

Minnesota Attorney General: Administrative Rules Proceedings

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August 20, 2018

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DEPARTMENT: Office of the Attorney General **STATE OF MINNESOTA**

OFFICE MEMORANDUM

DATE: January 4, 1990

TO: SARAH M. MULLIGAN
Special Assistant Attorney General
525 Park Street, Suite 500 (55103)

FROM: CHARLENE W. HATCHER
Special Assistant Attorney General
525 Park Street, Suite 500 (55103)

PHONE: 296-9422

SUBJECT: In the Matter of the Adopted Rule Relating to Certificate Procedures for Environmental Testing Laboratories

The above-referenced rule has been approved as to its legality by the Attorney General on January 4, 1990.

Enclosed is your copy of the approved rule. This office has already filed two copies with the Secretary of State, who will forward one copy to the Revisor of Statutes. The fourth is being retained by this division of the Attorney General's Office for its records.

Also enclosed are any petitions, requests, submissions or comments along with any extra copies of documents which you submitted to the Attorney General.

Your next step is to arrange for publication of the Notice of Adoption in the State Register. In a day or two, you should receive from the Revisor's Office three copies of the notice of adoption of your rule. You should submit two copies of the Notice of Adoption to the State Register for publication. A permanent rule without a hearing does not become effective until five days after a notice of adoption is published in the State Register in accordance with Minn. Stat. § 14.27. An emergency rule becomes effective five working days after approval by the Attorney General; however, the agency must publish a notice in the State Register in accordance with Minn. Stat. § 14.34.

If you have any questions in this regard, please contact me.

CH:bbl
Enclosures
cc: William Brown, Chief Judge (memo only)
MaryAnn Hruby " "

Department of Health

Adopted Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories

Rules as Adopted

4740.2010 DEFINITIONS.

Subpart 1. **Scope.** The terms used in parts 4740.2020 to 4740.2040 have the meanings given them in this part.

Subp. 2. **Acceptable performance or acceptable results.** "Acceptable performance" or "acceptable results" means analytical test results generated by a laboratory using methods as specified in part 4740.2030, subpart 1, that fall within the range of standard deviations of the mean allowed by the approved provider.

Subp. 3. **Approved provider.** "Approved provider" means a provider of performance evaluation samples that the commissioner has determined:

A. provides an adequate volume of samples to perform statistically valid analyses;

B. calculates the number of standard deviations of the mean allowed using the results of all labs submitting test results after the exclusion of outlying values; and

C. allows a range of standard deviations of the mean no less stringent than the range allowed by the EPA.

Subp. 4. **Base certification.** "Base certification" means acknowledgment by the commissioner that a laboratory has the policies, procedures, equipment, and practices to produce reliable data in the analysis of environmental analytes described in part 4740.2040.

Subp. 5. **Commissioner.** "Commissioner" means the commissioner of health or the commissioner's designee.

Subp. 6. **EPA.** "EPA" means the United States Environmental Protection Agency.

Subp. 7. **Fees.** "Fees" means the fees described in

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Minnesota Statutes, section 144.98, subdivision 3.

Subp. 8. **Inspection.** "Inspection" means an on-site evaluation of laboratory facilities, records, personnel, equipment, methodology, and quality assurance practices by the commissioner for compliance with the applicable provisions of this chapter.

Subp. 9. **Performance evaluation sample.** "Performance evaluation sample" means a sample obtained from an approved provider to evaluate the ability of a laboratory to produce an analytical test result meeting the definition of acceptable performance. The concentration of the analyte in the sample is unknown to the laboratory at the time of analysis.

Subp. 10. **Quality control data.** "Quality control data" means data generated to assess the accuracy and precision of test data. Quality control data includes data on calibration standards, performance evaluation samples, blind standards, known standards, duplicate samples, blanks, spiked samples, and limits for quality control spiked samples, reference standards, duplicates, and detection levels.

4740.2020 ADMINISTRATIVE PROCEDURES REGARDING CERTIFICATION.

Subpart 1. **Application.** A laboratory may request to be certified by the commissioner for the analysis of the environmental analytes described in part 4740.2040.

A. The laboratory must specify the analytes for which it seeks certification. No analyte shall be certified without the laboratory meeting base certification requirements.

B. The laboratory shall apply on a form that is provided by the commissioner and that requests the following information:

~~A.~~ (1) the address and phone number of the laboratory;

~~B.~~ (2) the ownership of the laboratory;

~~C.~~ (3) the names of officers or managing agents of the laboratory and the laboratory director;

~~D.~~ (4) signatures of two managing agents with

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authority to bind the laboratory and proof of their authority to bind;

~~E.~~ (5) the names of principal, lead, or supervisory professional staff performing or responsible for the analyses, their educational level, field of study, and analytical laboratory experience; and

~~F.~~ (6) written assurance that the laboratory meets the standards of parts 4740.2010 to 4740.2040.

C. With the application the laboratory shall submit:

(1) the applicable fees, including a nonrefundable base certification fee and fees for each test category in which the lab seeks certification;

(2) a quality assurance plan meeting the standards of part 4740.2030, subpart 4;

(3) a laboratory procedures manual meeting the standards of part 4740.2030, subpart 6; and

(4) the most recent performance evaluation results on the analytes for which the laboratory seeks certification. The performance evaluation samples must be from an approved provider and be analyzed within one year of the date of the application.

D. The commissioner shall certify a laboratory at a specific location. When a laboratory owns or manages laboratory facilities at different locations, a separate application must be submitted for each separate laboratory location.

Subp. 2. **Application review.** Within 60 days after receiving the application and information required in subpart 1, the commissioner shall:

A. issue provisional certification with the expiration date clearly marked; or

B. reject the laboratory's application if the performance evaluation results are not acceptable or if the quality assurance plan or laboratory procedures manual does not meet the standards of part 4740.2030, subparts 4 and 6; or

C. notify the laboratory in writing of any omission or error in application. If the laboratory does not submit to

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the commissioner the required information within 60 days after receiving the error notice, the commissioner shall reject the application.

Subp. 3. **Issuance of provisional certification.** The commissioner shall issue a provisional certification to a laboratory that:

A. has submitted all required and requested information;

B. has demonstrated acceptable performance in the testing for analytes for which the laboratory seeks certification;

C. has paid the fees; and

D. provides written assurance that the laboratory adheres to base certification and analyte specific certification requirements of parts 4740.2010 to 4740.2040.

The provisional certification is valid until the commissioner, after an inspection, approves or denies certification. If, one year after the date of issuance of the provisional certification, the commissioner has not inspected the laboratory, the commissioner shall renew a provisional certification if the laboratory files a renewal application according to subpart 6.

Subp. 4. **Denial of certification.** When the commissioner determines after inspection that a provisionally certified laboratory does not comply with applicable provisions of parts 4740.2010 to 4740.2040, the commissioner shall, within 60 days after the inspection, notify the laboratory in writing of the deficiencies preventing certification. Within 30 days after receiving the notice, the laboratory must remedy the deficiencies and provide documentation of the correction to the commissioner. If the laboratory provides no documentation of deficiency corrections within 30 days, the commissioner shall notify the laboratory that its certification is denied. The laboratory may not reapply for certification until it has corrected all deficiencies. The laboratory must submit written documentation of the steps taken to correct the deficiencies

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with its new application.

Subp. 5. **Certification approved.** The commissioner shall approve base certification and analyte certification for a laboratory when the commissioner determines, after an inspection, that the laboratory complies with the applicable provisions of parts 4740.2010 to 4740.2040. The certification approval is valid for one year from the date of issuance of the provisional certification.

Subp. 6. **Certification renewal.** The commissioner shall renew a base certification and analyte certification if the commissioner receives the following from the laboratory at least 30 days before the expiration date of the certificate: (1) an application meeting the standards of subpart 1, items A; B; C, subitems (1) to (3); and D; and part 4740.2030, subpart 2; and (2) appropriate fees ~~at least 30 days before the expiration date of the certificate~~. With the renewal application the laboratory shall submit any changes to the quality assurance plan or laboratory manual or a statement that the plan and manual continue to accurately describe current practices. The revised manual and plan must continue to meet the standards of part 4740.2030, subparts 4 and 6. The renewal certification is valid for one year. The commissioner shall inspect a laboratory certified by renewal at least once every three years.

Subp. 7. **Suspension of certification.** The following are grounds to suspend a base certification or analyte certification of the laboratory:

A. failure to report unacceptable results on a performance evaluation sample or to submit a corrective action plan to the commissioner as described in part 4740.2030, subpart 2;

B. failure to notify the commissioner within 30 days of changes described in part 4740.2030, subpart 10; ~~or~~

C. failure to use approved methodology or follow methodology in sample analysis; or

D. suspension of certification by an authority with which the commissioner has a reciprocity agreement.

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The commissioner shall restore the certification when the laboratory demonstrates it is in compliance with parts 4740.2010 to 4740.2040.

