. Bags that meet this test are readily available from bag manufacturers so that it is reasonable to require that the bag meet this standard. If no standard were given for the bag, very thin plastic bags that tear easily could be used. Bags that do not meet the ASTM standard would not provide a reasonable degree of protection from rupture and release of the infectious waste. It is therefore reasonable to require that bags used to contain infectious waste meet the 165-gram dropped dart impact resistance test.

Item E requires the plastic bags of infectious waste that will be shipped offsite must be packaged for storage or handling by placement in corrugated fiberboard boxes or equivalent rigid containers such as a reusable pail, carton, or portable bin. Item E also requires that the containers have tight fitting covers and be securely sealed. It is reasonable to require plastic bags of infectious waste that will be transported offsite to be placed in a rigid container, because the rigid container provides the additional containment needed to maintain the integrity of the package during routine handling and transport. During transport, bags of infectious waste will be jostled and bounced around, subjecting the bags to stresses that may exceed the ASTM standard. This could result in bags tearing and spilling blood, needles, syringes, and other types of infectious waste onto the floor of the transport vehicle. Bags of infectious waste placed in cardboard boxes or other rigid containers will prevent waste spillage and unnecessary exposure of the transporter or others to the infectious waste.

In addition, this requirement is reasonable because the bags of infectious waste may contain sharps containers. In the event that a sharps container breaks open inside the bag, the sharps would puncture the plastic bag. The corrugated cardboard box or equivalent rigid container provides a second barrier to prevent the sharps from exposing workers to injury. It is therefore reasonable to require plastic bags of infectious waste to be placed in an

additional container because the additional container provides further worker protection from needlestick injuries.

Finally, most incinerators and other treatment facilities use conveyor systems to transport waste within the facility. To contain the infectious waste and to prevent the spillage of infectious waste onto the conveyor, it is necessary to place the bags of infectious waste into a corrugated cardboard box or equivalent rigid container. It is therefore reasonable to require that bags of infectious waste be placed in a rigid container.

Item E also requires that the containers have tight fitting covers or that they be securely sealed. During routine handling, containers are sometimes handled in a manner which may allow the bags to come out of the rigid container. It is reasonable to require that the container have a secure lid to insure that the bags remain within the container.

Item F requires boxes and/or equivalent rigid containers of infectious waste to be labeled with the words "Infectious Waste" in letters at least one inch high, with a stroke width of at least one-eigth inch, or the international biohazard symbol, at least three inches by three inches. Minn. Stat. § 116.78, subd. 2 requires containers of infectious waste to be labeled with the words "Infectious Waste" in letters at least one inch high or with the international biohazard symbol. The rule adds the stroke width of one-eighth inch to the standards for the "Infectious Waste" label. It is reasonable to require a stroke width of one-eighth inch so that the label is easily identifiable. If no stroke width were specified, the width of the stroke could be the same as a pen stroke and thus would not be easily identifiable. It is also reasonable to specify a size for the biohazard symbol so that it is large enough to be easily identified.

Item G requires that containers that have been in direct contact with infectious waste be disinfected before further use. Item G also requires that the disinfection methods in subpart 6, item C, must be used. It is reasonable to require that containers that have been in direct contact with infectious waste be disinfected to reduce the number of pathogens present, and to render the containers safe for future use. It is reasonable to require that the disinfection methods in subpart 6, item C, be used because these methods have been proven successful in decontaminating surfaces.

Subpart 2. Storage Requirements. This subpart provides storage requirements that apply to the offsite storage facilities for infectious waste.

Onsite storage of infectious waste, by the generator, is not covered by these rules because the statute (Minn. Stat. § 116.81, subd. 1, 2.) divided the regulatory responsibilities for infectious waste management between the MDH and the Agency. The MDH is responsible for activities that occur onsite, at the point of infectious waste generation, and the Agency is responsible for activities that occur once the waste leaves the point of generation, or is managed offsite. Onsite storage of infectious waste by the generator must be in compliance with the statutory requirements (Minn. Stat. § 116.78, subd. 6) until the MDH develops rules to provide more specific storage requirements.

Item A requires infectious waste to be segregated from other wastes in a storage area that is designed to prevent the entry of vermin. This requirement is reasonable because vermin can act as a vector, providing a route of transmission for infectious agents to be transferred to other areas and potentially to people. The segregation requirement of this item is reasonable because it prevents the possibility of other wastes, such as hazardous waste, from being managed as infectious waste. The segregation requirement does not preclude the use of a single storage facility for several waste types, as long as the different waste types have separate areas within the storage facility.

Item A also requires that the area be secured to deny access to unauthorized persons and must be prominently marked with the biohazard symbol and the words "Infectious Waste" on or adjacent to the exterior of entry doors or access gates. It is reasonable to deny access to unauthorized persons to prevent untrained individuals from coming in contact with the waste and to prevent individuals from tampering with or otherwise disrupting the integrity of the packaging. It is reasonable to require that the storage area be prominently marked to inform workers and the public that infectious waste is being stored in the area. This allows individuals entering the room to take the special precautions necessary to protect themselves from coming into direct contact with the waste.

Item B requires the interior surfaces of storage areas to be constructed of materials that are easily cleaned. This requirement is reasonable because it allows the room to be cleaned and disinfected with a surface disinfectant in the event of a spill. This will reduce the numbers of microorganisms present and thereby reduce the potential for infection.

Item C requires that offsite storage areas be designed to contain spills. It is reasonable to require the offsite storage area to contain spills to

minimize the potential for exposure from a spill, so that a spill can be properly cleaned up and so that access to the area by unauthorized persons is limited.

Item D states that infectious waste must not be allowed to become putrescent during storage. It is reasonable to prohibit the infectious waste from becoming putrescent to prevent the production of foul smelling odors because the odors would result in a nuisance condition for individuals proximal to the storage facility. This requirement means waste must be promptly moved out of offsite storage facilities and transferred to a treatment or disposal site. This requirement is reasonable because putrescible infectious waste will reach its ultimate disposal point within a reasonable time. This will allow the Agency to determine whether the storage facility contains infectious waste that has been abandoned. Infectious waste that contains little, if any organic matter, produces little odor. Sharps, for example, would contain very little organic matter and may not produce odors when stored for very long time periods. Many generators of infectious waste, including dentists and chiropractors, generate only sharps. And many transporters only provide a sharps collection service.

It has been suggested that these parts require that infectious waste be refrigerated during storage. It would be unreasonable to require all infectious waste to be refrigerated during storage, because not all infectious waste contains organic material, and thus does not putresce and create odors. It has also been suggested that a maximum time for storage be included as a requirement. Due to the varying rates of putrescence for sharps waste only versus other highly organic, infectious waste, it is difficult to establish a fixed maximum storage time that applies to all types of infectious waste. The requirement that infectious waste be stored to prevent putrefaction is reasonable because it can be applied to all types of infectious waste.

Item E requires storage facility owners and operators to comply with the spill containment procedures in 7035.9120, subpart 6. The cleanup and spill containment procedures in 7035.9120, subpart 6 are designed to limit exposure to workers and to the public. It is reasonable to require storage facility owners and operators to comply with the spill containment procedures to ensure that worker and public exposure to the infectious waste is limited.

Subpart 3. Decontamination Requirements. This subpart provides requirements that must be met for treatment facilities that are offsite, away from the point of generation. These requirements do not apply to treatment

methods that are implemented onsite by generators. The MDH is the regulatory authority that would determine the effectiveness of treatment methods that are implemented onsite.

This subpart provides standards that must be met by offsite incinerators and autoclave treatment units. A properly operated incinerator or autoclave, will eliminate all viable microbes from infectious waste and will render the waste safe for routine handling as a solid waste.

Soeiro (1988)[1] concluded that incineration temperatures of 1500 degrees Fahrenheit to 2000 degrees Fahrenheit guarantee sterility not only of virtually all growing bacteria, viruses (including AIDS and scapies) as well as fungi. Vesley and Lauer (1986)[2] concluded that decontamination of infectious waste is achieved in gravity displacement autoclaves at 121 degrees Centigrade, 15 pounds per square inch pressure, for 60 minutes.

Documentation on the incineration and autoclaving of infectious waste demonstrates that these two methods are effective in decontaminating infectious waste. "Decontamination", as defined in the statute (Minn. Stat. § 116.76, subd. 6), refers to a reduction in the number of microorganisms to a level that renders the material safe for routine handling. Technologies other than incineration and autoclaving, must be shown to achieve a substantial reduction in the infection potential of the waste through the submittal of data or other documentation deemed necessary by the Commissioner. This will allow the Agency to review and approve new technologies in the absence of specific criteria. This will also allow the Agency to consult with the Center for Disease Control, MDH, other states and experts in evaluating the effectiveness of new technologies.

Item A requires that incinerators be operated in compliance with chapters 7001 and 7005. This requirement ensures that the incinerator is operated in compliance with the Air Quality permit requirements and emission standards. It is necessary to require that an incinerator meet these requirements to ensure that the facility is either in compliance with Air Quality rules or is on a schedule to obtain compliance. This provides notice to incinerator operators that having an approved infectious waste management plan is only part of their regulatory responsibility.

Item B, subitem (1) requires that an offsite autoclave must be operated at 250 degrees Fahrenheit at 15 pounds per square inch pressure for one hour or at least equivalent settings. When autoclaves are used to sterilize surgical

instruments, equipment, or culture media, the parameters normally used are: 250 degrees Fahrenheit, 15 pounds per square inch pressure, for one half hour. The time varies somewhat depending upon the moisture content, volume, and the ability for steam to penetrate the items. No indicators exist that determine decontamination of infectious waste by autoclaving. It has been determined through scientific study that the best way to insure that the waste is rendered safe for routine handling therefore is to double the time requirement that is used when sterilizing clean items. (See Exhibit 23). It is therefore reasonable to require that infectious waste loads be autoclaved at normal temperature and pressure settings for one hour.

The time, temperature, and pressure settings are interdependent; that is, if the temperature increases, the time required to autoclave decreases. It is therefore reasonable to allow settings that are equivalent to the 250 degrees Fahrenheit at 15 pounds per square inch pressure for one hour. Stating all of the variable settings is not reasonable due to the variety of autoclave designs that are capable of decontaminating infectious waste.

Item B, subitem (2) requires that loading of infectious waste must not exceed the design capacity of the autoclave. If an autoclave is loaded beyond its design capacity, one cannot be assured that the waste has been decontaminated. It is therefore reasonable to require that the autoclave not be loaded beyond design capacity.

Item B, subitem (3) requires that an operating log for each load of infectious waste that has been decontaminated be kept onsite for three years. The log must contain the date, time, temperature, pressure, and operator name for each load of waste treated. Because there have been no biological or physical indicators developed to ensure that waste sterilization has been achieved, a log containing operating parameters is necessary to ensure that the operator is autoclaving the waste properly. The log will serve as a record that can be checked to determine if waste is being rendered safe for routine handling. By including the operator's name, interviews of the individual operating the autoclave can be conducted to further ensure proper operating procedures. It is therefore reasonable to require that an operating log be kept that indicates the parameters used, the date, and operator's name. It is reasonable to require that the log be maintained on file for three years in the event investigations or file inspections would be conducted.

Item C requires that other methods for decontaminating infectious waste offsite must receive Commissioner approval. To obtain approval, Item C requires that the facility owner or operator proposing the decontamination method submit evidence which demonstrates that the process decontaminates the waste. When properly operated, both autoclaves and incinerators have been used effectively as methods to reduce or eliminate the number of viable microorganisms in infectious waste. These two methods have been approved as methods for decontaminating infectious waste to render it safe for routine handling. Other, new decontamination methods that have not been shown to reduce or destroy the potential infectivity of a material require Agency review to determine whether they are effective treatment methods. Because decontamination methods other than autoclaving or incineration are not well established or shown to be effective in decontaminating waste, it is reasonable to require that the owner submit data or any other form of evidence that demonstrates that the decontamination method is effective.

Subpart 4. Commercial Transporter Requirements. This subpart establishes the requirements that must be met by commercial transporters of infectious waste. A person who transports infectious waste for profit is required to meet all of the requirements listed in this subpart. Generators that transport their own waste or generators that provide collection and transport services for other generators in a community are subject to minimal transport requirements. The minimal transport requirements apply only to generators of infectious waste, not to nonprofit organizations or other entities that do not fall within the definition of a generator.

Item A requires that a commercial transporter possess a valid transporter registration as described in part 7035.9140, subpart 3. Minn. Stat. § 116.80, subd. 3 requires that a commercial transporter register with the Commissioner of the Agency. It is reasonable that a commercial transporter possess a valid registration because it enables the Agency enforcement staff to quickly and easily determine whether or not the commercial transporter acknowledges and has agreed to implement the required management practices of these parts.

