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3-2200-4603-1

STATE OF MINNESOTA

OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA POLLUTION CONTROL AGENCY

In the Matter of Proposed

Permanent Rules Relating to REPORT OF THE

Infectious Waste Management, ADMINISTRATIVE LAW JUDGE

Parts 7035.9100 to 7035.9150

The above-entitled matter came on for hearing before Administrative Law Judge Allen E. Giles on May 17, 1990, at 9:30 a.m. in the Agency's Large Conference Room, 520 Lafayette Road, St. Paul, Minnesota and on June 11, 1990 at 4:00 p.m. in the Perham Community Center, 620 Third Avenue S.E., Perham, Minnesota.

This Report is part of a rulemaking proceeding held pursuant to Minn. Stat. § 14.131 to 14.20, to hear public comment, to determine whether the Minnesota Pollution Control Agency (MPCA) has fulfilled all relevant substantive and procedural requirements of law applicable to the adoption of the rules, whether the proposed rules are needed and reasonable and whether or not modifications to the rules proposed by the MPCA after initial publication are impermissible, substantial changes.

Kathleen Winters, Special Assistant Attorney General, 520 Lafayette Road,

St. Paul, Minnesota 55155, appeared on behalf of the MPCA at the hearing. The

MPCA's hearing panel included: Julie Ketchem, Program Development Planner;

Laurie Mezner, Pollution Control Specialist; and Robert McCarron, Program

Development Economist.

Fifteen persons attended the St. Paul hearing. Nine persons signed that hearing register. At the St. Paul hearing, the Administrative Law Judge received the MPCA Exhibits 1-11.

The exhibits referenced in the MPCA's Statement of Need and

Reasonableness (SONAR) were not entered into the hearing record. As a result of receiving eighty-four requests for hearing from persons in the Perham area, the MPCA scheduled a hearing in Perham. Fifty persons attended the Perham hearing. Twenty-seven persons signed that hearing register. Both hearings continued until all interested persons, groups or associations had an opportunity to be heard concerning the adoption of these rules.

The record remained open for the submission of written comments for twenty calendar days following the date of the Perham hearing, to June 21, 1990. Pursuant to Minn. Stat. § 14.15, subd. 1 (1988), three business days were allowed for the filing of responsive comments. At the close of business on June 26, 1990, the rulemaking record closed for all purposes. The Administrative Law Judge received two written comments from interested persons during the comment period. The MPCA submitted a written comment responding to matters discussed at the hearing and in the post-hearing comments.

This Report must be available for review to all affected individuals upon request for at least five working days before the agency takes any further action on the rule(s). The agency may then adopt a final rule or modify or withdraw its proposed rule. If the Commissioner makes changes in the rule other than those recommended in this report, he must submit the rule with the complete hearing record to the Chief Administrative Law Judge for a review of the changes prior to final adoption. Upon adoption of a final rule, the agency must submit it to the Revisor of Statutes for a review of the form of the rule. The agency must also give notice to all persons who requested to be informed when the rule is adopted and filed with the Secretary of State.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

#### FINDINGS OF FACT

##### Procedural Requirements

1. On March 27, 1990, the Minnesota Pollution Control Agency (MPCA) filed the following documents with the Chief Administrative Law Judge:

- (a) A copy of the proposed rules certified by the Revisor of Statutes;
- (b) The Order for Hearing;
- (c) The Certificate of Agency's Authorizing Resolution;
- (d) The Notice of Hearing proposed to be issued;
- (e) The Statement of Need and Reasonableness (SONAR);
- (f) A letter stating the expected length of the

hearing,

that additional notice would be given, and the anticipated attendance.

2. On March 27, 1990, the Board mailed the Notice of Hearing to all persons and associations who had registered their names with the Board for the purpose of receiving such notice.

3. On April 9, 1990, a Notice of Hearing and a copy of the proposed rules were published at 14 State Register 2419.

4. On May 15, 1990, the MPCA filed the following documents with the Administrative Law Judge:

(a.) The Notice of Hearing as mailed;

(b) A photocopy of the pages of the State Register containing the Notice of Hearing and the proposed rules.

(c) The Agency's certification that its mailing list was accurate and complete;

(d) The Affidavit of Mailing the Notice to all persons on the MPCA's mailing list; and

(e) The Affidavit of Mailing the Notice of Hearing to the Discretionary Mailing List; and

(e) The names of Board personnel who would represent it at the hearing.