During the time of suspension, the laboratory must notify ~~clients who request analysis of the analyte for which the certification has been suspended~~ an existing client or new client of the suspension if the client requests analysis of the analyte for which the certification has been suspended and requires the requested analysis to be performed by a certified laboratory.

Subp. 8. **Revocation of certification.** The following are grounds to revoke a base certification or analyte certification of the laboratory:

A. failure to comply with applicable standards of parts 4740.2010 to 4740.2040;

B. failure to correct deficiencies noted in the inspection report within the specified time frame;

C. use of another laboratory to analyze performance evaluation samples and reporting the results as the laboratory's own;

D. use of fraudulent or deceptive practices in the laboratory's analysis or reporting of data;

E. failure to produce acceptable results on an initial and follow-up performance evaluation sample; ~~or~~

F. revocation of certification by a certifying authority with which the commissioner has a reciprocity agreement; or

G. failure to cooperate with an inspector designated by the commissioner.

Within 30 days after the revocation, the laboratory must notify all existing and new clients ~~for which it is presently analyzing samples~~ whose analytical work requires a certified laboratory that it is not certified. ~~The laboratory must also notify new clients that it is not certified.~~ The laboratory shall provide verification of this notice to the commissioner. The laboratory shall not advertise itself as certified and shall

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remove or replace any advertisements that indicate that it is certified.

A laboratory that has had its certification revoked may not reapply for certification until it has corrected all deficiencies. It may reapply according to subdivision 1 and, with the application, must provide documentation of the steps taken to correct the deficiencies.

Subp. 9. **Certification of laboratories in other states.** A laboratory in another state may request certification in Minnesota. In addition to following the application process described in subpart 1, the laboratory shall submit with its application an out-of-state inspection fee unless a reciprocity agreement exists.

The commissioner may enter into agreements with federal agencies and agencies of other states for reciprocal recognition of laboratory certification programs or portions of programs as substantially equivalent. <u>The commissioner shall provide a list of reciprocity agreements upon request.</u>

When such an agreement exists, the commissioner shall certify an out-of-state laboratory that completes the application form under subpart 1, submits the appropriate fees, provides a copy of current certification from the reciprocal state, private or federal agency, and provides a copy of the certifying authority's most recent inspection report. The laboratory shall notify the commissioner within 30 days after any action relevant to certification that is taken by the reciprocal certifying authority.

Subp. 10. **Variance.** The commissioner may grant a variance from a requirement of parts 4740.2010 to 4740.2040. However, no variance shall be granted from an EPA approved method required for analysis under the Safe Drinking Water Program. To request a variance, a laboratory shall indicate in writing:

A. the rule part and language from which the variance is sought;

B. reasons for the request;

C. alternate measures that will be taken if the

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request for a variance is granted;

D. length of time of the variance; and

E. data to assure analytical results of equal reliability.

The commissioner shall review information submitted with the variance request. If the laboratory proposes alternatives equivalent or superior to those requirements in the rule and shows that strict enforcement of the rule would cause undue hardship, and that the variance will not adversely affect the reliability of the data produced by the laboratory, the commissioner shall grant the variance, provided the variance does not conflict with statutory provisions. The commissioner shall grant or deny the variance within 60 days after receipt of the request, giving the laboratory written justification for the decision.

Subp. 11. **Appeal of administrative decision.** The commissioner shall notify the laboratory in writing of the reasons for a decision to deny a variance or to deny, suspend, revoke, or refuse to renew a certification. The laboratory shall have 30 days from the date of receiving the decision to appeal the decision. A request to appeal the decision must be in writing, must indicate the facts the laboratory disputes, and must be signed by the laboratory director. Upon receipt of an appeal request, the commissioner shall initiate the procedure for a contested case hearing according to Minnesota Statutes, chapter 14, and the rules of the Office of Administrative Hearings.

4740.2030 REQUIREMENTS FOR BASE CERTIFICATION.

Subpart 1. **Methodology.** The laboratory shall specify the analytical methodology, sample collection, and preservation procedures used for each analyte for which it seeks certification. The analytical methodology, sample collection, and preservation procedures used for samples required to be analyzed under a permit, program, or rule administered by a state agency must meet the requirements specified by that

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permit, program, or rule. The analytical methodology, sample collection, and preservation procedures used to analyze samples for the Safe Drinking Water Program must comply with the Code of Federal Regulations, title 40, sections 141.21 to 141.24, and Minnesota Rules, chapter 4720. The analytical methodology, sample collection, and preservation procedures used to analyze samples under the Clean Water Program must comply with the Code of Federal Regulations, title 40, section 136.3.

When a client collects a sample, the laboratory must inform the client of the appropriate procedures. The laboratory may delegate responsibility for proper sample collection and submission under parts 4740.2010 to 4740.2040 to a client. The laboratory must report any deviations as noted in subpart 9, item A.

Alternative methodology may be used if the EPA approves the methodology and the laboratory submits a copy of the EPA approval to the commissioner.

Subp. 2. **Performance evaluations.** The laboratory shall analyze a performance evaluation sample for each certified analyte at least once during the term of certification. The laboratory shall handle and analyze the performance evaluation samples with its usual analysts, equipment, and methods. The laboratory shall obtain the performance evaluation samples from an approved provider. The commissioner shall publish at least annually in the State Register a list of approved providers of performance evaluation samples. If the commissioner determines performance evaluation samples are not available for an analyte, the commissioner may review the laboratory's quality control data to evaluate precision and accuracy for that analyte.

The laboratory must show acceptable performance as determined by the approved provider on each performance evaluation sample.

The laboratory shall provide the commissioner with the results of performance from the approved provider within ~~14~~ 30 days after the laboratory receives them. When a provider notifies the laboratory that a performance evaluation sample

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result falls outside acceptable results, the laboratory must promptly take corrective action. Within ~~14~~ 30 days after receiving notice of the unacceptable results, the laboratory must submit to the commissioner documentation of the corrective action planned and taken. Within 30 days after receiving notice of unacceptable results, the laboratory must request a follow-up performance evaluation sample from an approved provider. The laboratory shall provide the commissioner with the results of the follow-up performance evaluation within ~~14~~ 30 days after receiving them.

The commissioner may supply blind performance evaluation samples to certified laboratories on a randomly chosen basis and to a specific laboratory if the commissioner receives a complaint about the laboratory's performance or suspects fraud in the generation ~~of~~ or reporting ~~or~~ of test results. A blind performance evaluation sample is one that is not distinguishable as a performance evaluation sample.

Subp. 3. **Records.** The laboratory shall maintain records according to items A to ~~E~~ F for each sample processed.

A. The laboratory shall maintain the records in items ~~B, C, and D~~ to E for three years from the date of analysis for the Clean Water Program and ten years from the date of analysis for the Safe Drinking Water Program.

B. Each sample must be labeled with a number, bar code, or other identification affixed to the sample and to the accompanying paperwork. The paperwork must contain the collector's name, the date, the time of collection, and special remarks relevant to the sample. The laboratory shall record the date the sample was analyzed, the analyst, the method used, and any deviation from specified procedures.

C. The laboratory shall maintain records of the raw data generated and used in determining the final analytical data.

D. The laboratory shall maintain a record of quality control data generated as part of its quality assurance plan and quality control activities specific to each analysis.

~~D.~~ E. The laboratory shall maintain records of

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equipment. The records must include the name of the item of equipment, the manufacturer's name, the serial number, the date the item was placed in service, and the date it was removed from service. The laboratory shall maintain records of maintenance and repair on each item of equipment.

~~E.~~ F. The laboratory shall supply ~~any analytical, quality control, or equipment and maintenance data requested by~~ any data listed in items B to E upon request of the commissioner within the timeframes in item A. The laboratory shall maintain records for an additional period of time if the commissioner specifies the records and the time period in writing to the laboratory.

Subp. 4. **Quality assurance plan.** The laboratory shall possess and follow a written plan of quality assurance actions. The plan may incorporate documents by reference. The plan must contain a table of contents and numbered pages. Unless the laboratory states why an item is not applicable, the plan must describe policies and procedures used to:

A. collect samples, including containers and preservatives;

B. track samples from the time the laboratory receives them to the time they are disposed, including chain of custody procedures for samples requested to be processed for possible legal action;

C. calibrate instruments, including frequency;

D. check internal quality control;

E. maintain functional equipment, including routine maintenance procedures and schedules;

F. determine data accuracy and precision for each certified analysis, according to subpart 5;

G. validate data conversion, transcription, and reporting;

H. correct unacceptable performance evaluation results or internal quality assurance checks; and

I. record changes in training and education of laboratory personnel, including on-the-job training relevant to

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analysis tasks.