Item B requires that the commercial transporter's management plan required in part 7035.9130 be kept at the address identified as the transporter's principal place of business. Minn. Stat. § 116.80, subd. 2.c. requires that the management plan be kept at the commercial transporter's principal place of business. It is therefore reasonable to require the commercial transporter to

keep a copy of the management plan at the transporter's principal place of business. This will allow the Agency staff to read the plan during inspections to assure that the commercial transporter is complying with the plan. Any questions or discrepancies can be easily researched and resolved without delays that would occur if the plan were not available.

Item C requires that a commercial transporter who transports infectious waste offsite and facilities that receive the waste must be in compliance with subitems (1) to (9). These requirements are reasonable because they ensure the appropriate management of infectious waste which results in protection of human health and the environment.

Item C.1 requires that a commercial transporter must not accept infectious waste from a generator that does not have a management plan acknowledgment card issued by the MDH or a storage or treatment facility that does not have a management plan as described in part 7035.9130. It is reasonable to require commercial transporters to collect and transport waste only from generators, storage, or treatment facilities that can demonstrate that their plan has been received by the MDH or approved by the Agency since the management plan documents the safe management practices that will be implemented. The requirement also provides a self-enforcing mechanism for the rule requiring management plans. Those generators that must use offsite storage or disposal must have an approved management plan before a transporter will accept the waste.

Item C.2 requires infectious waste to be transported in a fully enclosed vehicle compartment. It is reasonable to require that the vehicle compartment be fully enclosed to ensure that containers of infectious waste are not exposed to the environment, and to ensure that the containers are transported in a manner that limits the release of infectious waste to the environment in the event of an accident.

Item C.3 requires that infectious waste be delivered for decontamination, storage, or disposal only to a facility that has an approved management plan or to a facility that is exempt from the requirements for a management plan. Minn. Stat. § 116.80, subd. 1.b. states that a transporter may not deliver infectious waste to a facility prohibited to accept the waste. Item C.3 is reasonable because it prevents infectious waste from being transferred to facilities that are prohibited from accepting it. Infectious waste management facilities in the state of Minnesota that do not have management plans are not considered approved

facilities and are prohibited from accepting infectious waste. This requirement is therefore reasonable because it reinforces the statute (Minn. Stat. § 116.80, subd. 1.b.).

Infectious waste management facilities that are located outside of Minnesota would not have to meet the statutory requirements for a management plan and thus would be exempt. However, an out of state facility that accepts infectious waste must be approved to manage infectious waste by the state in which it is located. These requirements are reasonable because they ensure that infectious waste is managed by facilities that are in compliance with the management practices required by the statute and by these parts, and thus are managing the waste in a manner that protects human health and the environment. This will also ensure that infectious waste generated in Minnesota is not taken to another state and indiscriminately dumped or disposed of illegally.

Item C.4 requires that a commercial transporter must not deliver infectious waste to a facility owner or operator prohibited from accepting the waste. This subitem is required by statute (Minn. Stat. § 116.80, subd. 1.b).

Item C.5 requires that surface areas of equipment used to transport infectious waste must be smooth and easily cleaned. It is reasonable to require surface areas of the transport equipment to be smooth so that the integrity of cardboard boxes or other types of infectious waste containers is not compromised. It is also reasonable to require that the surfaces be easy to clean so that in the event of a spill, the surfaces can be cleaned and disinfected. This will provide a safe and sanitary transport environment for workers or others who must enter the vehicle compartment.

Item C.6 requires that infectious waste must not be compacted during transport. This is a statutory requirement (Minn. Stat. § 116.78, subd. 7). This requirement does not prohibit the compaction of infectious waste, excluding sharps, that has been decontaminated. Item C.6 also requires that sharps, or infectious waste containers that include sharps containers, must never be compacted, whether or not the sharps have been decontaminated. The statute (Minn. Stat. § 116.78, subd. 4.2) prohibits the compaction of sharps, whether or not they have been decontaminated. This prohibition keeps sharps out of the municipal solid waste stream, where garbage is routinely compacted in the back of packer trucks. If decontaminated sharps were allowed to be compacted then they could be managed as municipal solid waste. Decontaminated sharps that enter the municipal solid waste stream would end up at solid waste processing

facilities, where waste is hand sorted. The noncompaction clause of the statute protects workers that hand sort garbage. It is therefore reasonable to prohibit the compaction of sharps containers, or other types of containers that may include a sharps container, whether or not the sharps have been decontaminated.

Item C.6 also requires containers to be secured to prevent movement during transport. This requirement is reasonable because restricted movement prevents the jostling of containers, which can result in breakage and release or spilling of infectious waste. Minn. Stat. § 116.78, subd. 1 requires infectious waste to be transported in a manner that prevents release of the waste material. A requirement to secure the containers of waste to prevent movement is therefore reasonable because it helps prevent the release of the waste material.

Item C.7 states that infectious waste must not be allowed to become putrescent during transport. The rules define putrefaction as the decomposition of organic matter by microorganisms, producing foul-smelling matter. It is reasonable to prohibit the infectious waste from becoming putrescent to prevent the production of foul odors because the foul odors would represent a nuisance condition and a public health threat. This requirement can be met by minimizing the holding time by transporting the waste to its destination in an expeditious manner. This requirement may also be met by refrigerating the waste; however, refrigeration of the waste is not required by these parts. Some persons have suggested that transport vehicles should be refrigerated. The Agency concludes that this would be unreasonable since some infectious waste collection and transport companies only manage sharps which contain little, if any organic material. Because the purpose of refrigeration is to slow the putrescence of organic material, it would not be reasonable to require sharps to be refrigerated.

In addition, the Agency does not require the refrigeration of other forms of solid waste that have an equal ability to become putrescent. It would therefore be unreasonable to require the refrigeration of infectious waste.

Item C.8 requires that a person must not transport, or receive for transport, infectious waste that is not packaged and labeled according to subpart 1. The statute (Minn. Stat. § 116.78, subd. 1) requires that 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. It is therefore reasonable to require infectious waste to be packaged and labeled before transport. It is also reasonable to require

untreated infectious waste to be packaged and labeled before transport offsite because the packaging provides a protective barrier between the infectious waste and the waste handlers or others that may have contact with the waste. The label provides those individuals that handle, or otherwise come into contact with the containers, with a means of recognizing the type of materials that are contained within the package and the precautions that need to be taken during handling. It is therefore reasonable to require the infectious waste to be packaged and labeled before leaving the site of generation.

Item C.9 requires commercial transporters to comply with the spill containment requirements of Part 7035.9120 subpart 6. It is reasonable to require transporters to comply with the spill containment requirements to ensure that infectious waste spills are managed appropriately. Appropriate management of spills is necessary to limit the number of persons coming into contact with the waste, to clean up the site, and to clean up and disinfect the transport vehicle and any equipment used during the clean up. By meeting the spill containment requirements, infectious waste spills are handled in a manner that protects human health and the environment from being adversely impacted.

Item D requires that commercial transporter vehicles bear labels or placards that comply with subitems (1) and (2). Subitem (1) requires that vehicles transporting infectious waste be identified on each side of the vehicle, and on the access doors to any area holding infectious waste, with the name of the transporter and the words "Infectious Waste" in letters six inches high with a stroke width of three-fourths inch or with the international biohazard symbol, eight inches by eight inches. It is reasonable to require the transport vehicle to be marked on each side and on the access door to ensure that individuals are aware of the contents of the vehicle and are fully knowledgeable of the risks present during handling and transport and in the event of a spill. It is reasonable to require the words "Infectious Waste" or the international biohazard symbol since these labels are required on all bags, boxes, and other containers used to collect, transport, or store infectious waste (Minn. Stat. § 116.78, subd. 2). It is reasonable to require the words "Infectious Waste" to be written in letters six inches high with a stroke width of three-fourths inch so that the marking is legible from a distance great enough to allow individuals coming near the vehicle to recognize the vehicle contents and to take whatever precautions they deem necessary.

It is reasonable to require the name of the transporter because it allows a second means for complainants to identify the transporter, other than by the registration number. The name allows for more efficient and timely compliance checks by Agency staff, and is therefore a reasonable requirement.

Item D Subitem (2) requires the vehicle identification number that is issued by the Commissioner under part 7035.9140, subpart 3, to be displayed on the single unit vehicle or trailer to which it is assigned in letters and numbers at least four inches in height with a stroke width of one-half inch. It is reasonable to require each transport vehicle to display the vehicle registration number to ensure efficient and timely identification of the vehicle for compliance purposes. The size and height requirements are reasonable since they allow compliance personnel to easily identify the registration number during inspections.

Subpart 5. Generator Transport Requirements. This subpart provides the requirements that must be met by generators that transport their own waste or provide not-for-compensation collection and transport services for other generators of infectious waste. The statute (Minn. Stat. § 116.76, subd. 4) defines a commercial transporter as "a person who transports infectious or pathological waste for compensation". The statute (Minn. Stat. § 116.8, subd. 3) further requires commercial transporters to be registered. These requirements do not apply to generators who transport infectious waste on a not-for-compensation basis. It is reasonable to assume that generators who choose to transport their own waste will transport it in a manner that protects human health and the environment since these generators are also healthcare providers. Many of the generators who choose to transport waste will not be generators of large quantities of infectious waste. Some generators, especially private practitioners, often find it difficult to obtain commercial transport services due to the small quantities generated and the resultant lack of need for weekly pickup. Some generators may only need monthly pickup, for a very small quantity of waste, which many commercial transporters are unwilling to provide because there is very little profit to be made. It is therefore reasonable to allow generators to transport their own waste to ensure that it is managed appropriately. The rule allows all generators of infectious waste to appropriately manage their own waste in what may be a cost effective manner. The requirements therefore provide some generators with an economic incentive to properly manage infectious waste.

Item A requires generators who transport their own infectious waste to an offsite decontamination, storage, or disposal facility to comply with the packaging, labeling, and storage requirements of subparts 1 and 2. It is reasonable to require these generators to package and label infectious waste as described in subpart 1 since the waste is leaving the point of generation and will be exposed to the same stresses and conditions that all infectious waste is exposed to during transport to offsite facilities. The packaging, labeling, and storage requirements are reasonable for the reasons stated previously.

Item B requires generators who provide not-for-compensation infectious waste collection and transport services to comply with the packaging, labeling, and storage requirements of subparts 1 and 2 and the transport requirements of subpart 4, item C. As stated previously, it is reasonable to require these generators to meet the packaging, labeling, and storage requirements since the infectious waste would be exposed to the same conditions that all infectious waste is exposed to during transport to an offsite facility. The packaging, labeling, and storage requirements are reasonable for the reasons stated previously. It is reasonable to require the additional requirements of subpart 4, item C, which includes vehicle standards, restrictions on the type of facility that infectious waste can be transferred to, and handling requirements, since this type of generator is managing infectious waste that is generated by other entities. Since there is generally less incentive to manage someone else's waste appropriately than there is to manage one's own waste appropriately, it is therefore reasonable to require generators who transport waste generated by other generators to meet these additional requirements.

Item C requires generator transport vehicles that exceed 7,000 pounds per gross vehicle weight to be identified on each side of the vehicle, and on the access doors to any area holding infectious waste, with the name of the transporter and the words "infectious waste" in letters six inches high with a stroke width of three-fourths inch or with the international biohazard symbol, eight inches by eight inches. The requirement allows the use of magnetic placards that meet the specifications. Accidents involving large infectious waste transport vehicles would represent a significant threat to public health and the environment. Generators that are transporting large quantities of infectious waste therefore need to identify transport vehicles in a manner that alerts the public as to the vehicle contents.

Item D requires generators that transport infectious waste in vehicles that exceed 7,000 pounds gross vehicle weight to comply with annual reporting and record keeping requirements in subpart 8, items B and C, in addition to identifying the person responsible for implementing infectious waste management activities that are consistent with these parts. Item D also requires this information to be submitted to the Agency prior to the initiation of transport activities. Because these transporters are managing large quantities of infectious waste which could pose a threat to human health and the environment if improperly managed, and because these transporters are not required to submit a management plan, it is reasonable to request this information so that transport activities can be monitored. By submitting this information prior to the initiation of any transport activities, Agency staff will be notified of generators who will be transporting large quantities of infectious waste. This requirement is therefore reasonable.

Subpart 6. Spill Containment Plan. This subpart contains requirements for responding to spills. These requirements apply to any activity involving the offsite management of infectious waste including transportation, storage, treatment and disposal. Facility owners and operators must include in their infectious waste management plan, methods to clean up spills which are consistent with these requirements. It is reasonable to require facility owners and operators to include spill response procedures in the infectious waste management plan to ensure that an infectious waste spill is cleaned up, properly contained or packaged, and responded to in a manner that limits exposure of workers and the public to infectious materials.

