STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

IN THE MATTER OF THE PROPOSED PERMANENT RULES RELATING TO CERTIFICATION OF ENVIRONMENTAL TESTING LABORATORIES

STATEMENT OF NEED AND REASONABLENESS

I. INTRODUCTION

Although the testing of environmental samples has been done for a long time, it was 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: the Clean Water Act, the Safe Drinking Water Act, the Clean Air Act, the Resource Conservation and Recovery Act, 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), issued permits 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 (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 Chemical lab, 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 Chemical 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.

On January 3, 1989 the commissioner published a "Notice of Solicitation of Outside Information or Opinions In the Matter of Rules Relating to Certification of Environmental Laboratories" in the State Register, affording interested parties 30 days to submit comments (13 S.R. 1694). In addition, on January 9, 1989 a meeting was held at the Department of Health to discuss possible rule language and scope. Invited to the meeting were approximately 25 members of a "Technical Advisory Group" consisting of laboratory professionals, water and waste water plant operators, scientists and staff from other state agencies. Written comments received from Pace and Serco Laboratories and Northern States Power Company after the published notice and meeting are included with this statement.

On June 1, 1989 another meeting was held with members of the Technical Advisory Group to receive further comments on a revised draft of the proposed rules. Further changes were made as a result of this meeting.

The rule as proposed describes 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. It reflects input from environmental health professionals, the Pollution Control Agency and the Technical Advisory Group.

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 Minnesota Statutes, section 144.98 which provides in relevant part:

The commissioner may adopt rules to implement this section, including:

1. procedures, requirements, and fee adjustments for laboratory certification, including provisional status and recertification;

2. standards and fees for certificate approval, suspension, and revocation;

3. standards for environmental samples;

4. analysis methods that assure reliable test results;

5. laboratory quality assurance, including internal quality control, proficiency testing, and personnel training; and

6. criteria for recognition of certification programs of other states and the federal government.

Additionally, Minnesota Statutes, section 144.12, gives the commissioner power to "adopt reasonable rules pursuant to chapter 14 for the preservation of the public health."

III. STATEMENT OF NEED

The need to adopt the proposed Minnesota Rule parts 4740.2010 to 4740.2040 arises from the need of environmental laboratories to know what actions they must take to apply for and maintain certification to test environmental samples for any given analyte and the criteria the commissioner will use to evaluate laboratory performance for certification.

It is needed to assure fairness and consistency by evaluating the performance of all laboratories according to the same described criteria.

Lastly the rule is needed to ensure reliability and comparability of data produced by laboratories for programs or permits designed to protect the public health and environment.

IV. STATEMENT OF REASONABLENESS

The proposed rule is reasonable because it closely parallels and is consistent with existing federal requirements and recommendations regarding drinking water laboratory certification, and other state certification programs. Since EPA would not recognize a certification program that was not as stringent as its own or inconsistent with its program, EPA requirements or recommendations as described in the "Manual for the Certification of Laboratories Analyzing Drinking Water"

(EPA-570/9-82-002) form the foundation for the basic minimum requirements in this rule. (See manual, p. 4: "Certification must be based upon criteria contained in this manual or State-developed equivalents at least as stringent as those herein.")

The laboratory certification programs of neighboring states, specifically North Dakota and Wisconsin, were also reviewed and portions adapted to the Minnesota situation.

The rule as proposed establishes a foundation of accepted good laboratory practices required to produce reliable data regardless of the analysis in requirements for base certification, yet does not require laboratories to have knowledge of specific analyses other than the test category or categories for which the laboratory chooses to request certification. The rule has been designed to be "expandable" to meet future needs, programs, and analyses. Frequent review and update of the rule is anticipated to accommodate growing analytical needs for environmental monitoring and testing and new environmental programs. Justifications for specific parts follow.

Part 4740.2010. DEFINITIONS.

Subpart 1. The proposed rule reasonably sets forth nine definitions to both clarify and shorten the rule.

Subpart 2. It is reasonable to define acceptable results in terms of the number of standard deviations because this is an objective measure of performance. It is reasonable to allow the provider to make this determination because the provider

collects data from a sufficient number of tests to perform this statistical measurement.