Subp. 5. **Minimum quality control practices.** The laboratory shall use at a minimum the quality control practices described in items A to G. The laboratory must record and maintain all quality control data in this subpart according to subparts 3 and 4.

A. At least one reagent blank must be analyzed on each analysis day for those tests for which reagent blanks are ~~considered good laboratory practice~~ required in the methodologies specified in part 4740.2030, subpart 1, or for which reagent blanks exist.

B. A duplicate must be run as part of every analysis set and at least ten percent of all samples run must be duplicates.

C. Duplicate samples must be collected in the field at least ten percent of the time for methodologies requiring extraction when the laboratory is doing the collection.

D. A spiked sample must be analyzed as a part of every analysis set, and at least ten percent of all samples run must be spiked when spiking is applicable to the method.

E. When 20 or more samples are run in an analysis set, the standard curve must be verified by running an additional working standard within the range of the standard curve.

F. When the verification value of the working standard is not within ten percent, or within another limit defined in the acceptable method, of the value indicated by the standard curve, appropriate corrective action must be taken.

G. When available, external reference standards for each analyte must be run periodically.

Subp. 6. **Laboratory procedures manual.** The laboratory shall possess a written document-controlled manual of procedures used by laboratory personnel to analyze samples. Actual practice must conform to the written procedures. The manual must have a table of contents and numbered pages. The manual must be reviewed annually and changes must be initialed by the

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laboratory director or the director's designee. The description of each test procedure must include sections describing the sample used for the analysis, the sample acceptance and rejection criteria, the reagents, supplies, and materials and equipment used, step-by-step analysis procedures, methods of calculation, detection limits, reporting limits, safety precautions, and limitations of the procedure.

Subp. 7. **Reagents.** The laboratory shall use analytical chemicals meeting or exceeding minimum standards required in the methodology. The chemicals must be dated at time of receipt and removed before expiration of shelf life.

Subp. 8. **Equipment.** Instruments must meet the specifications of the methodology required for the analyte and program and must be maintained, monitored, and calibrated to assure accuracy.

Subp. 9. **Sample reporting.** The laboratory shall ~~indicate~~ record on the data sheet when a sample ~~that is~~:

A. has been incorrectly collected or preserved ~~as determined by inspection~~; or

B. is not analyzed within the holding time specified in the methodology.

Subp. 10. **Duty to notify.** The laboratory shall notify the commissioner in writing within 30 days of changes in:

A. laboratory location;

B. laboratory ownership;

C. major analytical equipment;

D. test methodology; and

E. principal, lead, or supervisory professional staff performing or responsible for the analyses.

4740.2040 CERTIFIED TEST CATEGORIES.

Subpart 1. **Scope.** The commissioner shall certify the analytes in subparts 2 to 4 for a specific program. The programs for which the commissioner shall certify an analysis are:

A. the Clean Water Program, Code of Federal

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Regulations, title 40, part 136; and

B. the Safe Drinking Water Program, Code of Federal Regulations, title 40, part 141.

To be certified for a specific program, the laboratory shall use the sample collection, preservation, and handling techniques required in the methodology meeting the conditions of the specific program.

Subp. 2. **Inorganic analytes.**

A. Inorganic analytes eligible for certification under the Clean Water Program are:

(1) Acidity;

(2) Alkalinity;

(3) Biochemical Oxygen Demand, 5 day;

(4) Biochemical Oxygen Demand, carbonaceous;

(5) Chemical Oxygen Demand;

(6) Chloride;

(7) Color;

(8) Cyanide;

(9) Nitrogen, Ammonia;

(10) Nitrogen, Total Kjeldahl;

(11) Nitrogen, Nitrate;

(12) Nitrogen, Nitrite;

(13) Oil and Grease;

(14) Oxygen, dissolved;

(15) Phenol, Total Compounds;

(16) Phosphorus, Ortho;

(17) Phosphorus, Total;

(18) Residue (Solids), total;

(19) Residue (Solids), filterable (dissolved);

(20) Residue (Solids), nonfilterable (TSS);

(21) Residue (Solids), volatile;

(22) Specific Conductance;

(23) Sulfate;

(24) Sulfide; and

(25) Surfactant.

Total residual chlorine, pH, and turbidity analyses under

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the Clean Water Program need not be done by a certified laboratory as long as the analyses are performed as soon as practicable but not later than one hour after collection and the methodology used is that specified under the Code of Federal Regulations, title 40, section 136.3.

B. Inorganic analytes eligible for certification under the Safe Drinking Water Program are:

(1) Cyanide;

(2) Fluoride;

(3) Nitrogen, Nitrate;

(4) Nitrogen, Nitrite; and

(5) Sulfate.

Subp. 3. **Bacteriology.**

A. Bacteriological analytes eligible for certification under the Clean Water Program are:

(1) Fecal Coliform Bacteria;

(2) Total Coliform Bacteria; and

(3) Fecal Streptococci Bacteria.

B. Bacteriological analytes eligible for certification under the Safe Drinking Water Program are:

(1) Fecal Coliform Bacteria;

(2) Total Coliform Bacteria; and

(3) Escherichia coli.

Subp. 4. **Metal chemistry.** The analysis of lead is eligible to be certified for the Clean Water Program and the Safe Drinking Water Program.

REPEALER. Minnesota Rules, parts 4717.4600, 4717.4700, 4717.4800, 4717.4900, 4717.5000, 4717.5100, 4717.5200, and 4717.5300 are repealed 60 days after the effective date of parts 4740.2010 to 4740.2040.

Approved by Revisor _____

APPROVED AS TO LEGALITY

January 4, 1990

HUBERT H. HUMPHREY, III
ATTORNEY GENERAL

BY Charlene H. Hatcher
SPECIAL ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED

JAN 4 - 1990

Joan Anderson Growe
Secretary of State

1:10 pm

CH

RULE REVIEW CHECKLIST

File No. 1655 — Docket No. 05.0009.1410

DATE RECEIVED 12-21-89 — ADOPTED W/O HEARING X

REVIEW DATE 1-2-90 — EMERGENCY RULE _____

DUE DATE 1-4-90 — TO REVISOR ON 12-29-89

REVISOR APPROVED 1-3-90

APPROVED 1-4-90 CH — REVISOR DISAPPROVED _____

DISAPPROVED _____ — FILED W/SEC. OF STATE 1-4-90

WITHDRAWN _____ — RETURNED TO AGENCY 1-4-90

✓ Rule as adopted (4 copies)

✓ Notice to Solicit Outside Information/Opinion (if applicable)
- _____ Date published in State Register
- _____ Comments

_____ Petition for Adoption of a Rule (if applicable)

_____ Board's Authorizing Resolution
- _____ Date adopted

✓ Proposed Rule
- ✓ Revisor's Certificate

✓ Notice of Intent to Adopt Rule
- 144.97 144.98 Statutory Authority
- ✓ Small Business Statement
- N/A Expenditure of public money statement
- ~~no date~~ Signature

✓ Statement of Need and Reasonableness (if applicable)
- _____ Small Business Statement
- ✓ Fees - § 16A.128 - attached letters from the House and Senate

✓ Affidavit of Mailing Notice of Intent to Adopt Rule
- July 20, 1989 Date 30/25 days before adoption
- ✓ Notice attached - indicates it is attached
- _____ Copy of rule or summary attached

✓ Publication in State Register
- July 24, 1989 Date 30/25 days before adoption

_____ 180-day deadline from:
- _____ Effective date of law requiring rule (14.12) (both rules) not mandatory
- ✓ end of comment period (§ 14.26) (rules without hearing) aug-23- Dec 1
- _____ effective date of statutory authority (§ 14.29) (emergency rules)

_____ Resolution Adopting
- _____ ~~Date adopted~~

✓ Findings of Fact, Conclusions & Order Adopting
- Dec 15, 1989 Date

✓ Written requests, submissions or comments

✓ Declaration of attorney
- Sarah Mulligan Name of SAAG representing agency

_____ ~~Notice of Submission~~ to Atty. Gen. (if applicable)

_____ ~~Aff. of Mailing Notice to Atty. Gen.~~ (if applicable)

Stat Authority
144.98

The commissioner may adopt rules to implement this section - procedures standards, laboratory quality assurance

Substantial changes - Statement of need and reasonableness
such as 7, 8, 11, 13

Rules O.K.

my only concern is all the changes made

Charlene

Sarah is sick - she can hardly talk. If you have any questions about the Rules Call Dick Weber.