Item A requires a spill containment and cleanup kit to be available for use in areas used for the transport, decontamination, or storage of infectious waste. To meet this requirement, facility owners and operators must have a spill containment and cleanup kit available for their use. For transporters, it is not necessary to have a complete spill containment kit in each vehicle. The spill containment kit may be kept at the principal place of business and can then be taken out to the spill site. It is reasonable to require that a spill cleanup kit be available for use so that spills can be responded to in a timely manner to minimize exposure to infectious agents.

Subitem (1) requires that the spill kit contain absorbent material for spilled liquids. Absorbent material is used to maximize the recovery of liquid wastes. It is necessary to absorb as much spilled infectious liquid as possible

to limit or minimize the impacts to public health and the environment. It is therefore reasonable to require that the spill containment kit include absorbent material.

Subitem (2) requires that the spill containment kit include one gallon of hospital grade disinfectant or disinfectant made of a formula listed in item C. When properly used, these disinfectants are effective in reducing the number of viable microorganisms on surfaces. Because vehicle surfaces, equipment surfaces, and other items may become contaminated with infectious agents during spill response, it is reasonable to require that the spill containment kit include a disinfectant that has been proven effective in reducing the number of microorganisms on surfaces. It is reasonable to require that the spill containment kit include one gallon of disinfectant since the one gallon size is readily available, is easily transported and handled by and is a large enough quantity to disinfect any surfaces that come into contact with the infectious waste.

Subitem (3) requires that the kit contain packaging and labeling, as required in subpart 1 in quantities sufficient to accommodate the quantity of waste present. When an infectious waste spill occurs, the integrity of some of the packaging may not be maintained so that the spilled waste will require new packaging and labeling. It is therefore reasonable to require that the spill containment kit include packaging and labeling to accommodate the quantity of waste present.

Subitem (4) requires that the spill containment kit include a scoop shovel, push brooms, and plastic buckets. These items are necessary to clean up a spill site. These items can be reused after they have been disinfected by using one of the hospital grade or other disinfectants listed or if they have been autoclaved or otherwise decontaminated. Because these items are necessary to pick up spilled infectious waste and to clean up the spill site, it is reasonable to require that they be included in the spill kit.

Item B lists four requirements that must be met when responding to a spill: (1) access to the spill area by unauthorized personnel must be prevented; (2) broken containers and spillage be packaged and labeled as required in subpart 1; (3) absorbent material must be applied to surface areas that have been contaminated with infectious waste; and (4) reusable items must be cleaned and disinfected using the procedures in item C. It is reasonable to require that access to the spill area by unauthorized personnel be prevented because these

individuals would be unnecessarily exposed to infectious wastes. Unauthorized personnel usually are not trained in methods to properly handle infectious waste nor are knowledgeable of the precautions that should be taken when handling infectious waste. It is therefore reasonable to require denial of access to unauthorized personnel.

Subitem (2) requires broken containers and spillage to be packaged and labeled as required in subpart 1. It is reasonable to require infectious waste spillage to be repackaged to provide a barrier between the waste and handlers or others that may come into contact with the waste. By repackaging the waste, infectious agents are effectively contained during normal, routine handling and transport. It is therefore reasonable to require that the infectious waste be repackaged.

Subitem (3) requires absorbent material to be applied to surface areas that have been contaminated with infectious waste. Because not all surfaces are nonporous, liquid infectious waste is able to penetrate or be absorbed by equipment or other items, making them difficult to disinfect. The absorbent material draws infectious waste liquids out of porous surfaces. The absorbent material reduces the number of microorganisms present on or within the contaminated item by absorbing the fluid. It also allows subsequent disinfection of the surface with a surface disinfectant to be more effective because the microbial load and amount of organic material present is reduced. It is therefore reasonable to require the application of absorbent material to surface areas that have been contaminated with infectious waste.

Subitem (4) requires reusable items to be cleaned and disinfected using the procedures in item C. Item C lists procedures that must be used to disinfect surfaces that have been contaminated by having been in direct contact with infectious waste. For disinfection to be effective, it is necessary to follow the procedures listed in item C. It is reasonable to require reusable equipment to be disinfected to lower the risk of infection for workers or others that are in contact with it.

Item C requires routine disinfectant procedures for contaminated surfaces to include, but not be limited to, agitation to remove visible soil and application of a chemical sanitizer for the contact time specified on the manufacturer's label. It is reasonable to require agitation to remove visible soil from the surface of an item that is being prepared for disinfectant application because a soiled surface impedes the disinfecting capabilities of the disinfectant.

Visible excessive soil or waste spillage provides a protective barrier and shields the infectious agents from coming into contact with the disinfectant. The visible excessive soil also increases the microbial load of the contaminated surface by providing increased surface area and because the soil itself, especially if it is waste spillage, may contain large numbers of microorganisms. Additionally, organic material inactivates some disinfectants. If a surface is soiled with organic material, the effectiveness of some disinfectants is challenged due to the inactivating properties of the organic material. It is therefore reasonable to require that the visible excessive soil be removed from surfaces that are being prepared for disinfection.

The chemical sanitizers listed in subitems (1) through (3) are EPA registered intermediate level disinfectants that have a label claim for tuberculocidal activity. (See Exhibit 24). The intermediate disinfectants destroy mycobacterium tuberculosis, vegetative bacteria, most viruses and most fungi, but do not kill bacterial spores. Subitem (4) allows the use of other chemical sanitizer solutions of disinfectant strength equivalent to those listed in subitems (1) through (3). The manufacturer's specified application time is necessary to allow the disinfectant to come into contact with microorganisms and to give the disinfectant enough time to destroy the microorganisms present on the surface. An application time of less than the manufacturer specifies is not adequate for the listed disinfectants to act on and destroy microorganisms. This requirement is reasonable because items that are disinfected in this manner are rendered safe for routine handling by workers and others that may come into contact with them.

Subpart 7. Financial Assurance. Subpart 7 establishes financial assurance requirements for off-site storage facility owners and operators. The requirements are meant to encourage prudent financial planning and to discourage abandonment of stored infectious wastes. The financial assurance requirements are imposed only on this group because the MPCA has recently had reports of infectious wastes abandoned in trailers and warehouses on the East Coast. The abandonments occurred because infectious waste transporters were unable to find affordable disposal sites. Without a disposal destination, the wastes have simply been left in location that were intended only for temporary storage. The abandoned infectious wastes are a nuisance and a threat to human health and the environment.

The Agency has had no reports of abandonment involving on-site storage facilities or disposal facilities. Further, the Agency expects there will be no abandonments at these types of facilities because facility owners and operators have strong incentives to manage stored infectious wastes with care. On-site facility owners and operators have a compelling and personal interest in maintaining their businesses in clean and healthy conditions. The infectious wastes stored on-site are the generator's wastes. They are identifiable and easily linked to the generator's business.

Likewise, disposal facility owners and operators must meet health standards, both local and state, which will ensure that stored infectious wastes are not abandoned. Administration of State permits will ensure that infectious waste storage areas are properly managed. Disposal facility owners and operators also have strong internal incentives to make sure that stored infectious wastes are properly managed. Disposal facility owners and operators do not make money by storing infectious wastes. They make money by processing infectious wastes. This financial incentive will discourage long-term storage and abandonment of infectious wastes at disposal facilities.

The limited scope of the financial assurance requirements is reasonable because the scope of the problem to be addressed is also limited.

The financial assurance demonstration is required as a necessary condition for management plan approval. The relationship of financial assurance to the management plan makes sense for three reasons.

Estimated costs are likely to vary significantly among off-site storage facilities. Different types of infectious wastes will be stored in different off-site storage facilities. Transport distances will vary. Charges at different disposal facilities will also vary. A single-valued financial assurance standard would thus be unreasonable because of the differences in costs actually incurred. Management plans will have cost estimates and all of the information developed in support of the cost estimates. The plans will take into account available capacity and unit costs. The Agency believes that the process of developing management plans will encourage off-site storage facility owners and operators to minimize storage capacity. The management plan will be used to make sure that the facility owner or operator and the Agency take full account of local conditions before proceeding to operate the storage facility.

Estimated costs are also likely to vary over time. Transportation costs and disposal rates will change. Off-site storage facility owners and operators will

need to take these changes into account when planning for final disposal of stored infectious wastes. Management plans must be revised every two years. The regular process of review and revision will make sure that cost estimates are kept current.

Relating financial assurance to the management plan gives off-site storage facility owners and operators an incentive to develop accurate and timely plans. Off-site storage facility owners and operators cannot operate without approved plans. There may be a tendency to minimize cost estimates, but this tendency will be countered by the information requirements for the management plans. The management plans must be consistent will all storage requirements. The plans must also include information sufficient to justify the cost estimates. The Agency will not approve plans that have insufficient or incorrect information. The off-site storage facility owners and operator's interest is thus engaged in development of a full and accurate management plan.

The link between financial assurance and the management plan is reasonable because it makes the financial assurance requirement sensitive to local conditions and it provides an incentive for thorough management planning.

Item A presents one alternative financial assurance method off-site storage facility owners and operators may use to meet the requirements of this subpart. Off-site storage facility owners and operators may deposit securities with the State Treasurer. The value of the securities must at least equal the estimated costs of final disposal.

Subitem (1) limits the types of acceptable securities to: bonds issued by the federal government, bonds issued by the State of Minnesota and certificates of deposit issued by banks insured by the Federal Deposit Insurance Corporation (FDIC). The Agency limits the types of securities allowed because: a) having no limit on the types of acceptable securities would place an unmanageable administrative burden on the Agency and b) the types of securities allowed are conservative investments that are readily available.

The deposits serve three purposes. First, the deposits prove that there is financial capacity sufficient to dispose of any infectious wastes that remain after the off-site storage facility stops accepting infectious wastes. At any time during facility operations or after abandonment, the deposits serve as an available financial reserve that can be used to pay for final disposal.

Second, the deposits comprise a valuable performance incentive. Off-site storage facility owners and operators who abandon infectious wastes will lose

the value of the deposited securities. The Agency believes that few off-site storage facility owners and operators will want to surrender the deposits. The potential loss will encourage responsible facility management.

Third, allowing security deposits as a financial assurance alternative makes it possible for smaller-scale firms to meet the requirement. Complying firms will have to purchase securities and deposit the securities with the State Treasurer. There will be no transaction costs involved. Most important, the firm will not have to meet the credit standards of a bank or a surety. These standards can be fairly stringent for smaller firms.

The limits on allowable forms of security and the specific forms chosen are reasonable because they promote prudent financial planning and give off-site storage facility owners and operators a manageable range of compliance methods.

Subitem (2) requires that, within ten days of deposit, an off-site storage facility owner or operator who deposits securities with the State Treasurer must send a copy of the Treasurer's receipt to the Commissioner. This requirement is reasonable because the Agency will need to have proof that the off-site storage facility owner or operator has complied with the financial assurance requirement.

Subitem (3) requires that the deposited securities be assigned to the State. The form of the assignment is specified in this subpart. The assignment has a specific purpose, which is: "environmental protection under the Infectious Waste Control Act."

Subitem (4) authorizes the Commissioner and the State Treasurer to sell deposited securities if an off-site storage facility owner or operator abandons a site. This provision gives the financial assurance requirement its intended effect. It prevents long-term abandonment of infectious wastes. If an off-site storage facility owner or operator leaves infectious wastes behind after quitting a site, the Agency can use the deposited securities to pay for cleanup and disposal. This authorization, in combination with the assignment, ensures that the Agency can take care of abandoned off-site storage facilities even if the owner or operator cannot be found. This provision is reasonable because it makes explicit the Agency's authority to use deposited securities and it specifies the conditions under which that authority can be exercised. The Commissioner's authority over deposited securities is limited. The securities will be kept by the State Treasurer's Office, which is equipped to keep the securities safe. The

Commissioner can only order security sales if there is evidence that an off-site storage facility has been abandoned. The Commissioner can only order security sales with the permission of the Agency Board. The Agency's standard procedures in actions of this sort require that all affected and interested parties be notified of the pending action and that they be given a chance to argue before the Board against the pending action. These limits on the Commissioner's authority are reasonable because they give off-site storage facility owners and operators the opportunity to challenge a decision to sell securities.

Subitem (5) requires that any interest accruing to the securities is to be sent to the off-site storage facility owner or operator. This provision is reasonable because it decreases the opportunity costs off-site storage facility owners and operators will incur in meeting the financial assurance requirement. The Agency has no reason to use the earnings that accrue to the deposited securities. However the off-site storage facility owners and operators are required to take money that their firms could use to do business and send the money to the State Treasurer for safekeeping. It is reasonable to return interest earned to the off-site storage facility owners and operators in compensation for the earnings foregone because they have to comply with the financial assurance requirement.