Subpart 3. It is reasonable to define approved providers in terms of the statistical analyses they perform and apply because these are objective criteria which clearly establish statistical skills needed by every provider to assure that labs are subjected to performance evaluations of similar stringency, regardless of the provider they choose. Since the reliability of the statistical analyses is affected by the sample size, volume is an essential criterion. Since the calculations can be skewed depending on the choice of sample data, the requirement for use of all sample values is reasonable because it assures data manipulations favorable to a particular lab will not be allowed. Finally, specifying the range of standard deviations allowed by the EPA as the minimum standard is reasonable because the calculation of this range is a well defined, published procedure, widely used, providing a basis for comparing performance. A range of standard deviations less stringent than EPA's criteria would not be recognized by EPA as adequate to evaluate performance.

Subpart 4. This subpart clarifies that the term base certification applies to the scope of laboratory practices that are necessary for the production of reliable data regardless of the specific environmental analyte.

Subparts 5 through 8 delineate the scope of terms used in the rule with straightforward, common or statutory usage.

Subpart 9. Subpart 9 clarifies that performance evaluation is done by means of test samples supplied by approved providers. It is reasonable to clarify that this is what is

meant by performance evaluation because the alternative but equivalent term of "proficiency testing" is used in the statute (Minnesota Statutes, section 144.98,(5)). It is reasonable to use this method to evaluate because it is a standard practice in the field. It is reasonable to require that a sample must come from an approved provider to assure consistency in the evaluation process.

Subpart 10. This subpart reasonably clarifies what is meant by the general term of quality control data by including a list of specific kinds of data that the term encompasses and which are familiar lab practices.

Part 4740.2020. ADMINISTRATIVE PROCEDURES REGARDING CERTIFICATION.

Subpart 1. Application. Subpart 1 clarifies that it is the laboratory's responsibility to request certification. This is reasonable because the program is voluntary. It clarifies that a request must be both general and specific i.e. the lab must request base certification and must specify the particular analytes for which performance is to be certified. It is reasonable to require base certification because adherence to good laboratory practices is essential for any type of analysis. It is reasonable to allow the lab to specify the analyte certification desired because not all labs want or need to do all the analyses.

The address, phone number of the laboratory and names of administrators and owners are requested to allow the commissioner to contact the lab, and to know who is or may be

legally responsible for lab operations. The names of professional personnel and their experience and education levels alert the commissioner to possible competency concerns which may need to be scrutinized to assure the production of reliable data.

Because the commissioner cannot immediately inspect each laboratory that applies for certification, it is reasonable to require written assurance from the laboratory that it adheres to applicable standards until the necessary verification by inspection can be made.

It is reasonable to require the submission of the fees set by Minnesota Statutes, section 144.98, subd. 3 (1988), with the application because fees cover the cost of the operation of the program. It is reasonable to clarify that the base certification fee is nonrefundable because staff costs are fixed for the initial review, regardless of its outcome. Submission of recent performance evaluation data is reasonable because it is an objective measure of how effectively the laboratory is currently operating. Submission of a quality control plan and laboratory procedures manual is reasonable because these documents describe the lab's procedures and practices and review of them ~~is an~~ important element in judging the adequacy of the lab's operation.

Because the reliability of the test data is dependent upon the specific conditions present in a laboratory, including the laboratory environment, the equipment and the trained analysts, each laboratory must be inspected separately for adequacy in these areas; therefore, it is reasonable to have branch laboratories file separate applications. Also, since each

branch laboratory has different staff, may perform different tests and have available different equipment, it is reasonable to require demonstrated ability to produce acceptable results on performance evaluation samples and a quality assurance plan and laboratory manual specific to those conditions.

