

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH

In the Matter of the Proposed
Adoption of Amendments to
Part 4740.2040, Subpart 4
Relating to Metal Analytes
Eligible for Certification
Under the Environmental
Testing Laboratory Rules

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.

The influx of environmental testing data placed a burden on the state agencies to determine data reliability. Judgments 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 those analyses." In the 1988 session, the legislature authorized the Commissioner of Health (hereinafter "Commissioner") to certify laboratories that test 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, and this type of monitoring is expanding and generates the majority of analytical environmental test data produced in Minnesota.

In view of the history and legislative authority, the Commissioner adopted Minn. Rules pts. 4740.2010 to 4740.2040 on January 29, 1990. 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 the first phase of a multi-phased implementation of the legislation authorizing the Commissioner to certify environmental laboratories. The analytes contained in the rules basically covered the first three test categories listed in the fee section of the authorizing legislation. Minn. Stat. § 144.98, subd. 3. The proposed rule amendment, implementation phase two, solely expands the categories of analytes for which a laboratory may be certified. The amendment now brings in the fourth and fifth test categories listed in subdivision 3.

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.

III. STATEMENT OF NEED

As noted above in the Introduction section, the Commissioner decided to implement laboratory certification in stages. The reason for doing so is that the Department of Health had not previously been involved in a certification role of this scope. Administratively, the Department would have found it difficult to perform its role if certification were implemented all at once. Thus, with the rules adopted in January, 1990, the Department established the application process and certification standards and started with a list of analytes in part 4740.2040 which involved the simplest tests to perform. These tests were also the easiest for the Department to verify because they involve better established procedures. This approach to certification also enabled the largest number of

laboratories to become certified because laboratories are more likely to perform the easier rather than the more complex tests.

The Department is now ready administratively to perform the verification process for more complex test categories and thus to increase the number and types of analytes for which environmental laboratories may be certified. The new analytes require the use of more complicated tests which require more sophisticated instrumentation. By adding these analytes, the Department will have covered the first five test categories listed in Minn. Stat. § 144.98, subd. 3. (The remaining test categories will be addressed in future amendments to the rule.)

The adoption of the rules in January, 1990, only started implementation of section 144.98. With this proposed rule amendment, the Department will take another step toward implementation of the section, which it must do in order to make it fully effective. There is also a need to enable environmental laboratories to become certified to perform these additional tests on environmental samples because under the federal Safe Drinking Water Act and Clean Water Act certification is required.

IV. STATEMENT OF REASONABLENESS

The proposed rule is reasonable because it meets the existing federal requirements and recommendations regarding analytes to be tested in drinking water laboratory certification programs, and in permits issued by the Minnesota Pollution Control Agency to entities which discharge wastewater. Because the entire certification program is driven by the federal water quality programs, it is only logical for the Commissioner to expand the certification program to include analytes for which tests must be conducted under federal requirements as soon as the Department is able to effectively administer the expanded program. The Department is now able to do that with the analytes listed in the proposed rule amendments. As soon as these analytes have been incorporated into the certification program, other analytes will be added in future rule amendments.

V. AMENDMENT TO PART 4740.2040, SUBPART 4, CERTIFIED TEST CATEGORIES FOR METAL CHEMISTRY

The analytes listed are the ones most commonly requested or required for the specific programs after the analytes already specified in the rules adopted in January, 1990. They are grouped according to familiar laboratory analysis categories for ease of use and for consistency with the fee schedule outlined in the state. (The methodology for these analytes already exists in the certification rules adopted in January, 1990, which adopts by reference methodology specified in federal rules. See Minn. Rules pt. 4740.2030, subp. 1.)

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. As a general proposition, the subdivision asks an agency to consider whether regulatory requirements can be reduced or eliminated as applied to small business. The certification rules in general and the proposed amendments give businesses great latitude as demonstrated by the following:

1. Participation in the program is voluntary. There is no requirement to become certified.
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, possibly making it difficult for small laboratories. A small laboratory can proceed to add analytes according to its own schedule and capabilities or can delete analytes if they become uneconomical to analyze. No laboratory will be required to become certified for any of the analytes being added by the proposed amendments.
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 constraints.
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 certain design of facilities or numbers or degrees 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. § 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 analytes in the future.

2. All laboratories currently certified by the Department or in the application process and other interested parties will be directly mailed copies of the proposed rules and invited to comment.

VII. 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.

VIII. CONCLUSION

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

Dated: Dec. 17, 1990


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Commissioner of Health