5. Minnesota Rules part 1400.0600 requires that the documents stated in this Finding be filed with the Administrative Law Judge at least 25 days prior

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to the hearing. In this case, the filing was only 2 days prior to the hearing. Failure to comply with the rule constitutes a procedural error. Under the circumstances, however, the Administrative Law Judge finds that error to be harmless, not affecting the ability of the Board to adopt the proposed rules, S, City of Minneapolis v. Wurtele, 291 N.W.2d 386, 391 (Minn. 1980); See also, Handle With Care v. Department of Human Services, 406 N.W.2d 518 (Minn. 1987).

6. In determining whether a procedural error is harmless, one must examine the extent to which the Agency deviated from the requirements, whether the deviation was inadvertent, and the potential impact the procedural irregularity could have on public participation in the rulemaking process. Auerbach, Administrative Rulemaking in Minnesota, 63 Minn. L. Rev. 151, 215 (1979); but see, Johnson Bros. Wholesale Liquor Co. v. Novak, 295 N.W.2d 238, 241-42 (Minn. 1980). Here the documents pre-existed the late filing and were maintained in the Agency rule file for public

inspection. The documents were available for Inspection and copying at the Office of Administrative Hearings from the date of filing to June 26, 1990, the date the record closed. The failure to include all of the documents in the filing of March 27 was clearly inadvertent. Moreover, no member of the public requested an opportunity to review, prior to the hearing, the rulemaking file maintained by the Administrative Law Judge. At the hearing, no member of the public complained of prejudice resulting from the Board's failure to comply strictly with Minnesota Rules Part 1400.0600.

#### Nature of the Proposed Rules.

7. The proposed rules establish a system to control the movement and disposal of infectious wastes. Primary concerns of the rule are packaging and labelling of infectious wastes, storage requirements, decontamination requirements, transporter qualifications, requiring spill response plans, conducting proper recordkeeping, and standardizing qualifications to become an offsite storage facility for infectious wastes.

#### Statutory Authority.

8. In its Statement of Need and Reasonableness (SONAR), the MPCA cites Minn. Stat. § 115.03 (1988), Minn. Stat. § 116.07 (1988) and Minn. Stat. § 116.75, et (1988) as authorizing the adoption of the proposed rules. The statutes referred to in the SONAR all grant general rulemaking authority to the MPCA. Minn. Stat. § 116.81, subd. 1 specifically authorizes the MPCA to adopt rules necessary to implement the statutory scheme relating to infectious wastes (Minn. Stat. § 116.76 to 116.82) (hereinafter, "Infectious Waste Control Act"). The MPCA has statutory authority to adopt these rules.

#### Small Business Considerations in Rulemaking.

9. Minn. Stat. § 14.115, subd. 2 (1989), requires state agencies proposing rules affecting small businesses to consider methods for reducing adverse impact on those businesses. The MPCA noted in its SONAR that most of the businesses affected would be small businesses. The MPCA considered existing practices in waste handling, reducing the reporting requirements on small businesses, and exempting small businesses from the rules. The MPCA concluded that, owing to the potential pollution and health problems, the rules cannot be less rigorous as applied to small businesses. Exempting small

businesses would render the proposed rules ineffective, since most of the regulated public would qualify for such an exemption. The MPCA has adequately considered the impact of' the proposed rules on small businesses. Minn. Stat. § 14.115, subd. 2 (1989).

10. Minn. Stat. § 14.115, subd. 4 (1988), requires that specific notice of the proposed rules be given to affected small businesses. The notice provided by the MPCA satisfied the requirements of Minn. Stat. § 14.115, subd. 4(b) and (c) (1988). Ex. K.

#### Fiscal Note.

11. Minn. Stat. § 14.11, subd. 1 (1988), requires the preparation of a fiscal note when the adoption of a rule will result in the expenditure of public funds in excess of \$100,000 per year by local public bodies. The note must include an estimate of the total cost to local public bodies for a two-year period. The proposed rules will not require any expenditures by local governmental units or school districts, and thus no note is needed.

#### Impact on Agricultural Land.

12. Minn. Stat. § 14.11, subd. 2 (1988), imposes additional statutory requirements when rules are proposed that have a "direct and substantial adverse impact on agricultural land in this state". The proposed rules will have no substantial adverse impact on agricultural land within the meaning of Minn. Stat. § 14.11, subd. 2 (1988).

#### Economic Impact of the Proposed Rules

13. Minn. Stat. § 116.07, subd. 6 (1988) requires the MPCA, in a rulemaking context, to consider the impact which economic factors may have on the feasibility and practicability of the proposed rules. In Chapter VII of the SONAR the MPCA has undertaken a comprehensive analysis of economic factors related to the implementation of the proposed rules. In the analysis MPCA has considered anticipated costs and benefits of the proposed rules. Based on this analysis the MPCA has determined that the proposed rules will provide substantial public benefits while having only a negligible economic impact on the affected sectors. The MPCA has adequately considered the economic feasibility and practicability of implementation of the proposed rules as required by Minn. Stat. § 116.07, subd. 6.