Pat

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

Daniel J. McSweeney
for Sister Mary Madonna Ashton
Commissioner of Health

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the
Proposed Permanent Rules
Relating to Certification
Procedures for Environmental
Testing Laboratories, Proposed
Parts 4740.2010 to 4740.2040

DECLARATION OF COUNSEL

I, Sarah G. Mulligan, Special Assistant Attorney General, do hereby declare that I have examined the above-captioned rules and the supporting rulemaking record and that, based on my examination, the Administrative Procedure Act and Minn. Rules ch. 2010 have been followed. Any exceptions are listed below. For Attorney General billing purposes, the four-digit docket client code is 1410.

Dated: December 21, 1989.

SARAH G. MULLIGAN
Special Assistant
Attorney General

DEPARTMENT : ATTORNEY GENERAL

STATE OF MINNESOTA

Office Memorandum

DATE : December 21, 1989

TO : PATRICIA NOLTE
Legal Assistant

FROM : SARAH M. MULLIGAN SGM
Special Assistant
Attorney General

PHONE : 297-5926

SUBJECT : In the Matter of the Proposed Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories, Proposed Parts 4740.2010 to 4740.2040.

Enclosed for your review, pursuant to Minn. Stat. § 14.26 (1988) and Minn. Rules pt. 2010.0300 (1989), are the following documents to support the above-referenced rule:

1. Notice of Solicitation of Outside Information;

2. Letters to Chairs of House Appropriation and Senate Finance Committees;

3. Rules as proposed with a certificate of approval as to form by the Revisor of Statutes attached;

4. Notice of Intent to Adopt Rules Without a Public Hearing (as mailed);

5. Statement of Need and Reasonableness;

6. Affidavit of Mailing the Notice of Intent to Adopt Rules Without a Public Hearing and Certificate of Mailing List;

7. Notice of Intent to Adopt Rules Without a Public Hearing (as published in the State Register);

8. Rules as adopted (original and three copies);

9. Findings of Fact, Conclusions, and Order Adopting Rules Without a Public Hearing;

10. Comments or Requests for a Public Hearing; and

11. Declaration of Counsel.

SGM:pje
Enclosures

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

July 10, 1989



The Honorable Glen Anderson
Chairman, House Appropriations Committee
State Office Building, Room 365
St. Paul, Minnesota 55155

Dear Representative Anderson:

Pursuant to Minnesota Statutes 16A.128, subdivision 2a. "A Notice of Intent to Adopt Rules without Public Hearing" and a copy of "Proposed Permanent Rules Relating to Certification for Environmental Testing Laboratories", parts 4740.2010 to 4740.2040 are enclosed.

Sincerely yours,

Donald J. McInerney

for Sister Mary Madonna Ashton
Commissioner of Health

Enclosures
cc: Sarah Mulligan, Special Assistant
Attorney General's Office

an equal opportunity employer

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

July 10, 1989

The Honorable Gene Merriam
Chairman, Senate Finance Committee
Capital Building, Room 122
St. Paul, Minnesota 55155

Dear Senator Merriam:

Pursuant to Minnesota Statutes 16A.128, subdivision 2a. "A Notice of Intent to Adopt Rules without Public Hearing" and a copy of "Proposed Permanent Rules Relating to Certification for Environmental Testing Laboratories", parts 4740.2010 to 4740.2040 are enclosed.

Sincerely yours,

Sister Mary Madonna Ashton
Commissioner of Health

Enclosures
cc: Sarah Mulligan, Special Assistant
Attorney General's Office

an equal opportunity employer

- **The First Wisconsin Corporation,** 777 Wisconsin Avenue, Milwaukee, Wisconsin 53202, proposes to acquire the Stillwater Holding Company, Stillwater, Minnesota 55082, and thereby indirectly acquire control of the First National Bank of Stillwater, 213 Chestnut Street, Stillwater, Minnesota 55082, and First State Bank of Hugo, 14431 Forest Boulevard, North, Hugo, Minnesota 55038.

NOTICE

The Commissioner shall accept public comment on an application for a period of not less than 30 days from the date of the final publication in a newspaper of general circulation within the county in which the bank to be acquired or a proposed new bank is located; or 30 days after the date of the availability of the bulletin of Pending Applications which includes the listing of the acquisition.

Public Information

Copies of bulletins of pending applications prepared and updated with each new application filed with the Commissioner is available without charge to any person upon request by writing to Department of Commerce, Bulletin of Pending Applications, Reciprocal Interstate Banking Act, 500 Metro Square Building, Seventh and Robert Streets, St. Paul, Minnesota 55101.

Dated: 19 December 1988

Michael A. Hatch
Commissioner of Commerce

Department of Health

Notice of Solicitation of Outside Information or Opinions In the Matter of Rules Relating to Certification of Environmental Laboratories

NOTICE IS HEREBY GIVEN that the State Department of Health is seeking information or opinions from sources outside the agency in preparing to propose the adoption of a rule governing the certification of environmental laboratories. The adoption of the rule is authorized by Act of April 29, 1988, chapter 689, section 34, *Session Laws* of the State of Minnesota. Chapter 689, section 34 requires the agency to certify laboratories which supply data to the Minnesota Department of Health from tests on samples used to monitor drinking water supplies and laboratories which provide data used to monitor waste water operations to the Minnesota Pollution Control Agency.

The State Department of Health requests information and opinions concerning the subject matter of the rule. Interested persons or groups may submit data or views on the subject matter of concern in writing or orally. Written statements should be addressed to John Ikeda, Division of Public Health Laboratories, Minnesota Department of Health, Box 9441, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440. Oral statements will be received during regular business hours over the telephone at (612) 623-5681 and in person at the above address.

All statements of information and opinions shall be accepted until 30 days from the date of this publication. Any written material received by the State Department of Health shall become part of the rulemaking record to be submitted to the attorney general or administrative law judge in the event that the rule is adopted.

Dated: 14 December 1988

Sister Mary Madonna Ashton
Commissioner of Health

Labor and Industry Department

Labor Standards Division

Notice of Correction to Prevailing Wage Rates

The prevailing wage rate certified December 1, 1988 for labor classifications 404 — Carpenter in Anoka, Carver, Chisago, Dakota, Hennepin, Isanti, Kanabec, Ramsey, Scott and Washington county for commercial construction projects has been corrected.

Copies of the correct certification may be obtained by contacting the Minnesota Documents Division, 117 University Avenue, St. Paul, Minnesota 55155 or the Minnesota Department of Labor and Industry, Labor Standards Division, 443 Lafayette Road, St. Paul, Minnesota 55101.

Ken Peterson, Commissioner
Department of Labor and Industry

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of Proposed Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories, Proposed Parts 4740.2010 to 4740.2040

NOTICE OF INTENT TO ADOPT A RULE WITHOUT A PUBLIC HEARING

(1) Notice is hereby given that the Minnesota Department of Health (hereinafter "Department"), intends to adopt a rule relating to certification procedures for environmental testing laboratories, proposed parts 4740.2010 to 4740.2040. The Department intends to adopt the rule without a public hearing following the procedures set forth in the Administrative Procedure Act at Minn. Stat. §§ 14.22 to 14.28 (1988). The statutory authority to adopt the rules is Minn. Stat. §§ 144.97 and 144.98 (1988).

(2) All persons have 30 days in which to submit comment in support of or in opposition to the proposed rule or any part or subpart of the rule. Comment is encouraged. (3) Each comment should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed.

(4) Any person may make a written request for a public hearing on the rule within the 30-day comment period. (4) If 25 or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held unless a sufficient number withdraw their requests in writing. (5)(6) Any person requesting a public hearing should state his or her name and address and is encouraged to identify the portion of the proposed rule addressed, the reason for the requst, and any change proposed. (7) If a public hearing is required, the Department will proceed pursuant to Minn. Stat. §§ 14.131 to 14.20 (1988).

(5) Comments or written requests for a public hearing must be submitted to:

Mr. Al Tupy
Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440
Telephone: (612) 623-5680

(8) The proposed rule may be modified if the modifications are supported by data and views submitted to the Department and do not result in a substantial change in the proposed rule as noticed.

(11) The rule establishes procedures by which environmental testing laboratories may become certified by the Department to perform tests for certain specified analytes under two testing programs: the Safe Drinking Water Act, 42 U.S.C. §§ 300f et seq., Minn. Stat. §§ 144.381 et seq., and 40 C.F.R. § 141; and the Clean Water Act, 33 U.S.C. § 1251 et seq. and 40 C.F.R. § 136. The rule establishes application procedures; standards and procedures for the granting of provisional certification, base certification, test category certification, and certification renewal; and standards and procedures governing suspension and revocation of certification.