Subitem (6) requires that securities must remain on deposit until three months after the off-site storage facility stops taking in infectious wastes. This provision is meant to give the Agency time to determine whether the site has been abandoned and to take appropriate action. The Agency believes three months is enough time to determine, through regular inspections or through responses to complaints, that a site has been abandoned. With the information gathered during the three-month waiting period, the Agency can begin enforcement action to clean up the site. The three-month waiting period for release of deposited securities is reasonable because the Agency may need the time to develop a case against off-site storage facility owners and operators who have abandoned sites.

Subitem (7) allows deposited securities to be exchanged or replaced. This provision is reasonable because the acceptable securities have specific terms. Off-site storage facility owners and operators will pay for bonds or certificates of deposit in exchange for promises of repayment on a specified date and payment of specified interest. The securities do not pay interest

after their term ends. Off-site storage facility owners and operators will not want to have their money tied up in unproductive deposits. They will want to replace securities with terms that are about to expire. The normal procedure will be to have off-site storage facility owners and operators deposit replacement securities, then request return of the securities with expiring terms.

Subitem (8) requires that security deposits not be released without the Commissioner's written permission. This provision is reasonable because it makes effective the Agency's control of the deposited securities. The State Treasurer's office does not want to be responsible for determining whether it is proper to release securities. The off-site storage facility owners and operators cannot be given authority to withdraw deposits at will. The only reasonable course is to place the Commissioner in control of the deposits and to limit appropriately the Commissioner's discretion in exercising that control. The limits on the Commissioner's control are found in other provisions of this subpart.

The Commissioner must deny release of deposits if an off-site storage facility is abandoned or improperly closed. This provision is one of the limits to the Commissioner's control of security deposits. If an off-site storage facility owner or operator abandons or improperly closes a site, the owner or operator cannot get back the deposited securities. This provision is reasonable because the deposits will be needed to clean up the abandoned or improperly closed site.

Subitem (9) allows the off-site storage facility owner or operator to request return of deposited securities. Such requests must be sent by certified mail. This provision is reasonable because certified mailing gives proof of the date the Commissioner receives the request. This is a prudent measure which is important because the Commissioner must act on the request within a specified time period.

The Commissioner must, upon request, order the securities returned if:

* the off-site storage facility site is closed and clean,
* The owner or operator has substituted other securities of correct value for the securities that are requested; or
* there is a new off-site storage facility owner or operator who has gotten approval to run the facility.

This provision is reasonable because the Agency does not need to keep control of the security deposits if any of the conditions for return are met.

The Commissioner must refuse a return request if none of the conditions for return are met. This provision is reasonable because the conditions for return define the Agency's need to control the deposited securities. If the Commissioner were to return the deposited securities and none of the required conditions were met, there would be either: a) a lapse in financial assurance coverage or b) an abandoned site with no financial capacity available to properly dispose of remaining infectious wastes.

The Commissioner has 60 days to determine whether the conditions for return have been met. This time is allowed so that the Commissioner can review the request and determine, through site inspection or examination of receipts, whether the request is proper. The Agency expects that it will not always take 60 days to make this determination. When the request involves a routine substitution, the Commissioner can act very quickly on the request. However, circumstances may well arise that confound rapid response to return requests. The 60-day waiting period allows the Commissioner a reasonable amount of time to gather information in difficult cases.

The Commissioner must respond in writing within 30 days if it is found that none of the conditions for return have been met. This provision is reasonable because it gives the off-site storage facility owner or operator a tangible demonstration of the reason the return request is refused. An off-site storage facility owner or operator who has a return request refused may want to argue against this action before the Agency Board. The requirement that the response must be made in writing also, reasonably, compels the Commissioner to be clear and direct in stating the reasons for refusing the request.

Item B presents another alternative financial assurance method off-site storage facility owners and operators may use to meet the requirements of this subpart. Off-site storage facility owners and operators may send the Commissioner a surety bond.

A discussion of surety bonds and how they will function within the rules will be helpful here. The contract used to execute the surety agreement refers to the off-site storage facility owner or operator as the principal. The agreement specifies actions that the principal will perform, in this case proper final disposal of infectious wastes and substitution of alternative financial assurance in appropriate circumstances. If the principal fails to perform as

specified, the surety becomes liable for the costs of proper infectious waste disposal. The terms of the bond require payment to the Agency. This leaves the surety with a loss that must be recouped from the principal. Sureties charge for their assumption of this risk. The cost of a bond generally ranges from one percent to three percent of the penal sum. Sureties may also require other conditions, such as collateral, before they will execute the surety agreement.

The off-site storage facility owner's or operator's choice of surety is limited. Only sureties listed in a federal document, Circular 570 from the Department of the Treasury (published under Title 31, sections 9304 and 9308 of the U.S. Code). This document lists the sureties found to be acceptable bond writers for projects that involve federal funds. This list includes almost 300 companies, with over 30 located in Minnesota. Referring to this circular helps off-site storage facility owners or operators choose a responsible surety company. This requirement also relieves the Agency of the need to develop a certification program for firms concerning whose business the Agency has little experience. The limit on acceptable sureties is reasonable because it makes use of certification procedures already administered by the federal government.

Subitem (1) requires that the penal sum of the bond must at least equal the estimated costs of final disposal. All parties' interests are protected when the surety, the Agency and the off-site storage facility owner or operator know the extent of the surety's potential liability. This provision reasonably limits the surety's liability to the extent of the estimated need.

Subitem (2) requires that the surety agreement duplicate a model provided in another part of the rules (Part 7035.9150, subpart 1). This requirement reasonably limits the off-site storage facility owner's or operator's choices in the interest of uniformity and equity.

Subitem (3) specifies the actions of the off-site storage facility owner or operator that the surety will guarantee. The surety is required to guarantee that the off-site storage facility owner or operator will:

> properly dispose of all stored wastes after the off-site storage facility has stopped accepting wastes, and provide alternate financial assurance as specified in this subpart and obtain the commissioner's written approval of the assurance provided, within 90 days after receipt by the commissioner of a notice of cancellation of the bond from the surety.

These conditions specify the circumstances that the off-site storage

facility owner or operator, the Agency and the surety want to occur. As long as these conditions are met, there is no need to call in the bond. The surety promises that the off-site storage facility owner or operator will meet infectious waste disposal obligations and that these obligations will be continuously covered by acceptable financial assurance. This provision is reasonable because it gives the surety a specific description of the circumstances that will lead to the surety becoming liable on the bond.

Subitem (4) notifies the surety of its liabilities under the rules. If any of the conditions described in subitem (3) are not met, the surety is liable up to the amount of the penal sum. The surety's liability is limited to the amount of the penal sum. The surety must pay the penal sum to the Agency if the off-site storage facility owner or operator allows financial assurance to lapse or abandons the facility. This subitem amounts to a restatement, in the negative, of subitem (3). It clarifies the conditions under which the surety will incur cost because of the guarantees made in the surety agreement. This extra specification reasonably helps all parties understand who is responsible for what and when. Any ambiguities in these responsibilities would likely lead to unreasonable delays and unnecessary cost.

Subitem (5) covers situations in which cost estimates change. If the estimated costs of final waste disposal increase, the off-site storage facility owner or operator has 60 days in which to either increase the penal sum of the bond or find alternative means to cover the difference. This allows the off-site storage facility owner or operator owner or operator a reasonable time to make up for a gap in the facility's coverage.

If the estimated costs of final waste disposal decrease, the off-site storage facility owner or operator can reduce the bond's penal sum with written approval from the Commissioner. This provision reasonable allows the off-site storage facility owner or operator to reduce the level of coverage if it is not needed. The interests of facility users are protected by making the reduction contingent on the Commissioner's approval.

Subitem (6) specifies the method by which the surety may cancel the bond. The surety has to notify the Commissioner and the off-site storage facility owner or operator if the bond is to be canceled. The notices must be sent by certified mail. The cancellation cannot become effective until 120 days after the Commissioner receives the notice. Return receipts from the mailed notices will provide evidence of the date on which the Commissioner receives the notice.

This provision ensures that there will be no gaps in coverage caused by the surety's decision to cancel the bond. The period between first notification and final effects allows the off-site storage facility owner or operator time to find another surety or another means to comply with the financial assurance requirement. This period is 30 days longer than the time period set in subitem (3). The extra 30 days gives the Commissioner time to call on the bond, because during this 30-day period the surety is still liable to the bond's conditions.

An example will provide some help in understanding the process. Consider a case in which an off-site storage facility owner or operator gets notice that the surety bond will be canceled. If the off-site storage facility owner or operator provides an acceptable alternative financial assurance demonstration within 90 days, then the bond can be canceled 30 days later with no effect. There will be no gap in coverage. However, if the off-site storage facility owner or operator does not find an acceptable alternative, this means that within 30 days the estimated costs of final disposal will not be covered by financial assurance. The Commission can call on the bond during this 30-day period because one condition of the bond is that the off-site storage facility owner or operator will find an acceptable alternative within 90 days.

This provision gives the Agency a reasonable means to ensure that coverage will not lapse. Either the surety will guarantee that the off-site storage facility owner or operator will properly close the facility or the surety will pay the Agency enough money to close the facility.

Subitem (7) describes the conditions under which the off-site storage facility owner or operator may cancel the bond. The bond may be canceled if the conditions of subitem (3) are met; namely, that the facility is closed an all wastes remaining are properly disposed or that an acceptable alternative financial assurance demonstration has been provided. Bond cancellation requires the Commissioner's written approval. This requirement is reasonable because it allows the off-site storage facility owner or operator some flexibility in using a financial assurance method of choice and, at the same time, it ensures that there will be no gaps in coverage.

Subitem (8) places a further limit on the surety's liability. The off-site storage facility owner or operator will at some point be released from financial assurance responsibilities. This subitem provides the surety with a release from liability after the Commissioner has done away with the off-site storage facility owner's or operator's compliance responsibility. There is no reason to

carry the surety bond agreement in full force after the Agency has determined there is no need to continue the financial assurance requirement.

Item C presents another alternative financial assurance method off-site storage facility owners and operators may use to meet the requirements of this subpart. Off-site storage facility owners and operators may send the Commissioner a letter of credit.

A letter of credit extends the credit of one individual or organization (often a bank) which has credit superior to that of a second individual or organization (the off-site storage facility owner or operator, in this case) to a third individual or organization (the Agency, in this case) on behalf of the second individual or organization.

The letter of credit will provide security in much the same way as the surety bond described under item B. A bank issues the off-site storage facility owner or operator credit equal to the estimated costs of final waste disposal. The letter of credit will remain in effect until the off-site storage facility owner or operator is released from responsibility to comply with the financial assurance requirement. While the letter is in effect, the bank will honor any draft properly presented by the Commissioner. The Commissioner can present a draft only if the off-site storage facility owner or operator has failed to meet specified conditions; namely, proper care of a closed facility and timely replacement of lapsed financial assurance arrangements.

A bank will recover from the off-site storage facility owner or operator any credit used by the Commissioner. Banks charge for letters of credit at rates which are comparable to rates charged for surety bonds. Banks also charge interest on outstanding balances of extended credit.

The off-site storage facility owner's or operator's choice of banks is limited. Only banks regulated by a federal or Minnesota State agency can extend an acceptable letter of credit. This requirement helps off-site storage facility owners or operators choose a responsible surety company. This requirement also relieves the Agency of the need to develop a certification program for firms concerning whose business the Agency has little experience. The limit on acceptable banks is reasonable because it makes use of certification procedures already administered by the federal and state governments.

Subitem (1) requires that the credit extended must at least equal the estimated costs of final disposal. All parties' interests are protected when

the bank, the Agency and the off-site storage facility owner or operator know the extent of the bank's potential liability. This provision reasonably limits the bank's liability to the extent of the estimated need.

Subitem (2) requires that the letter of credit duplicate a model provided in another part of the rules (Part 7035.9150, subpart 2). This requirement reasonably limits the off-site storage facility owner's or operator's choices in the interest of uniformity and equity.

Subitem (3) requires that the off-site storage facility owner or operator identify the institution that issues the letter of credit. This requirement is reasonable because the agreement needed to issue a letter of credit is not nearly as detailed as the surety contract. The off-site storage facility owner or operator must send the Commissioner a letter that refers to:

1. the identification number of the letter of credit,
2. the name of the issuing institution,
3. the date on which the credit is issued,
4. the identification number, name and address of the facility, and
5. the amount of the estimated cost of final waste disposal.

This information provides the Commissioner with the information that reasonably will be needed to administer the system.

Subitem (4) specifies certain conditions the bank must include in the letter of credit. The credit must be irrevocable for a period of one year. This requirement reasonably gives the off-site storage facility owner or operator and the Commissioner certainty about the period that is covered. The letter of credit must also be extended automatically for one year following the expiration date. This extension is not absolute. It would not be reasonable to make the bank extend credit indefinitely. Banks can cancel the letter of credit under certain conditions. The main condition is proper notification.

