STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Amendments to Part 4740.2040, Subparts 1, 2 and 5 and to Add Subpart 6 Relating To Synthetic Organic Compounds Eligible for Certification Under the Environmental Testing Laboratory Rules and Repeal of 4720.5000

STATEMENT OF NEED AND REASONABLENESS

I. INTRODUCTION

Although the practice of laboratory testing of environmental samples has been ongoing for many years, it has historically related to human health concerns about waste water and drinking water. With the dawning of environmental awareness in the early 1970's, Congress enacted expansions of the narrowly focused environmental programs and developed ambitious new ones such as the Clean Water Act, the Safe Drinking Water Act, the Clean Air Act, the Resource Conservation and Recovery Act, and the Superfund. These programs covered a variety of environmental media including water, air, and land and caused an explosion in environmental testing.

The primary regulatory agency at the federal level, the U.S. Environmental Protection Agency (EPA), established environmental programs with substantial monitoring and testing requirements. A state could be delegated permit and regulatory authority from EPA if a state program existed that was consistent with and at least as stringent as the federal program. Minnesota received such authority to run the major environmental regulatory programs. The Minnesota Department of Health (hereinafter "MDH")

has responsibility for enforcement of the Safe Drinking Water Act; the other major environmental programs are administered by the Pollution Control Agency (MPCA).

The influx of environmental testing data placed a burden on the state agencies to determine data reliability. Judgements about compliance and impacts were only as good as the data upon which they were based. Although EPA inspected and certified the MDH Laboratory, few other laboratories in Minnesota doing environmental testing were subject to review for the adequacy and reliability of their operation.

In 1986, Congress amended the Safe Drinking Water Act, increasing the number of chemical, biological, and radiochemical measurements in public water supplies from 23 to 83. Although the MDH Laboratory had performed all necessary tests on public water supplies under the Safe Drinking Water Act, this increased workload of necessity would need to be distributed among laboratories outside the Department of Health. In February, 1987, the Office of the Minnesota Legislative Auditor issued a report on "Water Quality Monitoring". The report recommended the establishment of a state certification program for environmental laboratories. Voicing concern about the amount of money spent on water quality monitoring in Minnesota and the impact the monitoring results have on regulatory decisions, the auditor stated: "It is important that decisions on these matters be based on accurate data. The best way to ensure accuracy is to require laboratories to demonstrate their ability to perform these analyses." In the 1988 session, the legislature authorized the

Commissioner of Health (hereinafter "Commissioner") to certify laboratories that analyze environmental samples.

Although the legislation speaks broadly to environmental samples, to initiate the certification program the Commissioner decided to focus on environmental analytes in water and wastewater because these analytes have a long history of testing. Well established procedures exist to monitor them and the methodology is well defined and widely distributed. Historically, because of the human health concerns, dischargers of wastewater and providers of public drinking water supplies have had to monitor wastewater and drinking water, and this type of monitoring is expanding and generates the majority of analytical environmental test data produced in Minnesota.

In view of this legislative authority, the Commissioner adopted Minn. Rules pts. 4740.2010 to 4740.2040 in January 1990 and amendments thereto on April 29, 1991 and April 28, 1992. The rules specify the administrative procedures associated with certification of environmental laboratories, requirements for base certification, and the various kinds of analytes for which the Commissioner will certify a laboratory's performance. These rules were adopted as a multi-phased implementation of the legislation authorizing the Commissioner to certify environmental laboratories. The analytes contained in the rules to date cover the first six test categories listed in the fee section of the authorizing legislation, Minn. Stat.§§ 144.98, subd. 3.

The proposed rule amendment, implementing phase three, expands the categories of analytes for which a laboratory may be certified. In addition, MDH proposes to repeal Minn Rule part

4720.5000 because, as described below, it is obsolete. This rule part to be repealed prescribes fees which the state laboratory performed for the public water supplies from 1986 through 1989.

II. STATEMENT OF THE COMMISSIONER'S STATUTORY AUTHORITY

The Commissioner's statutory authority to adopt a rule related to certification procedures for environmental testing laboratories is set forth in Minn. Stat. §§ 144.98 which provides in relevant part that the Commissioner may adopt rules to implement this section, including the test categories for which certification is available as specified in Minn. Stat. §§ 144.98, subd. 3. The authority to charge fees for laboratory services is contained in Minn. Stat. §§ 16A.128 and 144.98, subd. 2, (1), 3(d), and 4.

III. STATEMENT OF NEED

As noted above MDH is now ready to implement the certification process by proposing the last of the groups of analytes listed in Minn. Stat. §§144.98, subd. 3, ie., other organic compounds. There is also a need to enable environmental laboratories to become certified to perform these additional analytes on environmental samples because certification is now required under the federal Safe Drinking Water Act which the Department administers and by the Pollution Control Agency which administers the Clean Water Act.

The MPCA requested the addition of analytes it routinely monitors through its Resource Conservation and Recovery program ministered by its Division of Groundwater and Solid Waste. A

reference for the methods had to be added to accommodate this request. Certification of laboratories is required by the MPCA for two of its major programs, specifically the Clean Water Act and Resource Conservation and Recovery Act monitoring.

IV. STATEMENT OF REASONABLENESS

The proposed rule is reasonable because it conforms with federal requirements for certification established for tests performed on public drinking water supplies, and it fulfills the conditions of permits issued by the Minnesota Pollution Control Agency to entities which discharge wastewater.