#### Proposed Rule 7035.9100 -Scope.

14. Proposed Rule 7035.9100 establishes which persons and entities are required to comply with this rule. The

rules apply to "owners and operators of facilities, to commercial transporters, and to all infectious waste without regard to quantity." The proposed rule part specifically exempts "waste generated by households, farms, agricultural businesses, or, except where specified, generators." The scope of the proposed rules is limited by Minn. Stat. § 116.81, subd. 2, which grants the Minnesota Department of Health (MDH) the rulemaking responsibility regarding generators.

Further, Minn. Stat. § 116.77 specifically exempts waste generated by households, farm operations, or agricultural businesses from the Infectious Waste Control Act. Lori Hething of Care Providers of Minnesota suggested that the term "facilities" be clarified. The MPCA has declined to do so. The term "facilities" is used in

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Minn. Stat. § 116.81, subd. 1 and is defined both in statute and in the proposed rule. The scope provision of the proposed rule part conforms to the statutory limits of the MPCA's authority and is needed and reasonable.

Proposed Rule 7035.9110 Definitions.

15. This proposed rule part is composed of 23 subparts, each defining a term used in the proposed rules. Fifteen of those definitions are found in the Infectious Waste Control Act.

Minn. Stat. § 116.76. The remaining eight definitions are for the terms "disinfection," "management plan," "offsite," "operator," "owner or facility owner," "putrefaction," "spill," and "storage." Of these eight terms, only "putrefaction" and "storage" attracted critical comments.

16. Subpart 18 defines "putrefaction" as "the decomposition of organic matter by microorganisms, producing foul-smelling matter." Steven Carter, Chief Executive Officer of the Minnesota Medical Association (MMA), objected to this definition in that it does not establish objective factors by which putrefaction can be measured. Mr. Carter questioned whether the smell would be measured at ten paces or whether the consistency of the waste would determine putrefaction.

Preventing putrefaction of infectious waste is a goal of these rules; proposed rule 7035.9120, subp. 20. Some comments suggested that this goal requires that such waste be refrigerated, particularly in the summer months. The MPCA responded that refrigeration is not required under the rules, since refrigeration is costly and tends to extend the life of infectious agents in the waste. Rather, the MPCA intends that the waste be disposed of promptly to comply with proposed rule 7035.9120, subp. 2D. The comments at the hearings suggest that the MPCA intends to use a "smell test" as the standard for determining whether stored organic

matter has putresced. Although a "smell test" is potentially a subjective standard, none of the commentators suggested an objective test to replace the MPCA approach. The Agency's general odor rule, part 7005.0900 et seq. requires the use of an odor panel, which seems excessive in the context of this rule. Further, the term "putrefaction" has a commonly understood meaning which can be applied by most persons without undue risk of subjective results. It is concluded that subpart 18 has been justified as needed and reasonable as proposed.

17. "Storage" is defined in subpart 23 as "the offsite holding of infectious waste for more than 48 hours." The effect of this definition is to require that any entity holding offsite generated infectious waste for more than 48 hours must operate under the required practices provisions of proposed rules 7035.9120 to 7035.9150. The MPCA did not state its basis for choosing 48 hours in the SONAR. At the hearings, the MPCA suggested that 48 hours is considered to be the most time allowable to prevent putrefaction. The Minnesota Hospital Association (MHA) argued that the 48 hour limitation for waste is not reasonable, since any generator can hold its own waste for longer periods of time in compliance with existing rules.

18. The MHA also suggested that the 48 hour limitation could pose a serious problem for doctors traveling between several clinics. These "circuit-riding" doctors usually transport the small amounts of infectious waste that they generate at satellite clinics to the central clinic. Once there, the waste is held until it is taken to a hospital for disposal. The MPCA opined at the St. Paul hearing that the generation of waste at satellite clinics is "onsite" for the purposes of these rules. The "onsite" status is

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lost only when the waste is transported to the hospital. However, for some hospitals, waste is typically dropped off late on Fridays. This is a problem for the hospital if the incinerator is not operated over the weekend. The MHA stated that many smaller hospitals only operate their incinerators during the week, to coincide with the times that the most infectious waste is generated. The MHA objects to the 48 hour limitation as being overly restrictive, not in accordance with present hospital practices, and placing hospitals at risk of being required to meet the more stringent rules for offsite infectious waste facilities. The MPCA responded to these objections by inquiring into the financial impact of operating a small hospital incinerator.