The bank has to notify the Commissioner and the off-site storage facility owner or operator if the letter of credit is to be canceled. The notices must be sent by certified mail. The cancellation cannot become effective until 120 days after the Commissioner receives the notice. Return receipts from the mailed notices will provide evidence of the date on which the Commissioner receives the notice.

This provision ensures that there will be no gaps in coverage caused by the bank's decision to cancel the letter of credit. The period between first

notification and final effects allows the off-site storage facility owner or operator time to find another bank or another means to comply with the financial assurance requirement. This period is 30 days longer than the time period set in subitem (7) below. The extra 30 days gives the Commissioner time to call on the bond, because during this 30-day period the bank is still required to honor a sight draft presented properly by the Commissioner.

An example will provide some help in understanding the process. Consider a case in which a off-site storage facility owner or operator gets notice that the letter of credit will be canceled. If the off-site storage facility owner or operator provides an acceptable alternative financial assurance demonstration within 90 days, then the letter of credit can be canceled 30 days later with no effect. There will be no gap in coverage. However, if the off-site storage facility owner or operator does not find an acceptable alternative, this means that within 30 days the estimated costs of final disposal will not be covered by financial assurance. The Commission can draw on the letter of credit during this 30-day period because it remains in effect for 120 days following the notice of cancellation.

This provision gives the Agency a reasonable means to ensure that coverage will not lapse. Either the bank will extend the credit needed to guarantee that the off-site storage facility owner or operator will properly close the facility or the bank will pay the Agency enough money to close the facility.

Subitem (5) covers situations in which cost estimates change. If the estimated costs of final waste disposal increase, the off-site storage facility owner or operator has 60 days in which to either increase the amount of the letter of credit or find alternative means to cover the difference. This allows the off-site storage facility owner or operator owner or operator a reasonable time to make up for a gap in the facility's coverage.

If the estimated costs of final waste disposal decrease, the off-site storage facility owner or operator can reduce the amount of the letter of credit with written approval from the Commissioner. This provision reasonably allows the off-site storage facility owner or operator to reduce the level of coverage if it is not needed. The interests of facility users are protected by making the reduction contingent on the Commissioner's approval.

Subitem (6) specifies the conditions under which the Commissioner shall draw on the letter of credit. If the off-site storage facility owner or operator abandons the facility, the Commissioner is required to draw on the letter of

credit. This provision is reasonable because it clarifies the conditions under which the bank will incur cost. This specification helps all parties understand who is responsible for what and when. Any ambiguities in these responsibilities would likely lead to unreasonable delays and unnecessary cost.

Subitem (7) describes another condition under which the Commissioner is required to draw on the letter of credit. The off-site storage facility owner or operator is given 90 days after receiving a cancellation notice to find another means to comply with the financial assurance requirement. If the off-site storage facility owner or operator does not find an acceptable alternative, the Commissioner must draw on the letter of credit.

The Commissioner may delay this action if the bank further extends the credit. However, the Commissioner must draw on the letter of credit during the last 30 days of any extension if, before the 30 days begins, the off-site storage facility owner or operator has not submitted an acceptable alternative financial assurance demonstration.

These provisions give the Agency a reasonable means to ensure that coverage will not lapse. Either the bank will guarantee that the off-site storage facility owner or operator will properly close the facility or the bank will pay the Agency enough money to close the facility.

Subitem (8) places a further limit on the bank's liability. The off-site storage facility owner or operator will at some point be released from financial assurance responsibilities. This subitem requires the Commissioner to return the letter of credit if the off-site storage facility owner or operator properly closes the facility or provides an acceptable financial assurance alternative. This requirement provides the bank with a release from liability after the Commissioner has done away with the off-site storage facility owner's or operator's compliance responsibility. There is no reason to carry the letter of credit in full force after the Agency has determined there is no need to continue the financial assurance requirement.

Subpart 8. Reporting and Record Keeping. This subpart includes requirements for annual reporting and record keeping. This subpart requires facility owners and operators and commercial transporters to maintain records for a minimum of three years. If the three-year period expires during an unresolved enforcement action, the period is automatically extended until resolution of the pending enforcement action. This subpart also lists the information required in the annual report. The annual report is submitted on

the anniversary date of management plan approval. The annual report differs from the management plan in that the annual report provides Agency staff with minimal information on a yearly basis; whereas, a management plan provides the Agency with detailed and specific information that is submitted every two years. It is reasonable to require submittal of an annual plan to more accurately assess the quantities of infectious waste that are being managed in the state which, in turn, allows Agency staff to assess its program needs. A compilation of the annual reports will allow Agency staff to evaluate the infectious waste management needs of the state and predict and react to potential problem areas in the state. The annual report is therefore a reasonable requirement.

It is reasonable to require that annual reports be kept on file for three years to insure the receipt of data by the Agency and to insure that current, significant, data is available at the facility site for review during inspections. It is reasonable to require extension of the three year holding period during an unresolved enforcement action to insure that the necessary and pertinent data are available for reference. It is reasonable to require facility owners and operators and commercial transporters to report the information on the anniversary date of management plan approval since it is necessary to establish a date for submittal. It is reasonable to select the anniversary date of plan submittal as the date for report submittal so that the facility owner or operator must only remember one date for submission of plans and reports.

Item A requires the title and name of the individual responsible for implementation of the management plan as specified in part 7035.9130, item A. It is reasonable to require the title and name of the individual responsible for implementation of the management plan so that the individual can be contacted if information in the report needs to be clarified, or if Agency staff has other questions that need to be answered. It is reasonable to require both the name and title, since personnel changes may result in a different person being responsible for preparing and submitting the report. The title may be used to contact the person currently responsible for the annual report instead of the name of the person.

Item B requires that incidents in which infectious waste is released to the environment be reported. It is reasonable to require reports of spills as a compliance measure to ensure that the facility owner or operator or commercial transporter cleaned the spill up properly. It is also reasonable to request

information on infectious waste spills so that Agency staff is aware of them in the event that there are future environmental or public health impacts that need to be followed up. Finally, information on infectious waste spills allow the Agency staff to evaluate its spill containment requirements and determine whether additional requirements or changes are needed.

Item C requires descriptions of the amounts of infectious waste managed. Item C specifically requires owners and operators of storage and decontamination facilities to submit information regarding the quantities of infectious waste and sharps managed that were generated in Minnesota and quantities of infectious waste and sharps managed that were generated outside of Minnesota. Item C requires commercial transporters to submit information regarding only the quantities of infectious waste and sharps managed that were generated in Minnesota. It is reasonable to require storage and decontamination facility owners and operators to submit information regarding both the sources and quantities of the waste because these facilities will be located and permitted in Minnesota. Storage and decontamination facilities may be managing both infectious waste that is generated in Minnesota and infectious waste that is generated in other states. To obtain accurate data on the amounts of infectious waste generated in Minnesota, and to determine the available capacity for infectious waste generated in Minnesota, it is necessary for storage and decontamination facility owners and operators to differentiate between the amounts of waste managed that was generated in Minnesota versus the amounts of waste managed that was generated outside of Minnesota. Because the storage and decontamination facilities will be providing data on the amounts of infectious waste and sharps managed that are coming from outside the state, it is not necessary to require commercial transporters to quantify waste generated in Minnesota versus waste generated outside of Minnesota. Furthermore, the question of capacity, or the ability for existing storage and decontamination facilities to manage infectious waste generated in Minnesota is not dependent upon transport activities. It is therefore reasonable to allow commercial transporters to submit only the information regarding the quantities of waste managed that was generated in Minnesota.

Subitem (1) and (2) require the weight or number and size of containers of infectious waste or sharps transported, decontaminated, stored, and disposed of, giving the decontamination and disposal methods used, to be included in the annual report. If sharps containers are routinely placed into bags of

infectious waste, making quantification difficult, it is reasonable for the facility owner or operator or commercial transporter to submit only the weight or number and size of containers of infectious waste. Currently, Minnesota has no data on the amounts of infectious waste generated. It is reasonable to request information regarding the quantities of waste generated so that Agency staff can assess program needs on an annual basis and so that Agency staff can evaluate infectious waste management needs in various parts of the state. The annual reporting of quantities will also allow Agency staff to gauge future capacity needs for management of this type of waste. The annual reports will also provide the data necessary to demonstrate to federal policymakers the effectiveness of Minnesota's infectious waste program versus the federal manifest system. The annual reporting of quantities of infectious waste and sharps by facility owners or operators and commercial transporters is therefore reasonable.

D. Reasonableness of Proposed Part 7035.9130 MANAGEMENT PLAN

This part requires each facility owner or operator and commercial transporter to develop and submit to the Commissioner for approval a management plan that meets the requirements of this part. This requirement is reasonable because it is required by the Infectious Waste Control Act (Minn. Stat. § 116.75). This part also requires that a copy of the management plan be updated and resubmitted at least once every two years to the Commissioner and to the county solid waste officer. The statute requires the submittal of an infectious waste management plan once every two years (Minn. Stat. § 116.79, subd. 1.e). It is reasonable to require that a copy of the management plan be submitted to the county solid waste officer since infectious waste is a solid waste. Counties may wish to be informed on solid waste management practices occurring in their jurisdiction. Although infectious waste requires different handling and management methods than municipal solid waste, once decontaminated, infectious waste is managed as a solid waste. It is reasonable for county solid waste officers to receive a copy of the management plan so that they are aware of the amounts of infectious waste being managed in the county and to determine future capacity needs. This part also requires that a current copy of the management plan be maintained onsite. This requirement is reasonable because it allows Agency inspectors to determine whether the facility owner or operator or

commercial transporter has a current, approved management plan and whether the facility or commercial transporter is operating in compliance with the plan. A facility owner or operator or commercial transporter who cannot provide a current, updated plan is in violation of the statute (Minn. Stat. § 116.79, subd. 1.C). This part also requires that the management plan include management methods that are consistent with the statutory requirements and with the requirements in this part. The statute provides minimal requirements for a management plan. Additional requirements are included in this part. The additional requirements will result in the Agency having valuable information. It is reasonable to require the submission of the information required by statute and additional information required by this part.

Item A requires the name and title of the individual responsible for the implementation of the management plan. The statute (Minn. Stat. § 116.79, subd. 1.b.6) requires the submission of the name of the individual responsible for the management of infectious or pathological waste. Because companies go through personnel changes, it is reasonable to request the title of the individual responsible for implementation of the management plan.

Item B requires a description of packaging and identification labels used for the packaging and offsite transport of infectious or pathological waste as specified in part 7035.9120, subpart 1. The submission of information on packaging and labeling will allow Agency staff who are reviewing the management plans to determine whether the owner/operator acknowledges the packaging and labeling requirements by these parts. If the management plan specifies packaging and labeling that is different than what is required by part 7035.9120, subpart 1, then the management plan will not be approved. Because the submittal of this information helps to determine compliance with the packaging and labeling requirements, it is reasonable to request the information.

Item C requires that the facility owner or operator or commercial transporter submit a spills containment plan, that includes personal protection, cleanup, and repackaging, as specified in part 7035.9120, subpart 6. The spills containment plan should be incorporated as part of the infectious waste management plan. If the spills containment plan is incomplete, or contains information that is not consistent with the requirements of part 7035.9120 subpart 6, the infectious waste management plan will not be approved. It is reasonable to require the submittal of a spills containment plan to ensure that

the facility owner or operator or commercial transporter acknowledges the precautions that need to be taken to effectively clean up a spill. By complying with the requirements in part 7035.9120, subpart 6, a facility owner or operator or commercial transporter will be responding to an infectious waste spill in a manner that limits the risk of exposure to workers and others that may come into contact with the infectious waste. By including spill containment procedures in the infectious waste management plan, the facility owner or operator or commercial transporter is declaring that all infectious waste spills will be responded to in compliance with these parts.

Item D requires that a staff training and continuing education plan for employees who handle infectious or pathological wastes must be included in the infectious waste management plan. The statute (Minn. Stat. § 116.79, subd. 1.b.5) requires the submission of information regarding 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. A staff training and continuing education program that instructs workers on the appropriate handling, packaging and labeling of infectious waste will result in minimizing the exposure of the employees to infectious agents and thus, achieve the goals of the statute. It is therefore a reasonable requirement.

Item E requires facilities that decontaminate infectious waste to develop a contingency plan that identifies alternative management methods that will be used during shutdown. It is reasonable to request information regarding alternative management methods that will be implemented in the event of facility shutdown to ensure that the waste continues to be managed in a manner that protects human health and the environment. If no contingency plan were developed, the facility may not be prepared to manage the waste. By providing a contingency plan as part of the infectious waste management plan, the facility is preparing for the potential inability of the facility to manage the waste. The contingency plan provides assurance to the Agency staff that the waste will be managed appropriately by the alternative identified in the contingency plan.