(11) A copy of the proposed rule is attached to this notice.

(12) A Statement of Need and Reasonableness that describes the need for and reasonableness of each provision of the proposed rule and identifies the data and information relied upon to support the proposed rule has been prepared and is available from Al Tupy upon request at the above address.

(14) Pursuant to Minn. Stat. § 14.115, subd. 2, the impact on small businesses has been considered in the promulgation of the rule. Anyone wishing to present evidence or argument as to the rule's effect on small businesses may do so. The Department's position regarding the impact of the rule on small businesses is set forth in the Statement of Need and Reasonableness.

(9) If no hearing is required, upon adoption of the rule, the rule and the required supporting documents will be submitted to the Attorney General for review as to legality and form to the extent the form relates to legality. Any person may request notification of the date of submission to the Attorney General. Persons who wish to be advised of the submission of this material to the Attorney General or who wish to receive a copy of the adopted rule must submit a written request to Al Tupy at the above address.

Dated: July ____, 1989

by Daniel J. McInerney

SISTER MARY MADONNA ASHTON
Commissioner

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of Proposed Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories, Proposed Parts 4740.2010 to 4740.2040

AFFIDAVIT OF MAILING THE NOTICE OF INTENT TO ADOPT A RULE WITHOUT A PUBLIC HEARING AND CERTIFICATE OF MAILING LIST

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

Roxanne Severson, being first duly sworn deposes and says:

I hereby certify that the list of persons and associations who have requested, pursuant to Minnesota Statutes sections 14.14, subdivision 1.a., and 14.22 or 14.30, that their names be placed on the Department of Health rulemaking mailing list for certification procedures for environmental testing laboratories, is accurate, complete, and current as of this 20 day of July, 1989.

That on the 20 day of July, 1989, at the City of Minneapolis, County of Hennepin, State of Minnesota, I mailed the attached Notice of Proposed Adoption of a Rule Without a Public Hearing by depositing in the State of Minnesota Central Mail system for United States mailing a copy thereof, with postage prepaid, to all persons and associations on the aforementioned mailing list.

Roxanne Severson

Subscribed and sworn to before me

this 20 day of July, 1989.

Louise Kaniuk
(Notary Public)

LOUISE KANIUK
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
MY COMMISSON EXPIRES FEBRUARY 22, 1991

Subp. 5. **Approval.** Upon receipt of an application from a group, the commissioner shall, within 30 days of receipt of the application, approve or disapprove it. If disapproved, the commissioner shall provide the applicants with a written explanation on which the denial was based. The commissioner may ask for additional information or statements at any time before the application is considered complete. All group applications, except for applications from groups made up of members of existing credit unions or groups made up of people who have a common employer which qualifies them for membership in an existing credit union, will be considered separately from any consideration of the membership provisions of existing credit unions.

Subp. 6. **Subsequent action by an existing credit union.** For an existing credit union to qualify for approval of a bylaw amendment to include an eligible select group in its field of membership, in addition to the requirements in Minnesota Statutes, section 52.02, the existing credit union must be capable of serving the eligible select group, and the commissioner may require:

A. the existing credit union and representatives of the eligible group to agree on and submit a plan of operation to facilitate servicing of the members of the eligible select group for the commissioner's consideration on a case by case basis; and

B. a statement that solicitations will not be directed at individuals to join the select group as a condition for membership in the credit union.

Department of Health

Proposed Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories

Notice of Intent to Adopt a Rule Without a Public Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Department of Health (hereinafter "Department"), intends to adopt a rule relating to certification procedures for environmental testing laboratories, proposed parts 4740.2010 to 4740.2040. The Department intends to adopt the rule without a public hearing following the procedures set forth in the Administrative Procedure Act at *Minnesota Statutes* §§ 14.22 to 14.28 (1988). The statutory authority to adopt the rules is *Minnesota Statutes* §§ 144.97 and 144.98 (1988).

All persons have 30 days in which to submit comment in support of or in opposition to the proposed rule or any part or subpart of the rule. Comment is encouraged. Each comment should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed.

Any person may make a written request for a public hearing on the rule within the 30-day comment period. If 25 or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held unless a sufficient number withdraw their requests in writing. Any person requesting a public hearing should state his or her name and address and is encouraged to identify the portion of the proposed rule addressed, the reason for the request, and any change proposed. If a public hearing is required, the Department will proceed pursuant to *Minnesota Statutes* §§ 14.131 to 14.20 (1988).

Comments or written requests for a public hearing must be submitted to:

Mr. Al Tupy
Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440
Telephone: (612) 623-5680

The proposed rule may be modified if the modifications are supported by data and views submitted to the Department and do not result in a substantial change in the proposed rule as noticed.

The rule establishes procedures by which environmental testing laboratories may become certified by the Department to perform tests for certain specified analytes under two testing programs: the Safe Drinking Water Act, 42 *United States Code* §§ 300f *et seq.*,

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." ADOPTED RULES SECTION — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

Minnesota Statutes §§ 144.381 *et seq.*, and 40 *Code of Federal Regulations* § 141; and the Clean Water Act, 33 *United States Code* § 1251 *et seq.* and 40 *Code of Federal Regulations* § 136. The rule establishes application procedures; standards and procedures for the granting of provisional certification, base certification, test category certification, and certification renewal; and standards and procedures governing suspension and revocation of certification.

A copy of the proposed rule is attached to this notice.

A Statement of Need and Reasonableness that describes the need for and reasonableness of each provision of the proposed rule and identifies the data and information relied upon to support the proposed rule has been prepared and is available from Al Tupy upon request at the above address.

Pursuant to *Minnesota Statutes* § 14.115, subd. 2, the impact on small businesses has been considered in the promulgation of the rule. Anyone wishing to present evidence or argument as to the rule's effect on small businesses may do so. The Department's position regarding the impact of the rule on small businesses is set forth in the Statement of Need and Reasonableness.

If no hearing is required, upon adoption of the rule, the rule and the required supporting documents will be submitted to the Attorney General for review as to legality and form to the extent the form relates to legality. Any person may request notification of the date of submission to the Attorney General. Persons who wish to be advised of the submission of this material to the Attorney General or who wish to receive a copy of the adopted rule must submit a written request to Al Tupy at the above address.

Sister Mary Madonna Ashton
Commissioner

Rules as Proposed (all new material)

4740.2010 DEFINITIONS.

Subpart 1. **Scope.** The terms used in parts 4740.2020 to 4740.2040 have the meanings given them in this part.

Subp. 2. **Acceptable performance or acceptable results.** "Acceptable performance" or "acceptable results" means analytical test results generated by a laboratory that fall within the range of standard deviations of the mean allowed by the approved provider.

Subp. 3. **Approved provider.** "Approved provider" means a provider of performance evaluation samples that the commissioner has determined:

A. provides an adequate volume of samples to perform statistically valid analyses;

B. calculates the number of standard deviations of the mean allowed using the results of all labs submitting test results after the exclusion of outlying values; and

C. allows a range of standard deviations of the mean no less stringent than the range allowed by the EPA.

Subp. 4. **Base certification.** "Base certification" means acknowledgment by the commissioner that a laboratory has the policies, procedures, equipment, and practices to produce reliable data in the analysis of environmental analytes described in part 4740.2040.

Subp. 5. **Commissioner.** "Commissioner" means the commissioner of health or the commissioner's designee.

Subp. 6. **EPA.** "EPA" means the United States Environmental Protection Agency.

Subp. 7. **Fees.** "Fees" means the fees described in *Minnesota Statutes*, section 144.98, subdivision 3.

Subp. 8. **Inspection.** "Inspection" means an on-site evaluation of laboratory facilities, records, personnel, equipment, methodology, and quality assurance practices by the commissioner for compliance with the applicable provisions of this chapter.

Subp. 9. **Performance evaluation sample.** "Performance evaluation sample" means a sample obtained from an approved provider to evaluate the ability of a laboratory to produce an analytical test result meeting the definition of acceptable performance. The concentration of the analyte in the sample is unknown to the laboratory at the time of analysis.

Subp. 10. **Quality control data.** "Quality control data" means data generated to assess the accuracy and precision of test data. Quality control data includes data on calibration standards, performance evaluation samples, blind standards, known standards, duplicate samples, blanks, spiked samples, and limits for quality control spiked samples, reference standards, duplicates, and detection levels.