19. The MHA is appropriately concerned with the effect of noncompliance with the 48 hour limitation. By accepting waste from clinics, hospitals risk the

imposition of more stringent requirements from which the hospitals are otherwise exempt. However, any hospital that is concerned about the 48 hour limitation (and does not operate its incinerator over the weekend) can avoid the problem altogether by imposing a deadline for the acceptance of offsite generated waste. If the incinerator is last operated on Fridays, the hospital could refuse to accept waste after Thursday night. This would ensure that the storage rule will not be violated, since no offsite waste would be accepted until after the weekend when it could be incinerated within the 48 hour limitation. The proposed subpart is needed and reasonable as proposed.

20. The MPCA could resolve this potential problem by including a "weekend exemption" to the 48 hour limitation. Such an exemption would define storage as "the offsite holding of infectious waste for more than 48 hours, except when such waste is accepted on a Friday, provided that any waste so accepted must be disposed of not later than the following Monday." This language or something similar may be used to meet the concerns of the MHA, if the MPCA so chooses. This alteration, if adopted, would not constitute a substantial change.

21. The MHA also suggested that the definition of "offsite" (found in subpart 13) be changed by replacing "the" with "a" before the word "generator." The effect of the change would be to exempt any generator from the more restrictive and stringent rules for offsite infectious waste facilities. The MPCA declined to make that change, because the Infectious Waste Control Act does not grant rulemaking authority to the MPCA to exempt generators. Minn. Stat. § 116.81, subd. 1. The MPCA's action is consistent with its statutory authority, and is needed and reasonable.

22. The MPCA has chosen to alter the definition of "generator" found in subpart 9. The change excludes from the definition of "generator" licensed ambulance services, boards of health, community health boards, public health nursing agencies and school health services. The MPCA justified the change on the ground that the definition of "generator" found in Minn. Stat. § 116.76, subd. 9 has been changed by recent legislation. Laws of Minnesota 1990, Ch. 568, Art. 2, sec. 2. The changes made by the MPCA are intended to conform the rule definition to the new statutory definition. Modifying subpart 9 does not constitute a prohibited substantial change.

23. The definitions set forth in proposed rule

7035.9110 are needed and reasonable. The change in the proposed rule is not a substantial change.

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Proposed Rule 7035.9120 Required Practices for Facility Owners and Operators and Commercial Transporters.

Subpart 1 Packaging and Labeling Requirements.

24. Subpart 1 of part 7035.9120 prohibits commercial transporters, facility owners and facility operators from receiving infectious waste not packaged according to the procedures established under Items A through G. The MPCA maintains that most of the practices required by Items A through G are already in use. Item A requires "sharps" (e.g. needles, scalpel blades, or discarded glass) to be placed in rigid, puncture-resistant containers which can be capped to prevent the loss of any of the contents. Under Item B, the sharps must remain packaged until disposal. If designed for reuse, the rigid container may be reused if otherwise allowable under these rules.

25. David Meyers of Medical Disposal Systems objected to the Item C requirement that sharps containers be labelled. The objection centered on the size of the labels required. Mr. Meyers asserted that the minimum size of the label would not fit on the smallest sharps containers. No containers were exhibited at the hearing or introduced into the record. The MPCA staff testified that they had seen the usual containers used for sharps storage and transportation and that the labels would fit on the containers. The minimum height of the letters (one inch) is set by statute. Minn. Stat. § 116.78, subd. 2. The MPCA maintains that the minimum stroke width is needed to ensure that the words on each label are easily readable.

26. Item D requires all infectious waste, except sharps, to be contained in plastic bags which will prevent seepage and bursting under normal use. The MPCA has incorporated by reference ASTM Standard D 1709-75 as the puncture-resistance standard the plastic must meet for this application. The MPCA has modified the language of Item D to add the phrase "and is not subject to frequent change." This addition was suggested at the hearing and merely conforms the MPCA adoption by reference to the requirements of Minn. Stat. § 14.07, subd. 4(a). The change does not alter the effect of the rule and does not constitute a substantial change.