Item F requires the facility owner or operator to report the length of time that waste will be stored at a storage facility. This requirement applies to the offsite storage of infectious waste. Persons that provide storage for more than forty-eight hours for waste that is generated offsite are infectious waste storage facilities. For example, an offsite decontamination facility, such as a commercial incinerator, where waste is held for more than forty-eight hours is

also a storage facility and must submit a separate management plan. By requiring a facility owner or operator to report the length of time that waste will be stored, Agency staff can determine if the facility is a storage facility. Requiring submission of this information is reasonable because it allows Agency staff to cross reference management plans to ensure compliance with the storage requirements.

Item G requires the owner or operator to submit information on the method of receiving infectious or pathological waste to ensure that infectious or pathological waste is handled separately from other waste until decontamination is completed. Item G also requires the owner or operator to submit information on methods used to prevent unauthorized persons from having access to or contact with the waste. The statute (Minn. Stat. § 116.78, subd. 1) requires all untreated infectious waste to be segregated from other waste material at its point of generation. It is reasonable to require the owner or operator to submit information on methods used to achieve the statutory requirement. If the infectious waste that is received by the facility is stored for more than forty-eight hours, the segregation information submitted must comply with the storage requirements of part 7035.9120 subpart 2.A. The management plan cannot be approved unless the information is consistent with part 7035.9120 subpart 2.A. It is reasonable to require that the owner or operator submit this information to ensure compliance. The requirement for information regarding methods used to prevent unauthorized persons from having access to or contact with the waste is reasonable because the facility owner or operator acknowledges that precautions need to be taken to minimize the risk of exposure to unauthorized persons.

Item H requires that the owner or operator include a description of the methods used to unload and process infectious waste to limit the number of employees handling the waste and minimize the possibility of exposure of employees. It is reasonable to require the owner or operator to submit information on the measures that will be taken to minimize risk of exposure to employees to ensure that the measures being taken result in safe handling practices that reduce the risk of accidents and disease. The overall intent of the statute is to protect human health and the environment through proper management of infectious waste. Proper management includes worker safety. It is therefore reasonable to require the owner or operator to include a

description of the methods used to unload and process infectious waste that minimize the possibility of exposure of employees.

Item I requires that the owner or operator include a description of the methods used to disinfect emptied reusable containers, surface areas of transport vehicles, and facility equipment that has been in contact with infectious waste. When these surfaces have been in contact with infectious waste, the risk of acquiring an infection increases. By requiring the disinfection of these surfaces with one of the disinfectants listed in part 7035.9120 subpart 6, the numbers of microorganisms existing on these surfaces is substantially reduced. This reduces the risk of infection. It is reasonable to require that the owner or operator submit information on the disinfection methods to insure compliance with part 7035.9120 subpart 6 and 7035.9120 subpart 1.G.

Item J requires information regarding the methods used to store and transport infectious or pathological waste in a manner that prevents putrefaction to be included in the infectious waste management plan. By including this information in the management plan, the facility owner or operator is declaring that transportation and storage of waste is done in a manner that prevents putrefaction, and therefore will result in the waste being managed appropriately. It is therefore reasonable to require this information since it ensures that the waste does not putresce and cause a nuisance condition.

Item K requires the owner or operator to submit information on the weight or number and size of containers of infectious waste and sharps to be stored, transported, decontaminated, or disposed of at an approved facility to be included in the management plan. This information is necessary to plan for future program needs, to determine future capacity needs for managing infectious waste, and to obtain valuable information that is needed to affect federal policymaking. It is therefore reasonable to require this information. Item K requires storage and decontamination facility owners and operators to differentiate between quantities of waste managed that was generated in Minnesota versus quantities of waste managed that was generated outside of Minnesota, in other states. It is necessary to require this information to determine the ability of facilities permitted in Minnesota to manage infectious waste that was generated in Minnesota. Available capacity to manage Minnesota's infectious waste needs to be determined to plan for future capacity needs.

Commercial transporters must submit information regarding only the quantities of infectious waste managed that was generated in Minnesota. Because the transport of infectious waste does not affect the available capacity at permitted facilities in Minnesota, only the quantities of infectious waste managed that was generated in Minnesota needs to be quantified.

Item L requires that a list containing the name, location, and contact persons of the decontamination, storage, or disposal facilities that will be used, must be included in the infectious waste management plan. It is necessary to require information on the facility that will be used to decontaminate, store or dispose of infectious waste to ensure compliance with Minn. Stat. § 116.80, subd. 1.A. that the waste be managed only at approved facilities. It is therefore reasonable to require this information to ensure compliance.

Item M requires an estimate to be made of all costs that will be incurred after the storage facility ceases to accept infectious wastes. This requirement is reasonable because it is needed to set financial assurance rates. Moreover, there is the added benefit derived from storage facility operators' knowledge of future costs. Putting this information in the management plan assures the Commissioner that the operator knows the magnitude of long term care costs.

E. Reasonableness of Proposed Part 7035.9140 MANAGEMENT PLAN CERTIFICATION PROCEDURES

Subpart 1. Management Plan Application. Item A requires that a management plan submitted to the Commissioner for approval must provide the information listed in part 7035.9130 and be signed. One criteria that must be met for management plan approval is that the plan be complete. An incomplete plan does not contain the information needed to ensure compliance with the statute. It is therefore reasonable to require a management plan to include all of the requirements listed in the part 7035.9130, to be approved.

Item B requires an existing facility owner or operator or a commercial transporter to submit a management plan within 45 days of the adoption of parts 7035.9100 to 7035.9150. It is reasonable to require existing facility owners or operators or commercial transporters to submit management plans within 45 days of adoption of these parts since these individuals have been kept informed of the proposed requirements and the progress of developing these parts. Since these individuals have been given the opportunity to review the developing

standards throughout the process, the forty-five day time period in which plans must be submitted is sufficient and thus, reasonable. In addition, the statute (Minn. Stat. § 116.75) required the submission of management plans by January 1, 1990. The MPCA extended the submission date to allow for the development of rules. Owners and operators have had an extended period of time to develop management plans. It is therefore reasonable to require management plans to be submitted within 45 days of adoption of these parts.

Item C requires a facility owner or operator or commercial transporter that begins the transport, storage, decontamination, or disposal of infectious waste after adoption of parts 7035.9120 to 7035.9150 to submit to the Commissioner a copy of the management plan before initiating the handling of the infectious waste. It is reasonable to require new infectious waste management facilities to obtain an approved management plan before beginning to handle infectious waste to ensure compliance with parts 7035.9120 to 7035.9150.

Item D requires a generator that also incinerates infectious waste to submit a management plan for incineration activities in addition to any plan required by the MDH. The statute (Minn. Stat. § 116.79, subd. 3.C.) requires generators that incinerate infectious waste to submit a separate management plan for incineration activities to the Agency. It is therefore reasonable to include this requirement.

Item E requires a facility owner or operator that has an approved management plan to update and resubmit a plan every two years. This requirement is included in the statute (Minn. Stat. § 116.79, subd. 1.e.). Item E also requires an updated plan to be submitted at least 30 days before the expiration date of the plan. This requirement is reasonable to ensure that the Agency receives the updated plan before the expiration date of the previous plan. This ensures that the facility owner or operator or commercial transporter will remain in compliance with statute and rules. This also gives Agency staff time to review the plan and get it back to the owner or operator before the current management plan expires. It is therefore reasonable to require the submittal of an updated plan at least thirty days prior to the expiration date of the plan to determine the compliance status.

Subpart 2. Certification Fees. This subpart requires all management plans that are submitted to the Agency to include the certification fee. Management plans that are prepared by facility owners or operators that store, decontaminate, or dispose of infectious waste, other than at the facility that

generates the infectious waste, or a management plan prepared by a facility that incinerates onsite at a hospital must be submitted to the Commissioner with the certification fee. Since the fee is required by the statute (Minn. Stat. § 116.79, subd. 4) it is reasonable to require that the certification fee be submitted along with the management plan.

Subpart 3. Commercial Transporter Registration. This subpart requires commercial transporters to register with the Commissioner. This requirement is reasonable because the statute requires all commercial transporters to be registered (Minn. Stat. § 116.8, subd. 3). This subpart also requires that the management plan application procedures comply with part 7035.9140 subpart 1. It is reasonable to require all management plan submittals, including commercial transporter management plan submittals, to comply with the procedures in 7035.9140 subpart 1. These requirements are reasonable for the reasons stated previously.

This subpart also requires registered transporters to keep registration cards in each single unit vehicle or trailer and at the address identified as the principal place of business. It is reasonable to require that the registration cards be kept at each of these locations to allow Agency staff who are inspecting the facility to easily determine whether the facility has an updated and approved management plan. This subpart also requires that the vehicle identification number be displayed as required in part 7035.9120, subpart 4, item D, subitem (1). It is reasonable to require that the identification numbers be displayed on each of the registered vehicles to allow easy identification by Agency staff or others during inspections. The numbers allow for easy determination of the compliance status of the registered transporter.

Subpart 4. Exemption From Commercial Transporter Registration. Subpart 4 identifies conditions under which transporters are exempt from commercial transporter registration. Transporters who are exempt from the commercial transporter requirements are not exempt from packaging and labeling requirements for infectious waste found in part 7035.9120, subpart 1. It is reasonable to require all transporters of infectious waste to package and label the waste as required by part 7035.0120, subpart 1 since all infectious waste that is transported to offsite facilities is subject to the same handling and transport stresses.

Item A exempts from registration generators that transport their own infectious waste to an approved facility. It is reasonable to exempt these transporters from registration requirements since these transporters are hauling only their own infectious waste and are not collecting and transporting other generator's waste for compensation. This type of transporter does not fall within the statutory definition of "commercial transporter" (Minn. Stat. § 116.79, subd. 4). The statute only requires the registration of commercial transporters (Minn. Stat. § 116.80, subd. 3). It is therefore reasonable to exempt generators who transport their own infectious waste, if the infectious waste is transported to a facility that has been approved to accept the waste.

Item B exempts a generator that provides not-for-compensation infectious waste collection and transport services for other generators. It is reasonable to exempt these transporters since they do not fall within the definition of a "commercial transporter" (Minn. Stat. § 116.79, subd. 4). The statute only requires the registration of commercial transporters (Minn. Stat. § 116.80, subd. 3). It is therefore reasonable to exempt generators that provide not-for-compensation infectious waste collection and transport services for other generators. The additional requirements that these transporters must meet ensures the proper management of the infectious waste. The registration exemption applies only to generators that provide not-for-compensation infectious waste collection and transport. Other not-for-compensation collection and transport services, such as not-for-compensation civic groups, would not be exempt from the commercial transporter registration requirements. Because generators would be managing their own waste, in addition to other generator's waste, it is reasonable to expect that these generators are fully responsible and knowledgeable of the special precautions that must be taken during infectious waste handling and transport. It is therefore reasonable to allow generators who want to provide not-for-compensation infectious waste collection and transport services for other generators to be exempt from the commercial transporter requirements. In addition, generators of infectious waste must submit a management plan to the MDH for the management of infectious waste within the facility. Along with the management plan, the generator must submit a certification fee. It is therefore not reasonable to require an additional fee to be paid by generators who want to provide not-for-compensation collection and transport services. One of the purposes of the infectious waste management program is to ensure the proper management of infectious waste in a

cost effective and feasible manner. This exemption allows generators to properly transport infectious waste in a cost effective manner, and is therefore a reasonable requirement.

Item D exempts persons who provide collection and transportation of sharps for households as part of the feasibility study required by Laws 1989, chapter 337, section 10. It is reasonable to exempt a commercial transporter that participates in the feasibility study because the duration of the study will be for a short period of time. It would be unreasonable to require the preparation of a management plan and the submittal of a certification fee if the transporter is involved in the feasibility study only. As part of selecting the transporter for the feasibility study, the transporter will be submitting information regarding handling, transport, decontamination, storage, and disposal of the sharps. This information will replace an infectious waste management plan. It is therefore reasonable to exempt this type of transporter from the management plan, certification fee, and registration requirements.

Subpart 5. Transporter Registration Fees. This subpart requires management plans prepared by commercial transporters of infectious waste to be submitted to the Commissioner with the registration fee required under Minnesota Statutes, section 116.80, subdivision 3. Since both the registration fee and the management plan are statutory requirements, it is reasonable for the Agency to require that they are submitted together.

Subpart 6. Signatories to Management Plans. This subpart requires that all management plans be signed by an individual who takes responsibility for implementation of the plan. Item A requires plans that are submitted by corporations, to be signed by an executive officer, or an agent or representative of the executive officer if the agent or representative is responsible for the implementation and evaluation of the management plan. It is reasonable to require that plans submitted by corporations be signed by the executive officer of the corporation because the executive officer is responsible for the corporation. By signing the management plan, the executive officer acknowledges his/her responsibility to ensure the corporation complies with these parts. Item B requires management plans that are submitted by a municipality, or state, federal, or other public agency, to be signed by either an executive officer or a ranking elected official and by the individual responsible for implementation of the management plan. It is reasonable to allow the plan implementation and evaluation to be conducted by an individual

other than an elected official or executive officer since either an elected official or an executive officer may not directly oversee activities involving infectious waste management. It is, however, reasonable to require the signature of either an elected official or an executive officer because it is necessary to have an individual in a responsible position accept and acknowledge responsibility for whomever is appointed to implement and evaluate the management plan. It is also reasonable to require the signature of the individual who is responsible for plan implementation and evaluation so that this individual fully acknowledges the responsibilities he/she must carry out to remain in compliance with these parts.