4740.2020 ADMINISTRATIVE PROCEDURES REGARDING CERTIFICATION.

Subpart 1. **Application.** A laboratory may request to be certified by the commissioner for the analysis of the environmental analytes described in part 4740.2040. The laboratory must specify the analytes for which it seeks certification. No analyte shall be certified without the laboratory meeting base certification requirements. The laboratory shall apply on a form that is provided by the commissioner and that requests the following information:

A. the address and phone number of the laboratory;

B. the ownership of the laboratory;

C. the names of officers or managing agents of the laboratory and the laboratory director;

D. signatures of two managing agents with authority to bind the laboratory and proof of their authority to bind;

E. the names of professional staff performing or responsible for the analyses, their educational level, field of study, and analytical laboratory experience; and

F. written assurance that the laboratory meets the standards of parts 4740.2010 to 4740.2040.

With the application the laboratory shall submit:

(1) the applicable fees, including a nonrefundable base certification fee and fees for each test category in which the lab seeks certification;

(2) a quality assurance plan meeting the standards of part 4740.2030, subpart 4;

(3) a laboratory procedures manual meeting the standards of part 4740.2030, subpart 6; and

(4) the most recent performance evaluation results on the analytes for which the laboratory seeks certification. The performance evaluation samples must be from an approved provider and be analyzed within one year of the date of the application.

The commissioner shall certify a laboratory at a specific location. When a laboratory owns or manages laboratory facilities at different locations, a separate application must be submitted for each separate laboratory location.

Subp. 2. **Application review.** Within 60 days after receiving the application and information required in subpart 1, the commissioner shall:

A. issue provisional certification with the expiration date clearly marked; or

B. reject the laboratory's application if the performance evaluation results are not acceptable or if the quality assurance plan or laboratory procedures manual does not meet the standards of part 4740.2030, subparts 4 and 6; or

C. notify the laboratory in writing of any omission or error in application. If the laboratory does not submit to the commissioner the required information within 60 days after receiving the error notice, the commissioner shall reject the application.

Subp. 3. **Issuance of provisional certification.** The commissioner shall issue a provisional certification to a laboratory that:

A. has submitted all required and requested information;

B. has demonstrated acceptable performance in the testing for analytes for which the laboratory seeks certification;

C. has paid the fees; and

D. provides written assurance that the laboratory adheres to base certification and analyte specific certification requirements of parts 4740.2010 to 4740.2040.

The provisional certification is valid until the commissioner, after an inspection, approves or denies certification. If, one year after the date of issuance of the provisional certification, the commissioner has not inspected the laboratory, the commissioner shall renew a provisional certification if the laboratory files a renewal application according to subpart 6.

Subp. 4. **Denial of certification.** When the commissioner determines after inspection that a provisionally certified laboratory does not comply with applicable provisions of parts 4740.2010 to 4740.2040, the commissioner shall, within 60 days after the inspection, notify the laboratory in writing of the deficiencies preventing certification. Within 30 days after receiving the notice, the laboratory must remedy the deficiencies and provide documentation of the correction to the commissioner. If the laboratory provides no documentation of deficiency corrections within 30 days, the commissioner shall notify the laboratory that its certification is denied. The laboratory may not reapply for certification until it has corrected all deficiencies. The laboratory must submit written documentation of the steps taken to correct the deficiencies with its new application.

Subp. 5. **Certification approved.** The commissioner shall approve base certification and analyte certification for a laboratory when the commissioner determines, after an inspection, that the laboratory complies with the applicable provisions of parts 4740.2010 to 4740.2040. The certification approval is valid for one year from the date of issuance of the provisional certification.

Subp. 6. **Certification renewal.** The commissioner shall renew a base certification and analyte certification if the commissioner receives from the laboratory an application meeting the standards of subpart 1 and appropriate fees at least 30 days before the

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expiration date of the certificate. With the renewal application the laboratory shall submit any changes to the quality assurance plan or laboratory manual or a statement that the plan and manual continue to accurately describe current practices. The revised manual and plan must continue to meet the standards of part 4740.2030, subparts 4 and 6. The renewal certification is valid for one year. The commissioner shall inspect a laboratory certified by renewal at least once every three years.

Subp. 7. **Suspension of certification.** The following are grounds to suspend a base certification or analyte certification of the laboratory:

A. failure to report unacceptable results on a performance evaluation sample or to submit a corrective action plan to the commissioner as described in part 4740.2030, subpart 2;

B. failure to notify the commissioner within 30 days of changes described in part 4740.2030, subpart 10; or

C. failure to use approved methodology or follow methodology in sample analysis.

The commissioner shall restore the certification when the laboratory demonstrates it is in compliance with parts 4740.2010 to 4740.2040.

During the time of suspension, the laboratory must notify clients who request analysis of the analyte for which the certification has been suspended of the suspension.

Subp. 8. **Revocation of certification.** The following are grounds to revoke a base certification or analyte certification of the laboratory:

A. failure to comply with applicable standards of parts 4740.2010 to 4740.2040;

B. failure to correct deficiencies noted in the inspection report within the specified time frame;

C. use of another laboratory to analyze performance evaluation samples and reporting the results as the laboratory's own;

D. use of fraudulent or deceptive practices in the laboratory's analysis or reporting of data;

E. failure to produce acceptable results on an initial and follow-up performance evaluation sample; or

F. revocation of certification by a certifying authority with which the commissioner has a reciprocity agreement.

Within 30 days after the revocation, the laboratory must notify all clients for which it is presently analyzing samples that it is not certified. The laboratory must also notify new clients that it is not certified. The laboratory shall provide verification of this notice to the commissioner. The laboratory shall not advertise itself as certified and shall remove or replace any advertisements that indicate that it is certified.

A laboratory that has had its certification revoked may not reapply for certification until it has corrected all deficiencies. It may reapply according to subdivision 1 and, with the application, must provide documentation of the steps taken to correct the deficiencies.

Subp. 9. **Certification of laboratories in other states.** A laboratory in another state may request certification in Minnesota. In addition to following the application process described in subpart 1, the laboratory shall submit with its application an out-of-state inspection fee unless a reciprocity agreement exists.

The commissioner may enter into agreements with federal agencies and agencies of other states for reciprocal recognition of laboratory certification programs or portions of programs as substantially equivalent.

When such an agreement exists, the commissioner shall certify an out-of-state laboratory that completes the application form under subpart 1, submits the appropriate fees, provides a copy of current certification from the reciprocal state, private or federal agency, and provides a copy of the certifying authority's most recent inspection report. The laboratory shall notify the commissioner within 30 days after any action relevant to certification that is taken by the reciprocal certifying authority.

Subp. 10. **Variance.** The commissioner may grant a variance from a requirement of parts 4740.2010 to 4740.2040. However, no variance shall be granted from an EPA approved method required for analysis under the Safe Drinking Water Program. To request a variance, a laboratory shall indicate in writing:

A. the rule part and language from which the variance is sought;

B. reasons for the request;

C. alternate measures that will be taken if the request for a variance is granted;

D. length of time of the variance; and

E. data to assure analytical results of equal reliability.

The commissioner shall review information submitted with the variance request. If the laboratory proposes alternatives equivalent or superior to those requirements in the rule and shows that strict enforcement of the rule would cause undue hardship, and that the variance will not adversely affect the reliability of the data produced by the laboratory, the commissioner shall grant the variance,

provided the variance does not conflict with statutory provisions. The commissioner shall grant or deny the variance within 60 days after receipt of the request, giving the laboratory written justification for the decision.

Subp. 11. **Appeal of administrative decision.** The commissioner shall notify the laboratory in writing of the reasons for a decision to deny a variance or to deny, suspend, revoke, or refuse to renew a certification. The laboratory shall have 30 days from the date of receiving the decision to appeal the decision. A request to appeal the decision must be in writing, must indicate the facts the laboratory disputes, and must be signed by the laboratory director. Upon receipt of an appeal request, the commissioner shall initiate the procedure for a contested case hearing according to *Minnesota Statutes*, chapter 14, and the rules of the Office of Administrative Hearings.

4740.2030 REQUIREMENTS FOR BASE CERTIFICATION.

Subpart 1. **Methodology.** The laboratory shall specify the analytical methodology, sample collection, and preservation procedures used for each analyte for which it seeks certification. The analytical methodology, collection, and preservation procedures used for samples required to be analyzed under a permit, program, or rule administered by a state agency must meet the requirements specified by that permit, program, or rule. The analytical methodology, collection, and preservation procedures used to analyze samples for the Safe Drinking Water Program must comply with the *Code of Federal Regulations*, title 40, sections 141.21 to 141.24, and *Minnesota Rules*, chapter 4720. The analytical methodology, collection, and preservation procedures used to analyze samples under the Clean Water Program must comply with the *Code of Federal Regulations*, title 40, section 136.3.