27. Items E, F, and G require the use of rigid containers for transporting plastic bags containing infectious waste, require that the rigid containers be conspicuously labelled as "Infectious Waste" or display the international biohazard symbol, and permit the reuse of the rigid containers after disinfection. The MPCA asserts that rigid containers are needed to protect the integrity of plastic bags during transport, and act as a second layer of containment should the bags be breached. The labelling requirement is imposed

to alert persons handling the containers to their contents and promote proper cleanup procedures in the event of a spill. No one objected to these items. Waste Management of North America (Waste Management) suggested that the proposed rules should require trucks transporting infectious wastes to meet certain specifications, such as special floor design to contain leakage. The MPCA declined to follow that suggestion, asserting that the requirements of the proposed rule would be adequate for preventing spills.

28. At the Perham hearing concerned citizens raised several issues regarding the packaging and labeling of infectious waste. As its response MPCA states that the proposed rules adequately alert a worker to the contents

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of infectious waste containers and protect workers from direct contact with the waste. Citizens at the Perham hearing expressed concern about the reuse of containers for transport of infectious waste. MPCA responded that the containers can be safely disinfected before subsequent uses and that allowing reusable containers encourages waste reduction in the infectious waste stream. Citizens at the Perham hearing also expressed concern about Minnesota incinerators accepting infectious waste from outside the state and recommended that infectious waste containers show the state of origin of the waste. The MPCA indicated that it has no authority to prohibit a Minnesota facility from taking waste generated outside the state and that information regarding the origin of a shipment is required in the management plan that must be submitted to the MPCA by a disposal facility.

29. The MPCA has shown that subpart 1 of proposed rule 9035.9120 is needed and reasonable, as modified. The modification to the proposed subpart is not a substantial change.

#### Subpart 2 -Storage Requirements.

30. Subpart 2 requires offsite facility owners and operators, when storing waste, to meet the requirements set forth in items A through E. Item A specifies that infectious waste must be segregated from other waste, the storage area must be prominently marked as containing infectious waste, unauthorized persons must be denied access to the waste and the storage area must be designed to prevent the entry of vermin. These restrictions are intended to prevent inadvertent contact with the waste and eliminate possible disease vectors. Item B requires that interior surfaces of storage areas must be constructed of materials that are easily cleaned. Item C requires that offsite storage areas must be designed to contain spills. Item D requires that the stored waste may not be allowed to become putrescent. The objections to Item D are discussed at Finding 16, above. Item E requires storage facility owners and operators to comply with the spill response requirements in subpart 6 of

proposed rule 7035.9120. None of the items listed (except for item D) received adverse comment.

31. At the Perham hearing, citizens expressed concern about how long and the conditions under which infectious waste would be stored at a disposal facility. Most of the citizen's comments were suggestions to specify rigorous storage conditions such as refrigeration of the waste and a limit on the amount of time the waste could be held.

32. After due consideration the MPCA has concluded that the protective storage measures proposed by the Perham citizens are not warranted in these rules. The MPCA argues that the rule's 48 hour limitation encourages and requires prompt handling of infectious waste. In addition, storage facilities must process or ship infectious waste before it becomes putrescent. Finally, MPCA argues that refrigeration will not reduce the risk from the infectious waste because the waste is still infectious whether or not it is kept cold. The MPCA has shown that subpart 2 of proposed rule 9035.9120 is needed and reasonable.

#### Subpart 3 Decontamination Requirements.

33. This subpart authorizes facility owners and operators to use incineration, autoclaving, or other methods (approved by the Commissioner) to

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decontaminate infectious waste. Item A of subpart 3 requires operation of incinerators to comply with the rules regarding Air Quality (Minn. Rules ch. 7001 to 7005.). Item B requires autoclaving waste to be done at 2500 farenheit for one hour at 15 pounds per square inch (psi) of pressure, the loading of the autoclave must be within design limits of the device, and a log must be kept of the waste decontaminated with specifics including date, time, temperature, pressure, and operator name. Robert A. Harder, Executive Director of the Minnesota Dental Association, objected to this requirement since the autoclave used by Mr. Harder in his dental office has an automatic cycle setting for a higher temperature and higher pressure at a shorter length of time in addition to an automatic cycle setting for the temperature and pressure (but one-half the time) prescribed by the proposed rules. Mr. Harder asserts that other effective, less-restrictive cycles should be permitted. Haste Management supported the 2500, 15 psi, one hour standard. According to the SONAR, the MPCA based its standard for autoclaves on a study by Vesley and Lauer in 1986 that concluded the 250°, 15 psi, one hour standard is appropriate for decontaminating infectious wastes. Mr. Harder did not introduce any evidence to support alternative standards.