Subpart 7. Duration of Management Plan. This subpart states that a management plan is effective for two years after the date of plan approval unless enforcement actions result in the revocation of the plan. An approved management plan may not be valid for the two year period if the facility owner or operator or commercial transporter has enforcement actions brought against them. It is reasonable for the Commissioner to revoke an approved management plan for a facility that is out of compliance since the revocation will suspend infectious waste operations until the facility can be operated in a manner that is protective of human health and the environment. Actions taken by the Commissioner are subject to review by the Agency and other administrative processes that will preclude the Commissioner from arbitrary action.

Subpart 8. Review and Approval or Denial of Management Plans. This subpart identifies the methods that will be used to review and approve or deny a management plan. This subpart also lists conditions that must be met for plan approval. Item A requires all management plans to be reviewed for completeness by the Commissioner. It is reasonable to include completeness as a criteria for plan approval since an incomplete plan would not provide the information necessary to determine whether the facility is managing its infectious waste appropriately. Item A also states that the Commissioner shall promptly advise the signatory of the management plan of the incompleteness and that further processing of the management plan may be suspended until the necessary information is supplied. It is reasonable to suspend any further processing of the plan until the necessary information is submitted since an incomplete plan does not meet the threshold criterion of completeness.

Item B states that a management plan shall be approved if the plan is determined to be complete and consistent with these parts. A letter of approval

signed by the Commissioner shall be sent to the applicant upon approval of the plan. It is reasonable to require a management plan to be consistent with the required management practices and to include all the information required in a management plan to ensure that the facility acknowledges the management practices necessary to protect human health and the environment. By acknowledging appropriate infectious waste management practices, the facility owner or operator who submits the plan takes full responsibility for ensuring compliance with the plan (Minn. Stat. § 116.79, subd. 2). This item also states that part 7001.0100, subparts 4 and 5; and 7001.0110 do not apply to infectious waste plan approval since chapter 7001 governs the process for administrative permit approval. Approval under the infectious waste rules is not a permit under chapter 7001. This item also states that nothing in this part exempts facilities or generators from applicable air quality or solid waste permit requirements. It is reasonable to require facilities that need to obtain a permit under other Agency rules for air quality, water quality, solid waste or hazardous waste still must obtain those permits since the infectious waste management plans required by these rules do not include the information necessary to permit facilities for activities that may impact the environment in some other manner.

Item C states that approval shall be denied if the plan does not comply with this part and other applicable state or federal laws or rules or if approval is likely to cause pollution, impairment, or destruction of the air, land, or other natural resources of the state. It is reasonable to deny a management plan if the plan does not comply with these parts since a plan that is either incomplete or inconsistent with these parts does not insure the proper management of infectious waste. It is also reasonable to deny a management plan if approval would conflict with existing laws or other Agency rules.

F. Reasonableness of Proposed Part 7035.9150 FORMS

This rule provides off-site storage facility owners or operators with the exact language they must use to execute financial contracts which are acceptable under the financial assurance requirement in Part 7035.9120, subpart 7. The rationale for this provision has been considered before, in the introductory discussion of Part 7035.9120, subpart 7, but it bears repeating here. Requiring standard language in financial contracts extends equitable treatment

to all off-site storage facility owners and operators. Each off-site storage facility owner or operator will know the choices available to others. No one off-site storage facility owner or operator will be able to craft a contract that provides an advantage over competitors.

The use of standard language will also help minimize the costs of compliance. The Agency will spend less time reviewing standard documents than it would spend analyzing non-standard documents. Off-site storage facility owners and operators will benefit, since they will not have to spend time composing language for financial instruments. Sureties and banks will also benefit from rules providing consistent language that conforms with standard practice. The language in each document is consistent with standard business practices in Minnesota.

This rule is reasonable because it promotes equitable treatment of all off-site storage facility owners and operators and it minimizes some compliance costs.

Subpart 1. Surety bond. This subpart provides the language required in a surety bond that guarantees the off-site storage facility owner or operator will perform specified activities. The form of this bond is consistent with standard business practice in Minnesota. The first section of the bond is devoted to basic data.

1. The date the bond is executed by the principal and the surety.
2. The date on which the terms of the bond become effective.
3. The name of the principal.
4. A descriptive name for the off-site storage facility owner's or operator's organization (e.g., corporation).
5. The state in which a corporation is incorporated.
6. The name and address of the surety.
7. Names and addresses of all facilities covered and each individual facility's estimated costs for final waste disposal.
8. The total amount to be covered by the bond, which is known as the penal sum.

The information provided sets the basic parameters of the agreement. The contract would not be enforceable without them.

The first full paragraph defines the extent of the surety's commitment to the Agency. The statements in this paragraph set the surety's liability equal to the penal sum of the bond. If there are joint sureties, the liability is joint and several, but limited to actions arising from the activities described.

This requirement reasonably provides the surety and the off-site storage facility owner or operator with notice of the extent of the surety's liability.

The next paragraph describes the condition which has caused the off-site storage facility owner or operator and the surety to execute the agreement, namely, the off-site storage facility owner's or operator's obligation to meet the financial assurance requirement.

The next two paragraphs describe the conditions that the surety guarantees. If these conditions do not occur, the surety will be required to pay the penal sum to the Agency. The conditions guaranteed are:

a) the off-site storage facility owner or operator will properly dispose of all wastes remaining after the facility closes, and

b) the off-site storage facility owner or operator will provide acceptable alternate financial assurance in the event that the bond is canceled.

The next paragraph is a positive statement of the conditions under which the surety will become liable on the bond obligation; namely, failure of the principal to fulfill one of the conditions described above.

The next two paragraphs make it clear that the surety is not responsible for making sure that the off-site storage facility owner or operator complies with applicable rules and statutes. The surety does not become liable under the terms of the bond until the Commissioner gives proper notice.

The next paragraph is the surety's statement that changes in applicable laws or rules will not change the force of the surety's guarantee.

The next paragraph further specifies the limits of the surety's liability. This liability is not ended until the sum of payments made to the Agency equals the amount of the penal sum. A further statement explicitly limits the surety's liability to the amount of the penal sum.

The next paragraph makes provision for the surety to cancel the bond. The surety must notify the off-site storage facility owner or operator and the Commissioner of its intent to cancel. The actual cancellation may not take effect until 120 days after the Commissioner receives the notice.

The next paragraph makes provision for the off-site storage facility owner

or operator to cancel the bond. This cancellation may occur only if the Commissioner sends the surety a written authorization to cancel.

The next paragraph is optional and may be included if the surety and the off-site storage facility owner or operator want it. This paragraph makes provision for annual adjustments in the penal sum of the bond. The provision limits the increase to 20 percent. There is also a requirement that the penal sum not be decreased without the Commissioner's written permission.

The final two paragraphs certify the date of signing and the signatures of the surety(is) and the principal.

Subpart 5. Letter of credit. This subpart provides the off-site storage facility owner or operator with the language needed for a letter of credit. The letter appears very much like a standard business letter. Many of the identification requirements of the surety bond are not in the letter of credit. These identification requirements are to be met by the off-site storage facility owner or operator.

The first paragraph of the letter identifies the instrument and states that credit is extended in favor of the Agency on behalf of the off-site storage facility owner or operator. This paragraph also identifies the amount of credit extended. This amount is analogous to the penal sum of the surety bond. The credit becomes available when the Commissioner presents a sight draft to the bank which: refers to the bank's identification number for the letter and certifies that conditions defined in the infectious waste rules have occurred which call for the Commissioner to draw on the credit extended.

The next paragraph provides the effective date of the letter and specifies that it has a one-year term. The bank provides that the term of the letter will be extended automatically for another year beyond the expiration date and on each successive expiration date. The letter states that it can be canceled only under specified conditions; namely, the the bank sends the off-site storage facility owner or operator and the Commissioner notice of its intent to cancel and that this notice be sent 120 days before any current expiration date.

The next paragraph states the bank's intention to honor any properly presented drafts. When the bank honors a draft, it will pay the specified amount to the Agency.

There is a final certification that the language of the letter is the same as the language required by the infectious waste rules. This is followed by appropriate signatures and a reference to standards which the letter conforms.

The form of this letter is consistent with standard business practice in Minnesota.

VI. SMALL BUSINESS IMPACTS

The Agency is required to consider the impacts of proposed rules on small businesses:

> Subd. 1. Definition. For purposes of this section, "small business" means a business 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 sales of less than $4,000,000. For purposes of a specific rule, an agency may define small business to include more employees if necessary to adapt the rule to the needs and problems of small businesses.
>
> Subd. 2. Impact on small business. When an agency proposes a new rule, or an amendment to an existing rule, which may affect small businesses as defined by this section, the agency shall consider each of the following methods for reducing the impact of the rule on small businesses:
>
> (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 requirements for small businesses;
>
> (d) the establishment of performance standards for small businesses to replace design or operational standards required in the rule; and
>
> (e) the exemption of small businesses from any or all requirements of the rule.
>
> In its statement of need and reasonableness, the agency shall document how it has considered these methods and results.
>
> Subd. 3. Feasibility. The agency shall incorporate into the proposed rule or amendment any of the methods specified under subdivision 2 that it finds to be feasible, unless doing so would be contrary to the statutory objectives that are the basis of the proposed rulemaking.
>
> Minn. Stat. § 14.115 (1986).

Nearly all private firms that will be affected by the proposed rules are small businesses. The proposed rules were developed with the understanding that

the affected sectors consist mostly of small businesses. Because of this, small businesses cannot be exempted from some or all proposed requirements.

The proposed rules consist of three general types of regulations: a) prohibitions and prescriptions, b) reporting requirements and c) financial assurance requirements.

The Agency is directed to consider the proposed rules as either procedural requirements (subd. 2, items (a), (b) and (c)) or substantive requirements item (d)). Procedural requirements set reporting standards and schedules.

The Agency must have a certain amount of information from all affected firms if it is to regulate efficiently and fairly the state's infectious waste management system. There is now very little comprehensive, reliable information about the state's infectious waste management system. A decision to lower the proposed rules' information and reporting requirements would likely delay determination of whether the regulatory design is appropriate. This data problem can lead to analysis paralysis. Change is needed, but there is no way to determine, quantitatively, just how much change is needed. Agency staff believes that the proposed rules' information requirements are adequate to meet current needs and that they do not impose an excessive burden on affected firms.

The proposed rules' substantive requirements require affected firms to adopt safe handling practices. The standards set are performance-oriented. The standards require that infectious waste management methods meet specified goals. For example, the rules require that infectious waste materials be packaged in secure containers, but there is no specification for the containers' design or material composition. Most of the rules' standards are related in similar fashion to performance rather than design. The use of performance standards is in keeping with the law requiring consideration of small business impacts.

The financial assurance requirements apply only to the owners of off-site storage facilities. These requirements are designed to provide needed security at minimal cost. Although the costs involved are within the financial capacity of most small businesses operating in this sector, it is likely that some firms will find the financial assurance requirements too costly. This is a case in which the statutory basis for rulemaking conflicts directly with the goal of accommodating small business concerns.

The Infectious Waste Management Act compels the safe handling and disposal of infectious wastes. The proposed rules were developed in response to this Act. Proper storage of infectious wastes is a critical element in overall

system management. The Agency cannot allow stored wastes to be abandoned. The financial assurance requirements are made to give facility operators incentive to manage stored wastes with care. If this incentive does not work, the financial assurance requirements ensure that the Agency will be able to clean up the facility and properly dispose of abandoned wastes.

The financial assurance requirements compel a facility operator to have or develop financial capacity sufficient to ensure safe facility closure. If an operator does not have or cannot develop sufficient financial capacity, then the operator should not be given a facility permit.

The Agency believes the financial assurance requirements will not prove so costly as to keep a small firm from operating. Off-site storage facilities are developed and run by collection service firms. The storage facilities are adjuncts to the collection service; they are not important profit centers. A collection service firm does not have to operate a storage facility. A firm that finds the financial assurance requirements too costly can still run its collection service.

The Agency believes that the proposed rules meet the requirements of Minn. Stat. § 14.115. The rules accommodate small business concerns without compromising the environmental values that are the rules' policy foundation.