Alternative methodology may be used if the EPA approves the methodology and the laboratory submits a copy of the EPA approval to the commissioner.

Subp. 2. **Performance evaluations.** The laboratory shall analyze a performance evaluation sample for each certified analyte at least once during the term of certification. The laboratory shall handle and analyze the performance evaluation samples with its usual analysts, equipment, and methods. The laboratory shall obtain the performance evaluation samples from an approved provider. The commissioner shall publish at least annually in the *State Register* a list of approved providers of performance evaluation samples. If the commissioner determines performance evaluation samples are not available for an analyte, the commissioner may review the laboratory's quality control data to evaluate precision and accuracy for that analyte.

The laboratory must show acceptable performance as determined by the approved provider on each performance evaluation sample.

The laboratory shall provide the commissioner with the results of performance from the approved provider within 14 days after the laboratory receives them. When a provider notifies the laboratory that a performance evaluation sample result falls outside acceptable results, the laboratory must promptly take corrective action. Within 14 days after receiving notice of the unacceptable results, the laboratory must submit to the commissioner documentation of the corrective action planned and taken. Within 30 days after receiving notice of unacceptable results, the laboratory must request a follow-up performance evaluation sample from an approved provider. The laboratory shall provide the commissioner with the results of the follow-up performance evaluation within 14 days after receiving them.

The commissioner may supply blind performance evaluation samples to certified laboratories on a randomly chosen basis and to a specific laboratory if the commissioner receives a complaint about the laboratory's performance or suspects fraud in the generation of reporting or test results. A blind performance evaluation sample is one that is not distinguishable as a performance evaluation sample.

Subp. 3. **Records.** The laboratory shall maintain records according to items A to E for each sample processed.

A. The laboratory shall maintain the records in items B, C, and D for three years from the date of analysis for the Clean Water Program and ten years from the date of analysis for the Safe Drinking Water Program.

B. Each sample must be labeled with a number, bar code, or other identification affixed to the sample and to the accompanying paperwork. The paperwork must contain the collector's name, the date, the time of collection, and special remarks relevant to the sample. The laboratory shall record the date the sample was analyzed, the analyst, the method used, and any deviation from specified procedures.

C. The laboratory shall maintain a record of quality control data generated as part of its quality assurance plan and quality control activities specific to each analysis.

D. The laboratory shall maintain records of equipment. The records must include the name of the item of equipment, the

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manufacturer's name, the serial number, the date the item was placed in service, and the date it was removed from service. The laboratory shall maintain records of maintenance and repair on each item of equipment.

E. The laboratory shall supply any analytical, quality control, or equipment and maintenance data requested by the commissioner within the timeframes in item A. The laboratory shall maintain records for an additional period of time if the commissioner specifies the records and the time period in writing to the laboratory.

Subp. 4. **Quality assurance plan.** The laboratory shall possess and follow a written plan of quality assurance actions. The plan may incorporate documents by reference. The plan must contain a table of contents and numbered pages. Unless the laboratory states why an item is not applicable, the plan must describe policies and procedures used to:

A. collect samples, including containers and preservatives;

B. track samples from the time the laboratory receives them to the time they are disposed, including chain of custody procedures for samples requested to be processed for possible legal action;

C. calibrate instruments, including frequency;

D. check internal quality control;

E. maintain functional equipment, including routine maintenance procedures and schedules;

F. determine data accuracy and precision for each certified analysis, according to subpart 5;

G. validate data conversion, transcription, and reporting;

H. correct unacceptable performance evaluation results or internal quality assurance checks; and

I. record changes in training and education of laboratory personnel, including on-the-job training relevant to analysis tasks.

Subp. 5. **Minimum quality control practices.** The laboratory shall use at a minimum the quality control practices described in items A to G. The laboratory must record and maintain all quality control data in this subpart according to subparts 3 and 4.

A. At least one reagent blank must be analyzed on each analysis day for those tests for which reagent blanks are considered good laboratory practice.

B. A duplicate must be run as part of every analysis set and at least ten percent of all samples run must be duplicates.

C. Duplicate samples must be collected in the field at least ten percent of the time for methodologies requiring extraction when the laboratory is doing the collection.

D. A spiked sample must be analyzed as a part of every analysis set, and at least ten percent of all samples run must be spiked when spiking is applicable to the method.

E. When 20 or more samples are run in an analysis set, the standard curve must be verified by running an additional working standard within the range of the standard curve.

F. When the verification value of the working standard is not within ten percent of the value indicated by the standard curve, appropriate corrective action must be taken.

G. When available, external reference standards for each analyte must be run periodically.

Subp. 6. **Laboratory procedures manual.** The laboratory shall possess a written manual of procedures used by laboratory personnel to analyze samples. Actual practice must conform to the written procedures. The manual must have a table of contents and numbered pages. The manual must be reviewed annually and changes must be initialed by the laboratory director or the director's designee. The description of each test procedure must include sections describing the sample used for the analysis, the sample acceptance and rejection criteria, the reagents, supplies, and materials and equipment used, step-by-step analysis procedures, methods of calculation, detection limits, reporting limits, safety precautions, and limitations of the procedure.

Subp. 7. **Reagents.** The laboratory shall use analytical chemicals meeting or exceeding minimum standards required in the methodology. The chemicals must be dated at time of receipt and removed before expiration of shelf life.

Subp. 8. **Equipment.** Instruments must meet the specifications of the methodology required for the analyte and program and must be maintained, monitored, and calibrated to assure accuracy.

Subp. 9. **Sample reporting.** The laboratory shall indicate on the data sheet a sample that is:

A. incorrectly collected or preserved as determined by inspection; or

B. not analyzed within the holding time specified in the methodology.

Subp. 10. **Duty to notify.** The laboratory shall notify the commissioner in writing within 30 days of changes in:

A. laboratory location;

B. laboratory ownership;

C. major analytical equipment;

D. test methodology; and

E. professional staff performing or responsible for the analyses.

4740.2040 CERTIFIED TEST CATEGORIES.

Subpart 1. **Scope.** The commissioner shall certify the analytes in subparts 2 to 4 for a specific program. The programs for which the commissioner shall certify an analysis are:

A. the Clean Water Program, *Code of Federal Regulations*, title 40, part 136; and

B. the Safe Drinking Water Program, *Code of Federal Regulations*, title 40, part 141.

To be certified for a specific program, the laboratory shall use the sample collection, preservation, and handling techniques required in the methodology meeting the conditions of the specific program.

Subp. 2. **Inorganic analytes.**

A. Inorganic analytes eligible for certification under the Clean Water Program are:

(1) Acidity;

(2) Alkalinity;

(3) Biochemical Oxygen Demand, 5 day;

(4) Biochemical Oxygen Demand, carbonaceous;

(5) Chemical Oxygen Demand;

(6) Chloride;

(7) Color;

(8) Cyanide;

(9) Nitrogen, Ammonia;

(10) Nitrogen, Total Kjeldahl;

(11) Nitrogen, Nitrate;

(12) Nitrogen, Nitrite;

(13) Oil and Grease;

(14) Oxygen, dissolved;

(15) Phenol, Total Compounds;

(16) Phosphorus, Ortho;

(17) Phosphorus, Total;

(18) Residue (Solids), total;

(19) Residue (Solids), filterable (dissolved);

(20) Residue (Solids), nonfilterable (TSS);

(21) Residue (Solids), volatile;

(22) Specific Conductance;

(23) Sulfate;

(24) Sulfide; and

(25) Surfactant.

Total residual chlorine, pH, and turbidity analyses under the Clean Water Program need not be done by a certified laboratory as long as the analyses are performed as soon as practicable but not later than one hour after collection and the methodology used is that specified under the *Code of Federal Regulations*, title 40, section 136.3.

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B. Inorganic analytes eligible for certification under the Safe Drinking Water Program are:

(1) Cyanide;

(2) Fluoride;

(3) Nitrogen, Nitrate;

(4) Nitrogen, Nitrite; and

(5) Sulfate.

Subp. 3. **Bacteriology.**

A. Bacteriological analytes eligible for certification under the Clean Water Program are:

(1) Fecal Coliform Bacteria;

(2) Total Coliform Bacteria; and

(3) Fecal Streptococci Bacteria.

B. Bacteriological analytes eligible for certification under the Safe Drinking Water Program are:

(1) Fecal Coliform Bacteria;

(2) Total Coliform Bacteria; and

(3) Escherichia coli.

Subp. 4. **Metal chemistry.** The analysis of lead is eligible to be certified for the Clean Water Program and the Safe Drinking Water Program.