34. Item C permits other methods of decontamination to be approved for use. To obtain that approval the proposer must submit data to the commissioner proving that the proposed method does, in fact, decontaminate the waste. Stericycle, Inc., a corporation engaged in the decontamination of waste, recommended that gamma radiation be included as an approved method. The Administrative Law Judge cannot require the commissioner to include gamma radiation as a method of decontamination without a showing that excluding that method is unreasonable or including it is necessary. There are no facts in the record to compel either conclusion. Stericycle, Inc. is free to apply to the commissioner for approval under the provisions of Item C.

35. Medical SafeTEC, a corporation which manufactures decontamination equipment, recommended that the standard for demonstration of a waste decontamination method be "equivalency to the accepted methods in making the waste safe to handle as a solid waste." Medical SafeTEC also suggests that consistently achieving a high level of disinfection be "one of the criteria for evaluation." The MPCA declined to make that change. Minn. Stat.

§ 116.76, subd. 6 defines "decontamination" as "rendering infectious waste safe for routine handling as a solid waste." This statutory definition does not accept "equivalency" as a standard and, therefore, neither can the MPCA.

36. 3M is a Minnesota corporation engaged in various activities related to the waste disposal field. 3M and Waste Management both suggested that biological indicators be used to monitor autoclave decontamination performance. The MPCA responded that these indicators would test for sterilization, not decontamination. The MPCA maintains that this is a higher burden than required by statute. The MPCA is correct. Since no statute requires ordinary solid waste to be sterilized, and the statutory standard only requires decontamination to the level of ordinary solid waste, setting the standard higher would go beyond the MPCA's statutory authority.

37. Citizens who testified at the Perham hearing suggested that generators be required to demonstrate waste reduction efforts as part of the management plan. The rulemaking authority of the MPCA extends to transportation, storage, and disposing of infectious wastes. Minn. Stat. § 116.81, subd. 1. MDH has the

primary rulemaking responsibility regarding

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generators of infectious wastes. The MPCA lacks the statutory authority necessary to require waste reduction demonstrations from generators. The MPCA has shown that subpart 3 of proposed rule 7035.9120 is needed and reasonable as proposed.

Subparts 4-6 -Transport and Spill Response Requirements.

38. The substantive language of subpart 4 received few adverse comments. In lieu of reciting all the provisions of this subpart, only the language which received comment will be addressed. Steven Carter questioned whether personal automobiles could continue to be used for transporting small amounts of infectious waste (almost always sharps), because of the requirement that surface areas be smooth and easily cleaned (subp. 4C(5)) and that the waste be transported in a fully enclosed vehicle compartment (subp. 4C(2)). The MPCA is aware of the present practice of transporting small amounts of waste in personal autos. The MPCA has stated that it does not intend to prohibit the existing practices of not-for-compensation transporters. From that statement, the Administrative Law Judge concludes that the MPCA does not intend to strictly interpret the "smooth surface" requirement (when applied to small quantity, not-for-compensation transporters) and that personal autos are an adequate "enclosed space" for the purposes of the rule.

39. Haste Management objects to the partial exemption provided by proposed rule 7035.9120, subpart 58 for not-for-compensation transporters. Haste Management argues that the health and safety of the public are placed at risk by those transporters as by commercial transporters. It cites as an extreme example the risk that would occur should boy scouts or a Kiwanis group handle infectious waste and concludes that there are no factors which make such transporters less hazardous to public health. This argument does not accurately characterize those who would engage in not-for-compensation infectious waste transportation. The transporter must be a generator and, by virtue of proposed rule 7035.9120, subp. 58, must comply with many of the rules applicable to commercial transporters. Further, the MPCA is not aware of any spill that has occurred during such transportation. As noted above, the quantity of waste transported by such persons is small and consists of those items (sharps) least likely to cause a spill. The Infectious Waste Control Act explicitly regulates commercial transporters. The statute is silent regarding not-for-compensation transporters. The MPCA has shown that limited application of the commercial transporter rules to those who provide not-for-compensation transport is needed and reasonable.

40. The MPCA modified the language of subpart 58 at the hearing to include "at cost" transporters and groups of not-

for-compensation transporters in the partially exempt category, in addition to the not-for-compensation transporters. The MPCA's intent is to extend the partial exemption discussed in this paragraph to those non-commercial transporters whose costs of transportation (of infectious waste) are paid by the generator of the waste, but no profit is earned from the transaction by the transporter. Minn. Stat. § 116.76, subd. 4 uses the term "compensation" without specifying "for profit" or "not-for-profit." The statute is ambiguous and the MPCA's interpretation, that the Legislature meant those persons engaging in not-for-profit carriage of infectious waste when using the term "not-for-compensation," is reasonable. However, the MPCA and the regulated public should be aware that Minn. Stat. § 221 .011, subd. 16 defines "for hire" as "remuneration or compensation of any kind ... The Minnesota Department of Transportation  
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(MnDOT) may interpret that language to include generators who provide transportation of infectious wastes, "at cost." If that interpretation is made, persons who engage in that practice could be classified as "motor carriers" (Minn. Stat. § 221 .011, subd. 15), be required to obtain operating authority (Minn. Stat. § 221 .021), and otherwise comply with the laws and regulations governing motor carriage. All of the foregoing is conjecture based upon a possible interpretation of a statute by MnDOT. The proposed change by the MPCA was discussed at the hearing and does not constitute a substantial change.