Subpart 2. Application review. This part makes explicit the options the commissioner has for processing applications and the timeframes involved. Sixty days is reasonable because of the volume of material that must be reviewed. It is reasonable to reject an application if performance evaluation results are not acceptable because the lab has not demonstrated it can accurately perform the test. It is reasonable to reject an application for an inadequate quality assurance plan or laboratory procedures manual because these documents establish the necessary framework to produce reliable data consistently. To notify the lab of any missing information and allow 60 days to supply it is reasonable because the volume of information required for an initial application and unfamiliarity with the process may lead to inadvertent but easily correctable omissions. However, if the information is not supplied within the 60 day timeframe, it is reasonable to reject the application because the information initially submitted could be up to four months old and may have changed, the time between required performance evaluations would be extended and the submitted performance evaluation data may not be recent enough to provide an accurate indication of current laboratory performance.

Subpart 3. Provisional Certification. Provisional certification is a temporary interim status for labs which have no certification but have applied for it. It covers the period

of time between the application and the inspection which will evaluate adherence or lack of adherence to standards required for proper laboratory operation. Such recognition is reasonable to prevent penalizing labs due to the commissioner's inability to immediately inspect all labs that apply for certification. However, the standards for issuing a provisional certification must be sufficient to indicate probable competence in testing. It is reasonable to demand the submission of required and requested information so the commissioner can determine compliance with applicable requirements of this chapter which may be verified from documents or the application for certification. It is reasonable to require acceptable results on performance evaluation samples because it is an objective demonstration of performance. It is reasonable to require submission of the fees because Minnesota Statutes 144.98, subd. 3 so requires, and because they fund the personnel to review the application and inspect the lab. Requiring written assurance in the absence of inspection is reasonable to indicate the lab's awareness of and willingness to follow necessary standards. Allowing renewal of a provisional certification if the laboratory has not been inspected is reasonable because the laboratory has no control over the inspection schedule.

Subpart 4. Denial of certification. When an inspection uncovers deficiencies in meeting the standards of the rule, it is reasonable to provide written notice to the lab of the deficiencies that prevent its becoming certified so that the lab knows what actions it must take to become certified. Allowing a period of thirty days to correct the deficiencies is reasonable because a laboratory applying and being inspected for the first

time may be insufficiently familiar with the standards to meet the required level of detailed examination. Thirty days is reasonable because it assures deficiencies will be corrected promptly. Minor deficiencies can easily be corrected within this timeframe; however if major deficiencies exist which would impair analytical performance, 30 days reasonably limits the time suspect data may be produced. Thus the purpose of the certification program, assurance of the reliability of test data, is maintained while labs are not unnecessarily penalized for small oversights or minor problems. Requiring a laboratory which has been notified of its noncompliance with these rules to document the corrective actions it has taken is reasonable to prevent the expense associated with multiple inspections by the commissioner.

Subpart 5. Approval of Certification. It is reasonable to approve certification for a lab that meets all the provisions of this rule when the commissioner has verified its compliance by inspection. It is reasonable to make the approval retroactive to the date of provisional certification because annual certification fees are required to fund the program, and the analysis of performance samples must be assured within the term.

Subpart 6. Certification renewal. It is reasonable to require a lab to submit a renewal application 30 days in advance to allow for processing prior to the expiration date. Submitting only the changes to the quality assurance plan and lab manual is reasonable to cut down paperwork, storage needs and review time and to allow the commissioner to review changes for compliance with these rules. Requiring a statement that the

manual remains current is reasonable to focus attention on the importance of these documents to proper lab function and the duty of lab director to review them. A one year term of renewal reasonably allows the commissioner opportunity to reassess changes in the lab's status. Requiring the commissioner to inspect labs certified by renewal at least once every three years is consistent with the federal requirement for drinking water lab certification, and assures the maintenance of laboratory standards.

Subpart 7. Suspension of certification. The conditions under which the commissioner may suspend a certification all relate to reasonable concerns about responsibility for laboratory operations and the production of inaccurate and misleading data in the absence of adherence to these specific standards. They are conditions which the lab can correct within a relatively short period of time with instruction or incentive. To use the suspension process for these conditions is reasonable to allow that time and provide that incentive to the lab while protecting the quality of the data available to agencies and clients who, when informed of the suspension, can choose to seek another certified lab during the suspension of a particular lab.