The rule is also reasonable in that it does not restrict the use of methods. Rather it allows a laboratory to use any of a possible range of methods which the USEPA has authorized for such testing.

V. ANALYSIS OF PROPOSED RULE AMENDMENTS

- 1. 4740.2040 Subp. 1. The amendment to subpart 1 changing the reference to other subparts in the rule is needed to reflect the previous additions as well as those being made under this rule change. Subpart 5 added on April 28, 1992 and subpart 6 being added under this change. Also a new reference for a program has been added because it was requested by the MPCA which require methods used for this program.
- 2. 4740.2040 Subp. 2b. The analyte, "oxygen, dissolved", is being deleted from the list because the quality of the test cannot

be sufficiently controlled using current field collection methods. If quality cannot be controlled certification is not appropriate. The MPCA has requested this deletion.

The addition of "Organic Carbon, Total" is needed because it is an important criterion in monitoring effluents and waste water discharges permitted by the MPCA and was inadvertently omitted during the first rulemaking process.

3. 4740.2040 Subp. 5b. The amendment is needed to correct the name of the compound "1,1-dichloropropene".

The compound "1,2,4-trichlorobenzene" is being added because it was recently added by the USEPA under the Safe Drinking Water Act as a monitoring requirement.

The compound "Isopropylbenzene" is being added because this analyte is currently monitored by the MPCA.

4. 4740.2040 Subp. 6, (New) The Synthetic Organic Compounds. The analytes listed are those which are most commonly required for environmental monitoring programs. The compounds are grouped according to commonly used laboratory analysis categories. The methodology for these analytes already exists in the certification rules adopted in January, 1990, which adopt by reference the methodology specified in federal rules. See Minn. Rules pt. 4740.2030, subp. 1.

5. 4720.5000 is to be repealed because it is obsolete and has been replaced with another fee system. The MDH ceased billing according to the rule in 1989, after the Legislature appropriated sufficient funds to pay for public water supply testing. In 1992, the Legislature imposed a fee of \$5.21 per connection to a community public water supply, to pay for water supply testing (Minn. Laws 1992, Chap. 513, Art. 6, Sec. 3). These enactments supersede the MDH's rule and therefore, to eliminate any further confusion, it is reasonable that the fee setting rule be repealed.

VI. SMALL BUSINESS CONSIDERATIONS IN RULEMAKING

The impact of the rules on small businesses was examined as required by Minn. Stat.§§ 14.115, subd. 2, which asks an agency to consider whether regulatory requirements can be reduced or eliminated as applied to small business. The proposed amendments give businesses great latitude, as demonstrated by the following:

- 1. Participation in the program is voluntary. No laboratory is required to become certified for any of the analytes being added by the proposed amendments.
- 2. The laboratory chooses as many or as few analytes for which it wants to be certified. There is no requirement for whole groups of analytes to be certified at once, which might make it difficult for small laboratories. A small laboratory can add analytes according to its own schedule and capabilities or can delete analytes at any time and for any reason.
- 3. The laboratory chooses the methodology it uses for testing an analyte. A laboratory can review several approved

methodologies and choose the one most consistent with its equipment and personnel resources.

- 4. The primary measure of competency in testing analytes is a performance based standard, i.e. acceptable results in the analysis of performance evaluation samples. Certification does not require a certain design of facilities or qualifications of personnel or kinds of analytical equipment.
- 5. The variance procedure allows the Commissioner to consider undue hardship if a laboratory has difficulty in complying with parts of the rule.

Participation by small businesses in the rulemaking process was encouraged in two ways as specified in Minn. Stat. Sec. 14.115, subd. 4:

- 1. When the rules adopted in January, 1990, were being considered, at least one member of the technical advisory group which worked on the rules represented a small laboratory. The advisory group was aware of, and agreed with, the Department's proposal to add additional categories of analytes in the future.
- 2. All laboratories currently certified by MDH or in the application process and will be mailed copies of the proposed rules and invited to comment.

VIII. OTHER CONSIDERATIONS IN RULEMAKING

The adoption of these rules will not require expenditure of public money by local public bodies of greater than \$100,000 in either of the two years following promulgation, nor do these rules have any impact on agricultural land.

XIV. CONCLUSION

Based on the foregoing, the proposed rule amendments to the environmental testing laboratory certification rules are both needed and reasonable.

Dated: 12/5, 1992

MARLENE E. MARSCHALD Commissioner of Health

STATE OF MINNESOTA

DEPARTMENT :

HEALTH

Office Memorandum

DATE :

12-15-92

TO:

Maryanne V. Hruby, Executive Director

Legislative Commission to Review Administrative Rules

FROM:

Al Tupy, Chief

Laboratory Services Section

ACT

PHONE :

623-5680

SUBJECT :

Proposed Rules--Laboratory Certification--Synthetic Organic

Compounds

As required in Minnesota Statute 14.23, attached for your use are a copy of the "Notice of Intent to Adopt Rules Without a Public Hearing" and the "Statement of Need and Reasonableness" for Amendments to Part 4740.2040, Subparts 1,2 and 5 and to add Subpart 6 Relating to Synthetic Organic Compounds Eligible for Certification Under the Environmental Laboratory Rules and Repeal of 4720.5000.

This proposed rule will be published in the State Register on December 21, 1992. Also attached is the proposed rule for your use.

Enclosures

The Legislative Commision to Review Administrative Rules

DEC 1/6 1992