40. MnDOT requested that the MPCA add language informing commercial transporters that they must possess motor carrier operating authority, comply with the Code of Federal Regulations when hauling infectious waste containing etiologic agents, and comply with federal and state reporting laws in the event of spills. MnDOT suggests that incorporating this language will better serve to notify persons engaging in the hauling of infectious wastes of the various statutory and regulatory requirements. The MPCA declined to incorporate the suggested language, stating that many other laws and rules are related, in some fashion, to the proposed rules. Since it would be impossible for the MPCA to include all of them, the MPCA has chosen not to selectively include some. Refusing to incorporate the language suggested by MnDOT does not render the proposed rules unreasonable. All of the references suggested by MnDOT are available elsewhere,

and the persons who handle these types of waste (judging from the comments received at the rule hearing) are knowledgeable about the extent of their obligations under the various statutes and rules.

41. Proposed rule 7035.9120, subp. 6 sets the requirements for spill response plans. Item A details the contents of a "spill kit" which must be available in areas used for offsite storage, decontamination, or transportation. Steven Carter of MMA objected to this subpart as not being specifically authorized by statute and overly restrictive, owing to the great detail specified in the subpart. Mr. Carter is correct in his assertion that no portion of the statute requires spill kits. However, the rulemaking authority granted the MPCA in the Infectious Waste Control Act is very broad. Requiring a spill kit is a rule "relating to the transportation of infectious waste" and does not conflict with the Infectious Waste Control Act. 5, Minn. Stat. § 116.81, subd. 1. The proposed subpart is authorized by statute. As will be discussed below, the subpart is not overly restrictive.

42. Some of the citizens who testified at the Perham hearing suggested that each vehicle carrying infectious waste be required to carry a spill kit. The MPCA declined to adopt that suggestion, on the ground that the spill could contaminate the spill kit, thereby rendering it useless to decontaminate the area of the spill. The MPCA's choice has a reasonable basis and, therefore, does not constitute a defect. Nevertheless, the Administrative Law Judge suggests that the MPCA reconsider requiring a spill kit be carried in every vehicle transporting infectious waste. Given the small size of the kit, and, particularly for the larger commercial transporters, the somewhat larger size of the vehicles, the likelihood of losing the kit through its being contaminated is outweighed by the benefit of being able to initiate cleanup of small spills immediately. Should the MPCA adopt that suggestion, the change would not be a substantial change.

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43. Waste Management suggested that disposable coveralls, neoprene gloves, surgical gloves, a respirator, goggles, and warning tape all be included in the required contents of a spill kit. The MPCA declined to do so, since the list of required items is intended to be a minimum standard. Refusing to adopt Waste Management's suggestion does not render the rule unreasonable. Nevertheless, the MPCA and the regulated public should consider the items listed by Waste Management as good suggestions for including in their spill

kits. Should the MPCA adopt those items as being required in the spill kit, the change would not be a substantial change.

#### Subpart 7 Financial Assurance.

44. Financial assurance is required of offsite storage facility owners and operators by proposed rule 7035.9120, subp. 7. Comments directed to this subpart came from Waste Management, the Mayo Clinic, and concerned citizens at the Perham hearing. Waste Management and some of the interested members of the public suggested that all transporters be required to meet the financial assurance rules. The MPCA declined to adopt this change to subpart 7, on the ground that motor carriers are already required to carry insurance, by virtue of Minn. Stat. § 221.141. Since the lack of comment at the hearing arose from the MPCA position that only offsite storage facilities needed to comply (with the MPCA defining satellite clinics as onsite relative to the base clinic) and the financial assurance rules received little comment regarding reasonableness, changing the proposed rule to require financial assurance of all transporters would be a substantial change.