Unacceptable performance results that go unreported or uncorrected jeopardize the production of reliable data because performance evaluation samples are critical measurements of the laboratory's competence. If a performance evaluation sample is not analyzed accurately, and the source of the problem is not determined and corrected, clients and agencies using the data

cannot be assured of a lab's capability to perform that test accurately.

Changes in certain aspects of lab's ownership, operation, and personnel are required to be submitted to the commissioner because the production of reliable data is dependent on the interaction of all the listed factors and because the commissioner needs to know who is responsible and how to find them. A change in any one of them may indicate a need for review to assure that its replacement continues to meet applicable requirements of these rules and continues competent performance in supplying reliable data. The sanction of suspension for failure to report provides a strong incentive to report. It is also consistent with the federal requirement for drinking water lab certification.

It is reasonable to suspend the certification of a lab that fails to follow methodology or to use approved methodology because methodology is critical to the production of reliable data. Without use of proper methods, no comparison could be made of the data and the reliability must be suspect.

Subpart 8. Revocation of certification. The grounds for revocation are based on demonstrated actions that have produced or or are likely to lead to the production of misleading data or disguise the lab's inability to perform a test or to produce reliable data. They reflect serious disregard for practices essential to the operation of a reliable laboratory, and a flawed pattern of operation in which the lab cannot demonstrate its ability to perform tests, the basis for certification. Revocation is reasonable for the described conditions:

1. to provide a strong incentive to avoid the given situations;

2. to preserve the meaning of certification i.e. acknowledgment of demonstrated capability; and

3. to protect the lab's clients from the receipt of inaccurate and unreliable data.

It is reasonable to allow revocation of a certification when the lab does not comply with standards because the standards exist to assure performance that will produce reliable data. Likewise, failure to correct deviations from standards when noted causes data to be suspect. It is reasonable to revoke for fraudulent behavior. Revocation for two bad performance evaluation samples in a row is reasonable because the lab has provided evidence that it cannot produce an accurate test result. While one bad performance evaluation result could be fortuitous or a problem corrected, a bad result, even after corrective action taken, shows the lab no longer has demonstrated capabilities to perform the test. Revocation under a reciprocity agreement is reasonable because under such an agreement, the commissioner and other certifying authority recognize each other's programs as substantially equivalent. If the programs are equivalent, then the standards for certification and revocation thereof are substantially equivalent. It is reasonable to allow the commissioner to revoke certification under such circumstances.

It is reasonable to require the lab to notify clients of the revocation so that clients can choose other certified labs to produce data. It is reasonable to allow a lab to reapply for certification if all deficiencies have been corrected. Proof of

the corrective action for deficiencies is reasonable for if no changes have been made, the commissioner will not approve certification.

Subpart 9. Certification of laboratories in other states. To allow a lab in another state to be certified by Minnesota is reasonable because labs outside Minnesota may wish to have an acknowledgement of their ability to perform environmental tests, especially if the lab accepts work from clients in Minnesota or is located in a state which does not provide a certification program. Requiring an out-of-state inspection fee is reasonable because required by section 144.98, subd. 3 (C) (1989).

The development of reciprocity agreements with other authorities is reasonable because it is promoted by EPA as a way to encourage uniformity and consistency nationwide among certification programs. If two programs are mutually evaluated and recognized as the same in all critical elements, then it is reasonable to replace the requirement for an inspection by the commissioner with an inspection by the certifying authority, saving money for both the lab and the commissioner. The requirement to notify the commissioner of actions taken by the other certifying authority is reasonable to assist the commissioner in monitoring the status of the out-of-state lab, assuring that consistent actions are taken. The 30 day period is reasonable because it is a standard timeframe which assures reasonably prompt action.