VII. ECONOMIC CONSIDERATIONS

A. INTRODUCTION

Minn. Stat. § 116.07, subd. 6, (1988) reads as follows:

> In exercising all its powers the pollution control agency shall give due consideration to the establishment, maintenance, operation and expansion of business, commerce, trade, industry, traffic, and other economic factors and other material matters affecting the feasibility and practicability of any proposed action, including, but not limited to, the burden on a municipality of any tax which may result therefrom, and shall take or provide for such action as may be reasonable, feasible and practical under the circumstances.

That law has general applicability to all actions of the Agency. In the rulemaking context, this requirement has been interpreted by the Agency to mean that, in determining whether to adopt proposed rules or amendments, the Agency

must consider, among other evidence, the impact which economic factors may have on the feasibility and practicability of the proposed rules or amendments. In Finding No. 4 of the Agency's Findings of Fact and Conclusions In the Matter of the Proposed Revision to Minn. Rule APC 1, 6 MCAR sec. 4.0001, Relating to Ambient Air Quality Standards, the Agency discussed the requirements of Minn. Stat. § 116.07, subd. 6 as follows:

> In order for the Agency to duly consider economic factors when it determines whether to adopt the amendments to Minn. Rule APC 1, the record upon which the Agency will make its determination must include data on the economic impacts of those amendments. These economic impacts, however, need not be quantified with absolute certainty in order to be considered. Further, these economic impacts may include costs other than the cost of complying with a proposed rule. For instance, material losses, crop losses, health costs, and impacts on tourism are also economic factors that should be duly considered by the Agency in determining whether to adopt the amendments to Minn. Rule APC 1.

Public policy decisions must weigh the values of competing goals. The law and the administrative interpretation cited show that the Legislature and the Agency recognize the need to take into account different, sometimes competing, goals when setting environmental policy. Budget constraints in all economic sectors and at all income levels require decision makers to choose among programs and projects that compete for scarce budget resources.

The order is a cautionary note telling the Agency to be mindful of economic and financial limits. The Agency's daily business is to serve the public in the protection and improvement of Minnesota's air, water and land resources by: assessing the State's environmental status; regulating the quality of these resources; assisting local government, industry and individuals in meeting their environmental responsibilities; and implementing strategies that will protect and enhance public health and the State's environment.

This work is not done without cost. Environmental laws and regulations impose costs on people, businesses and other institutions. Some of the state's economic capacity must be devoted to environmental protection. The Agency is directed to take care that environmental regulations do not strain the limits of available economic resources. The Agency generally takes this directive a step further, seeking least-cost regulatory solutions over affordable ones if the least-cost solution does not compromise environmental goals.

B. ANALYSIS

The service sector of the economy which provides medical care will incur the largest total costs. Important affected sub-sectors in other parts of the economy are veterinarians, funeral homes and waste collection and disposal service firms, which altogether comprise nearly 45 percent of the total number of affected firms.

There is an economic model of the state's economy which presents estimates of economic activity for separate sectors. This model takes historic measures of economic activity and uses these historic data as the basis for making forecasts. The table below presents the forecast levels of real economic output for the affected sectors in 1991 and a forecast general price index. These two measures are used to calculate a current-dollar estimate of economic output in the affected sectors.

OUTPUT OF LOCAL INDUSTRIES
(IN $MILLIONS)

	REAL $ (1977)	PRICE INDEX 207.569	NOMINAL $ (1991)
MEDICAL			
Doctors & Dentists, Hospitals, Nursing & Personal Care Facilities, Other Medical & Health Svcs.	3,942.98		8,184.40
AGR., FISH, FOR. SVCS.			
Includes veterinary svcs.	413.30		857.88
PUBLIC UTILITIES			
Includes waste coll. & disposal svcs.	2,315.80		4,806.88
PERSONAL SVCS. & REPR.			
Includes funeral homes	1,055.64		2,191.18

This is an estimate of the financial capacity of the economic sectors that will have to comply with the proposed rules. Some part of this financial capacity will have to be used to pay for the actions required under the proposed rules.

The provisions of the rules that will impose costs are fairly easy to identify. It is less easy to determine how many firms will incur new costs. This is because the proposed rules embody much that has become standard practice within the affected sectors. Agency staff believes that most infectious wastes are now managed in ways that meet the requirements of the proposed rules. This is because most infectious wastes are handled by a small number of firms. Agency staff has discussed the rules with a number of affected firms and inspectors have visited several sites. These discussions and inspections indicate that nearly all infectious wastes are now handled in a safe, environmentally protective manner.

However, staff investigations have also determined that not all infectious wastes are properly handled. The group of business firms that generate and process infectious wastes has a very typical distribution of firm sizes. The sector has a relatively few large-scale firms and very many small-scale firms. The problems that exist generally are found in firms that generate small quantities of infectious wastes. This pattern is a very normal one, in the MPCA's experience. Small quantities of waste are usually regarded as small problems, which often do not get the attention they merit. The result is poor management through inadvertence, not design. Although it is known that this problem exists, the extent of improper management cannot be estimated with acceptable accuracy.

Recall the purpose of this chapter, which is to determine the economic and financial impacts of the proposed rules. One important goal of these rules is to gather the information that is needed to estimate the costs of proper infectious waste management. In the absence of reliable information, this analysis will assume conservative values that overstate both unit and total costs. This assumption is made in order to make sure that the Agency does not adopt rules that are extremely expensive. If the conservative assumptions in this analysis result in mild economic effects, then the actual costs of compliance will not cause economic stress.

The Agency estimates that the affected sectors consist of the following private and public firms:

TYPE OF FIRM	NUMBER
Generators	
Hospitals	177
Funeral homes	550
Veterinarians	2,508
Clinics (over 25 employees)	400
Clinics (under 25 employees)	273
Dentists	2,500
Dental clinics	15
Nursing homes	446
Boarding care homes	113
County nursing clinics	87
Research laboratories	20
Other	
Transporters	6
Dedicated incinerators	2
Municipal solid waste incinerators	5
Hospital incinerators	143
TOTAL	7,245

NOTE: There are 10,800 licensed medical doctors in Minnesota. This analysis assumes that each doctor is associated with a hospital, a clinic or another medical facility.

The Agency expects that waste generating firms in all but the hospital and clinic groups will have to make some changes in their management practices. The total number of firms in these sectors is 6,239. Assume that 3,000 of these firms will incur costs due to changes in infectious waste management practices.

The types of changes needed are:

1. Handling, packaging and labeling changes. These changes are required of processing and disposal facility operators, commercial transporters and generators who transport their own wastes. The proposed rules set standards for waste containers. (These standards were discussed in detail in Chapter ___.) The Agency expects that generators incurring these expenses as new costs will likely arrange with private collection firms to take care of their infectious wastes. Part of the service these firms provide is the supply of waste containers that meet appropriate standards.

Assume that private firms charge $50 monthly for waste collection and disposal. If the 3,000 affected generator firms buy new waste collection services, the total annual costs will be $150,000.

2. Storage requirements. The proposed rules require that stored infectious wastes be managed separately from other wastes. The Agency expects that generators will not have to construct new storage areas to meet this requirement. If any new costs are incurred, they will be minimal and they cannot be even approximated for this analysis.

3. Treatment. The proposed rules set treatment standards that are are now met by existing treatment facilities. There are also performance standards set for treatment methods other than incineration and autoclaving. These methods are not now in use. Instead, various firms have proposed alternatives to current standard treatment methods. If a firm wants to use an alternative waste management method, it will incur added costs in developing and presenting to the Agency evidence that the proposed alternative meets the rules' performance standards.

   The alternative management methods are still in the early stages of development. The process of developing the method and securing Agency approval will be costly, but the measure of costs simply cannot be estimated now.

4. Transportation. The proposed rules on infectious waste transportation focus on limiting the transporter's pick up points and destinations. There are some identification requirements that will impose minimal costs that are not worth including in this analysis.

5. Spills. The proposed rules require that all affected firms develop plans for handling spills and that the firms have on hand equipment needed to handle spills safely. This is another provision of the rules that simply takes current normal management practices and makes them standards enforceable under rule. The Agency believes that any new expenses incurred will be minimal.

6. Financial assurance. The proposed rules impose financial assurance requirements on the operators of off-site storage facilities. Only one facility is now operating. The Agency expects that a few more will begin operations within the near term.

   The financial assurance requirements impose different types of costs, depending on the facility operator's choice of compliance methods. Operators must secure surety bonds or letters of credit large enough to pay for cleaning up abandoned facilities. Operators may also deposit appropriately-valued securities with the State Treasurer - this is much like a collateral deposit. If the operator gets a surety bond or a letter of credit, there will be a direct charge for the coverage of one to three percent of the amount of coverage provided. If the operator sends securities to the State Treasurer, the cost incurred is the opportunity cost resulting when funds are tied up in security deposits. The assumption is that the operator could earn a higher rate of return on this money if it were invested elsewhere or used to pay for business operations.

This analysis will assume that service charges and opportunity costs are a rather high three percent. Assume further that: a) five facilities will incur financial assurance costs; b) the facilities' average capacity is six tons; 3) the average cleanup cost is 25 cents per pound. This means the average financial assurance responsibility will be 12,000 X .25 = $3,000. The incurred cost will be $3,000 X 3% = $90. Total costs for all facilities are then estimated to be $90 X 5 = $450.

7. Management plans. The proposed rules require all infectious waste transporters and facility operators to develop infectious waste management plans. The Agency has reduced plans to a standard form, in the interest of encouraging compliance. It is estimated that data gathering and compilation, clerical work and mailing will involve an average cost of $500 per plan.

   Thirteen of the firms now operating in the sector will have to meet the planning requirements. The Agency expects that a few more firms will soon begin operations. Assume that twenty firms will have to develop plans. This means total costs will amount to $500 X 20 = $ 10,000.

The table below summarizes the estimates of total costs to be incurred in each of the affected sectors:

TYPE OF COST	SECTOR			
	MEDICAL	AGRICULTURAL SERVICES	PUBLIC UTILITIES	PERSONAL SERVICES
Handling, etc.	$ 76,500	$ 60,300		$ 13,200
Financial assurance			$ 450	
Management plans			10,000	
New costs imposed by rule	$ 76,500	$ 60,300	$ 10,450	$ 13,200
Sectoral output ($millions)	$ 8,184	$ 858	$ 4,807	$ 2,191
Costs as a percent of output	0.00093	0.00703	0.00022	0.0006

The estimated costs of compliance with the proposed rules will not amount to very much when compared to the financial capacity of the firms that have to comply. The proposed rules are expected to have only a negligible economic impact on the affected sectors.

VIII. IMPACTS ON AGRICULTURAL LANDS

The Agency is required to consider the impacts of proposed rules on agricultural lands:

> If the Agency proposing the adoption of the rule determines that the rule may have a direct and substantial adverse impact on agricultural land in the state, the Agency shall comply with the requirements of sections 17.80 to 17.84.

Minn. Stat. § 14.11, subd. 2 (1988)

The definition of adverse impact which applies in this case is:

> "Action which adversely affects" means any of the following actions taken in respect to agricultural land which have or would have the effect of substantially restricting the agricultural use of the land: (1) acquisition for a nonagricultural use except acquisition for any unit of the outdoor recreation system described in section 86A.05, other than a trail described in subdivision 4 of that section; (2) granting of a permit, license, franchise or other official authorization for nonagricultural use; (3) lease of state-owned land for nonagricultural use except for mineral exploration or mining; or (4) granting or loaning of state funds for purposes which are not consistent with agricultural use.

Minn. Stat. § 17.81, subd. 2 (1988)

The Legislature has set agricultural land policies that guide administrative agencies' rulemaking efforts and determinations of adverse impact:

> It is the policy of the state to preserve agricultural land and conserve its long-term use for the production of food and other agricultural products by:
>
> (a) Protection of agricultural land and certain parcels of open space land from conversion to other uses;
> (b) Conservation and enhancement of soil and water resources to ensure their long-term quality and productivity;
> (c) Encouragement of planned growth and development of urban and rural areas to ensure the most effective use of agricultural land, resources and capital; and
> (d) Fostering of ownership and operation of agricultural land by resident farmers.

Minn. Stat. § 17.80, subd. 1 (1988)

The Agency finds that the proposed rules will not cause any adverse impacts on agricultural lands. The proposed rules apply to firms that generate, transport, process and dispose of infectious wastes. Farm operators and agribusiness firms are specifically exempted from compliance with the proposed rules.

IX. CONCLUSION

The Agency staff has in this document and its exhibits made its presentation of facts establishing the need for a reasonableness of the proposed rules governing infectious waste management practices, infectious waste management plans, and the review process for these plans. This document constitutes the Agency's statement of need and reasonableness for the proposed rules.

Based on the foregoing, the proposed Minn. Rules pts. 7035.9100 to 7035.9150 are both needed and reasonable.

Dated: March 16, 1990

Barbara Lindsey Sims
for Gerald L. Willet
Commissioner