45. The Mayo Clinic suggested that self-insurance be made an option for financial assurance. That suggestion was based on a case-by-case need approach. Thus, only if a facility could not pass a "financial test" would the financial assurance options (letter of credit, bond, or security deposit) be required. The MPCA responded that the Mayo Clinic suggestion, while used in other contexts, was not shown to be appropriate for infectious waste assurance. The MPCA maintains that the results from the statistical studies that form the basis of the self-insurance system do not apply to hospitals and other likely offsite storage facilities. The MPCA's reason for declining to add self-insurance as an option is valid. Subpart 7 is needed and reasonable as proposed.

#### Subpart 8 Recordkeeping.

46. Subpart 8 requires recordkeeping and reporting for facility owners, facility operators, and commercial transporters. The reporting required under this subpart relates to the quantity and type of waste handled and any incidents where infectious waste is released into the environment. Mr. Dunn of MMA objected to requiring the report to be submitted annually. He asserted that, since the management plan was to be submitted biannually, to require this report on an annual basis would conflict with the Infectious Waste Control Act. On the other hand, interested persons at the Perham hearing suggested that a report be filed at the time of the spill. The management plan is separate and distinct from the report required by this subpart (f, Finding 47, below). The contents of the annual report are not the same as for the management plan. The statutory two year schedule specifically refers to management plans. The MPCA argues that it cannot put the

contents of the

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annual plan to any good use should facilities and transporters file a report immediately upon the occurrence of each spill. The MPCA has shown that Subpart 8 is needed and reasonable, as proposed.

Proposed Rule 7035.9130 Management Plan.

47. Proposed rule part 7035.9130 requires each facility owner or operator and each commercial transporter to submit a management plan to the Commissioner for approval. An updated plan must be submitted every two years. The contents of the plan required by the proposed rule are consistent with the requirements set by Minn. Stat. § 116.79, subd. 1. Haste Management suggested that any exemptions to commercial transporter registration, such as that contained in proposed rule 7035.9130, subp. 4, be based on volume of waste, rather than commercial status. The distinction between commercial and noncommercial originates in the authorizing statute, not the proposed rules. Should the MPCA follow Haste Management's suggestion, the result would likely be beyond the statutory authority of the MPCA. The MPCA has shown that its system of management plans is needed and reasonable, and specifically authorized by statute.

Proposed Rule 7035.9140 Management Plan Certification Procedures.

48. Under proposed rule part 7035.9130 each facility owner or operator and each commercial transporter must submit a management plan to the Commissioner for approval. Proposed rule part 7035.9140 establishes the procedure to obtain that approval. No adverse comments were received regarding this proposed rule part. The MPCA seeks to change subpart 4 to conform with other changes in the rules regarding the description of noncommercial infectious waste collection and transport. In Item A, the term not-for-profit is replaced by "not-for-compensation or at cost." In Item B, the term not-for-profit is replaced by "not-for-compensation." The MPCA's reason for this change and a cautionary note from the Administrative Law Judge regarding a possible effect of this change are discussed above at Finding 40. The MPCA has shown that the proposed rule part is needed and reasonable. The modification to subpart 4 does not constitute a substantial change.

Proposed Rule 7035.9150 Forms.

49. In the SONAR, the MPCA asserts that forms are needed for the surety bonds and letters of credit to be used by offsite storage facilities. The MPCA cites administrative efficiency and equal treatment of the regulated public as the primary justifications for using forms. No adverse comments were received regarding this rule part. The MPCA has shown that the use of forms is needed to reduce time spent in legal review of contractual documents and maintain equal treatment for all facility owners and operators. The proposed rule

part is needed and reasonable.  
Based upon the foregoing Findings of Fact, the  
Administrative Law Judge makes the following:

CONCLUSIONS

1. The Minnesota Pollution Control Agency (MPCA) gave proper notice of this rulemaking hearing.

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2. The MPCA has substantially fulfilled the procedural requirements of Minn. Stat. § 14.14, subds. 1, 1a and 14.14, subd. 2, and all other procedural requirements of law or rule so as to allow It to adopt the proposed rules.

3. The MPCA has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn.

Stat. § 14.05, subd. 1, 14.15, subd. 3 and 14.50 (1) and (ii).  
4. The MPCA has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. § 14.14, subd. 2 and 14.50 (iii).

5. The additions and amendments to the proposed rules which were suggested by the MPCA after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3, and Minn. Rule 1400.1000, subp. 1 and 1400.1100.

6. Any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such.

7. A finding or conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the MPCA from further modification of the proposed rules based upon an examination of the public comments, provided that no substantial change is made from the proposed rules as originally published, and provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed rules be adopted consistent with the Findings and Conclusions made above.

Dated this of July, 1990.

ALLEN E. GILES

Administrative Law Judge

Reported: Tape Recorded; No Transcript Prepared.

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