Subpart 10. Variance. It is reasonable to allow a process for addressing unique circumstances that may make compliance with the requirements of the rule difficult for a certain lab or period of time. The proposed variance process appropriately

balances the need for reliable data with any special needs of the laboratory and for compliance with EPA requirements. In order to determine the impact of the request, it is reasonable to ask the lab for the information requested as to what rule it cannot meet, why it cannot meet it, for how long it will have problems meeting it, what measures it can take while not complying and what its impact will be on the data reliability. If the lab can demonstrate a requirement causes it hardship and can propose an equivalent alternative that has no adverse effect on data reliability, it is reasonable to grant the variance because the purpose of certification is maintained while preventing an undue burden on the laboratory. Sixty days to review the variance request is reasonable because the request may require technical verification i.e. the commissioner may need to document that the alternative has equal reliability or no adverse impacts on data generation. A written response provides the lab with opportunity to analyze and respond.

Subpart 11. Appeal of administrative decision. This section reasonably clarifies that a lab has access to an established appeals process prior to the commissioner effecting a change in its status that may be adverse to it. It is reasonable to specifically require the commissioner to provide written justification so the lab can evaluate the reasons for the commissioner's decision. Thirty days is reasonable because it is a standard response timeframe providing reasonable promptness. The requirement for the commissioner to initiate the process after being informed of the lab's request and objections is reasonable because only a state agency can initiate a contested case, it assures the lab of a hearing by an

objective third party while not preventing and perhaps even promoting a negotiated settlement via stipulation agreement, consent order etc. to address concerns.

PART 4740.2030. REQUIREMENTS FOR BASE CERTIFICATION.

The requirements for base certification all relate to laboratory practices essential for the production and maintenance of good data, regardless of the sample being analyzed.

Subpart 1. Methodology. Methodology, or a description of how a test is to be performed according to a established authority, is the most critical essential of any laboratory operation. Since different authorities may have different techniques for analyzing samples it is reasonable to require the laboratory to specify which method it uses to analyze samples. It is further reasonable to restrict the choice of method when a specific method is required by law, permit or rule, because data produced by any method other than the required method may not be comparable, and may not be useful in determining adherence to the requirements of that law, permit or rule. Specifying use of Code of Federal Regulations governing the Safe Drinking Water Program and Clean Water Program for analyses for those programs is reasonable because they are well established, easily located, finalized after extensive public comment, and a minimum required standard nationwide. Specifying use of methods in Minnesota Statute 4720 is reasonable because it specifically reflects the Minnesota Safe Drinking Water Program which is consistent with the federal program.

It is reasonable to accept an alternative methodology if EPA approves because EPA has approved the method originally, has an established process for evaluating proposed alternatives which the commissioner lacks, and would deem the commissioner's approval alone inadequate for its purposes, subjecting the lab to another review on the federal level. The commissioner's acceptance of EPA's approval eliminates one level of review without affecting the reliability of the data.

Subpart 2. Performance evaluations. It is reasonable to require the analysis of a performance evaluation sample during the term of certification because it is an objective demonstration of the lab's ability or inability to perform a test. It is reasonable to require analysis by usual analysts etc. because that gives an accurate demonstration of the reliability of performance that could be expected by any client requesting work. Requiring the lab to obtain the sample from an approved provider is reasonable to assure that all labs are subject to performance evaluation of the same stringency. The requirement for the commissioner to publish a list annually promotes compliance by providing up-to-date information on availability of performance evaluation samples. The information will also be available throughout the year from the Public Health Laboratory Division of MDH. Allowing the commissioner to view quality control data if no performance sample is available is reasonable because it provides an alternative evaluation of performance based on the objective criteria of precision and accuracy. It continues the emphasis on the importance of performance evaluation to the demonstration of a lab's ability to produce reliable test data. The requirement that the lab

show acceptable performance as defined in these rules is reasonable to provide evidence of the lab's ability to perform. The requirement to take corrective action promptly and to notify the commissioner when notified of unacceptable results is reasonable because bad results in one instance may indicate bad data is being generated and on other occasions a thorough review is required to document the cause of the poor performance and correct it. The requirement to request a follow-up sample in 30 days is reasonable to assure that the lab implements the necessary corrections required for good performance and promotes a quick resolution to doubts about the reliability of the lab's performance. Notification of second results within a 14 day period is reasonable because it is consistent with reporting the timeframe for first sample and allows the commissioner to act to protect public interest in a timely fashion. Allowing the commissioner to supply blind performance evaluation samples is reasonable because it is a tool for promoting good performance. In the cases where a lab's performance is suspect, it may be a vital tool to prove fraud or incompetence.

Subpart 3. Records. Since analyzing a sample without recording its origin and the results adequately makes the data useless, it is reasonable to require the specificity of information to be recorded (name of collector, dates, etc.) and the length of time the records may be useful. For the Clean Water Program, three years is a reasonable length of time because that allows adequate time for the regulatory agency, the Pollution Control Agency, to have reviewed data related to permit compliance or concerns about impacts of permitted facilities and verify with the lab the validity of data

submitted by the permittee. Three years is consistent with minimum EPA recommendations for chemical data.

For the Safe Drinking Water Program, ten years is reasonable because it is consistent with the federal requirement for the retention of all chemical data in that program by the operator of a public water supply system for ten years (40 CFR 141.33). Again, having the lab retain it for the same period of time allows concerns about the accuracy of the data to be explored and results verified. Additionally, EPA requires microbiological data for the Safe Drinking Water Program to be retained by the lab for five years. The ten year requirement reasonably includes the different timeframes.

It is reasonable to require all data, not just analytical data, to be kept for the same length of time because the other data i.e. the sample collection date, quality control data, and the equipment data are necessary to support the accuracy and precision of the analytical data. Also consistency in the retention times for a program makes errors in record retention much less likely. It is reasonable to allow the commissioner to request an extension of time for record retention if the commissioner limits the request to specific records for a specific time period.

Subpart 4. Quality assurance plan. The possession of a quality assurance plan is reasonable to insure that routinely generated analytical data are scientifically valid and defensible and are of known and acceptable precision and accuracy. Preparing a written description of its quality assurance activities assists the laboratory with accomplishing these goals and allows review by the commissioner for compliance

with the rules. The contents of the plan are reasonable because they incorporate the federal requirements which are well established, familiar to many labs, and required for a state certification program. (Manual for the Certification of Laboratories Analyzing Drinking Water, EPA-570/9-82-002.) It is reasonable to allow the incorporation by reference because most labs choose to follow recommended practices from recognized authoritative sources. Requiring page numbers and table of contents is reasonable to provide for ease of review by the commissioner. Allowing the lab to state why an item is not applicable is reasonable because not all labs perform a wide variety of tests or provide a wide range of services. For example, some labs never collect samples and thus have no need to devise collection procedures. Others may never receive requests for chain of custody procedures and therefore should not have to expend the effort to develop them.

Subpart 5. Minimum Quality Control Practices. It is reasonable to provide a list of minimum quality control practices because it clarifies for the laboratory what will be minimally acceptable to the commissioner in review of the quality assurance plan. The requirements themselves are derived from the quality assurance plan in use at the Department of Health, Chemical Laboratory, and all of them are either recommended by the EPA or the Wisconsin Lab certification program or other authoritative sources. They establish the minimum elements of quality control that a lab can carry out and still expect reliable results.

Subpart 6. Laboratory procedures manual. The requirement for a laboratory procedures manual is reasonable to promote

consistency in analytical technique regardless of the analyst. When analysts must use the manual to follow procedure, it minimizes the deviations that might occur if left to devise their own procedures. It eases inspection for the commissioner who can observe how well analysts adhere to procedure. The requirement for numbered pages and table of contents contributes to ease of use by the analyst and ease of review by the commissioner. The requirement for annual review and approval by the lab director assures consistency and currentness. Listing what must be in the manual clarifies for the lab what criteria the commissioner will use to evaluate the manual. The proposed criteria describe all analysis steps that the sample passes through from choice of a sample to reporting the results of sample analysis. This is reasonable because although the rule allows lab discretion by not specifying exact procedures, it thoroughly outlines the topics to be discussed, assuring consideration of all the steps and specification of them by the lab, promoting consistency in results.

Subpart 7. This subpart reasonably requires the use of unexpired chemicals to assure appropriate chemical activity in the analysis.

Subpart 8. This subpart reasonably requires maintenance of analytical equipment so it can perform properly.

Subpart 9. This subpart requires that a lab record on the data sheet occurances that could reasonably be expected to affect the reliability of the data. It is reasonable to require the lab to record such information so that the client can judge whether the data are acceptable for the client's purposes.

Subpart 10. Duty to notify. It is reasonable to require the lab to report all the listed changes because the production of accurate data depends on interaction of all of the above factors. When the commissioner is alerted to such changes, the commissioner can review the replacements during the next inspection to assure that the replacement is maintaining the production of reliable data. The commissioner certified the lab based on original equipment methodology, personnel, etc. Changes can affect reliability of data, change in location, and owners affects ability to find responsible people.

4740.2040. CERTIFIED TEST CATEGORIES.

Subpart 1. Scope. This subpart clarifies that the certification is both analyte and program specific. The certification process is linked in the proposed rules to specific environmental programs because it is the programs that drive the need to monitor, i.e. the great majority of monitoring is in response to a program requirement. By specifying a program, the framework for environmental sampling is established. Methods for testing under that program have been developed or approved by EPA which consider the unique difficulties and concerns of testing in a specific medium or situation. For example, to analyze lead in water, air and soil requires different procedures. Each program will have developed appropriate procedures for collecting and analyzing samples in a way that produces reliable data for that program's needs. This assures that the environmental protection goals of the program can be met.

Clients requesting testing that is not related to a program benefit by the high standard of reliability assured by program methodology.

Subparts 2, 3 and 4. The analytes listed are the ones most commonly requested or required for the specific programs. They are grouped according to familiar laboratory analysis categories for ease of use and for consistency with the fee schedule outlined in the statute. It is reasonable to state that pH, free chlorine and turbidity need not be done by a certified lab but must be done within one hour using approved methodology because this is recommended by EPA.

Repealer. The repealer addresses a current bacteriology certification program operated by the Department of Health. It is reasonable to replace the current program with the proposed program because the proposed program is more thorough and comprehensive in its scope. It is reasonable to allow 60 day delay for the repeal to allow labs certified under the existing program to be certified under the new program without loss of certification.

V. SMALL BUSINESS CONSIDERATIONS IN RULEMAKING

The impact of the rules on small businesses was examined as required by Minnesota Statutes, section 14.115. The impact has been minimized by the following construction of the rule:

1. Participation in the program is voluntary. There is no requirement to become certified.

2. The lab chooses as many or as few analytes as it wants to have certified. There is no requirement for whole groups of

analytes to be certified at once, possibly making it difficult for small labs. A small lab can proceed to add analytes according to its own schedule and capabilities or can delete analytes if they become uneconomical to analyze.

3. The lab chooses the methodology it uses. A lab can review several approved methodologies and choose the one most consistent with its equipment and personnel constraints.

4. The primary measure of competency 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 lab has difficulty in complying with parts of the rule.

Participation by small businesses was encouraged in two ways:

1. At least one member of the technical advisory group represented a small lab.

2. All labs which currently do work for the Pollution Control Agency permittees (over 200) and all labs currently certified by the Department for Microbiology (over 50) will be directly mailed copies of the proposed rules as published and encouraged to comment.

VI. 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.

VII. CONCLUSION

Based on the foregoing, the proposed rules for certification procedures for environmental testing laboratories are both needed and reasonable.

7/19/89
Date

for Sister Mary Madonna Ashton
Commissioner of Health

minnesota department of health
717 s.e. delaware st. p.o. box 9441 minneapolis 55440
(612) 623-5000

August 1, 1989

The Legislative Commission to Review Administrative Rules
Maryanne Hruby, Director
55 State Office Building
St. Paul, Mn. 55155

Dear Ms. Hruby:

Attached, as requested, is a copy of the Statement of Need and Reasonableness (SONAR) for the Proposed Permanent Rules Relating to Certification Procedures for Environmental Laboratories.

If you have any questions, please call me.

Sincerely,

Allen C. Tupy

Allen C. Tupy, Chief
Laboratory Services Section
Division of Public Health Laboratories
(612) 623-5680

ACT:DB