REPEALER. *Minnesota Rules*, parts 4717.4600, 4717.4700, 4717.4800, 4717.4900, 4717.5000, 4717.5100, 4717.5200, and 4717.5300 are repealed 60 days after the effective date of parts 4740.2010 to 4740.2040.

Department of Natural Resources

Proposed Permanent Rules Relating to Lake Superior Shoreland Management

Notice of Intent to Adopt Rule Amendments Without a Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Department of Natural Resources intends to adopt the above entitled amendments without a public hearing, following the procedures set forth in *Minnesota Statutes*, § 14.21-14.28. The proposed North Shore Rule will be an amendment to "Adopted Permanent Rules Relating to Management of Shoreland Areas," Part 6120.2500-6120.3900 which became effective on July 3, 1989.

Changes are proposed to Part 6120.2800, Subpart 1. "Responsibilities and Authorities" to adopt a special set of regulations for the management of the shoreline of Lake Superior and the lower reaches of its tributary streams. This rule amendment is authorized by *Minnesota Statutes*, Section 105.485, subdivision 3. The amendments are being made to incorporate the shoreland management standards in the document entitled "North Shore Management Plan," December 1988.

Persons interested shall have 30 days to submit comments on the proposed amendments. The proposed amendments may be modified in final adoption if modifications are supported by the data and views submitted to the Department of Natural Resources and do not result in a substantial change in the proposed language.

Unless twenty-five or more persons submit written requests for a public hearing on the proposed amendments within the 30-day comment period, a public hearing will not be held. The written request must be specific on which amendment(s) a hearing is desired. Identification of the particular objection, the suggested modifications, and the reasons or data relied upon to support the suggested modifications are desired. In the event a public hearing is required, the department will proceed according to the provisions of *Minnesota Statutes*, §§ 14.13-14.20.

Persons who wish to submit comments or written request for a public hearing, or persons who wish to receive a copy of this notice and/or a copy of the proposed amendments, should address their correspondence to:

Tom Lutgen—DNR Waters
500 Lafayette Road
St. Paul, Minnesota 55155-4032

Department of Health

Proposed Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories

Rules as Proposed (all new material)

4740.2010 DEFINITIONS.

Subpart 1. **Scope.** The terms used in parts 4740.2020 to 4740.2040 have the meanings given them in this part.

Subp. 2. **Acceptable performance or acceptable results.** "Acceptable performance" or "acceptable results" means analytical test results generated by a laboratory that fall within the range of standard deviations of the mean allowed by the approved provider.

Subp. 3. **Approved provider.** "Approved provider" means a provider of performance evaluation samples that the commissioner has determined:

A. provides an adequate volume of samples to perform statistically valid analyses;

B. calculates the number of standard deviations of the mean allowed using the results of all labs submitting test results after the exclusion of outlying values; and

C. allows a range of standard deviations of the mean no less stringent than the range allowed by the EPA.

Subp. 4. **Base certification.** "Base certification" means acknowledgment by the commissioner that a laboratory has the policies, procedures, equipment, and practices to produce reliable data in the analysis of environmental analytes described in part 4740.2040.

Subp. 5. **Commissioner.** "Commissioner" means the commissioner of health or the commissioner's designee.

Subp. 6. **EPA.** "EPA" means the United States Environmental Protection Agency.

Subp. 7. **Fees.** "Fees" means the fees described in Minnesota Statutes, section 144.98, subdivision 3.

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Subp. 8. **Inspection.** "Inspection" means an on-site evaluation of laboratory facilities, records, personnel, equipment, methodology, and quality assurance practices by the commissioner for compliance with the applicable provisions of this chapter.

Subp. 9. **Performance evaluation sample.** "Performance evaluation sample" means a sample obtained from an approved provider to evaluate the ability of a laboratory to produce an analytical test result meeting the definition of acceptable performance. The concentration of the analyte in the sample is unknown to the laboratory at the time of analysis.

Subp. 10. **Quality control data.** "Quality control data" means data generated to assess the accuracy and precision of test data. Quality control data includes data on calibration standards, performance evaluation samples, blind standards, known standards, duplicate samples, blanks, spiked samples, and limits for quality control spiked samples, reference standards, duplicates, and detection levels.

4740.2020 ADMINISTRATIVE PROCEDURES REGARDING CERTIFICATION.

Subpart 1. **Application.** A laboratory may request to be certified by the commissioner for the analysis of the environmental analytes described in part 4740.2040. The laboratory must specify the analytes for which it seeks certification. No analyte shall be certified without the laboratory meeting base certification requirements. The laboratory shall apply on a form that is provided by the commissioner and that requests the following information:

A. the address and phone number of the laboratory;

B. the ownership of the laboratory;

C. the names of officers or managing agents of the laboratory and the laboratory director;

D. signatures of two managing agents with authority to bind the laboratory and proof of their authority to bind;

E. the names of professional staff performing or responsible for the analyses, their educational level, field of

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study, and analytical laboratory experience; and

F. written assurance that the laboratory meets the standards of parts 4740.2010 to 4740.2040.

With the application the laboratory shall submit:

(1) the applicable fees, including a nonrefundable base certification fee and fees for each test category in which the lab seeks certification;

(2) a quality assurance plan meeting the standards of part 4740.2030, subpart 4;

(3) a laboratory procedures manual meeting the standards of part 4740.2030, subpart 6; and

(4) the most recent performance evaluation results on the analytes for which the laboratory seeks certification. The performance evaluation samples must be from an approved provider and be analyzed within one year of the date of the application.

The commissioner shall certify a laboratory at a specific location. When a laboratory owns or manages laboratory facilities at different locations, a separate application must be submitted for each separate laboratory location.

Subp. 2. **Application review.** Within 60 days after receiving the application and information required in subpart 1, the commissioner shall:

A. issue provisional certification with the expiration date clearly marked; or

B. reject the laboratory's application if the performance evaluation results are not acceptable or if the quality assurance plan or laboratory procedures manual does not meet the standards of part 4740.2030, subparts 4 and 6; or

C. notify the laboratory in writing of any omission or error in application. If the laboratory does not submit to the commissioner the required information within 60 days after receiving the error notice, the commissioner shall reject the application.

Subp. 3. **Issuance of provisional certification.** The commissioner shall issue a provisional certification to a

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laboratory that:

A. has submitted all required and requested information;

B. has demonstrated acceptable performance in the testing for analytes for which the laboratory seeks certification;

C. has paid the fees; and

D. provides written assurance that the laboratory adheres to base certification and analyte specific certification requirements of parts 4740.2010 to 4740.2040.

The provisional certification is valid until the commissioner, after an inspection, approves or denies certification. If, one year after the date of issuance of the provisional certification, the commissioner has not inspected the laboratory, the commissioner shall renew a provisional certification if the laboratory files a renewal application according to subpart 6.

Subp. 4. **Denial of certification.** When the commissioner determines after inspection that a provisionally certified laboratory does not comply with applicable provisions of parts 4740.2010 to 4740.2040, the commissioner shall, within 60 days after the inspection, notify the laboratory in writing of the deficiencies preventing certification. Within 30 days after receiving the notice, the laboratory must remedy the deficiencies and provide documentation of the correction to the commissioner. If the laboratory provides no documentation of deficiency corrections within 30 days, the commissioner shall notify the laboratory that its certification is denied. The laboratory may not reapply for certification until it has corrected all deficiencies. The laboratory must submit written documentation of the steps taken to correct the deficiencies with its new application.

Subp. 5. **Certification approved.** The commissioner shall approve base certification and analyte certification for a laboratory when the commissioner determines, after an inspection, that the laboratory complies with the applicable

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provisions of parts 4740.2010 to 4740.2040. The certification approval is valid for one year from the date of issuance of the provisional certification.

Subp. 6. **Certification renewal.** The commissioner shall renew a base certification and analyte certification if the commissioner receives from the laboratory an application meeting the standards of subpart 1 and appropriate fees at least 30 days before the expiration date of the certificate. With the renewal application the laboratory shall submit any changes to the quality assurance plan or laboratory manual or a statement that the plan and manual continue to accurately describe current practices. The revised manual and plan must continue to meet the standards of part 4740.2030, subparts 4 and 6. The renewal certification is valid for one year. The commissioner shall inspect a laboratory certified by renewal at least once every three years.

Subp. 7. **Suspension of certification.** The following are grounds to suspend a base certification or analyte certification of the laboratory:

A. failure to report unacceptable results on a performance evaluation sample or to submit a corrective action plan to the commissioner as described in part 4740.2030, subpart 2;

B. failure to notify the commissioner within 30 days of changes described in part 4740.2030, subpart 10; or

C. failure to use approved methodology or follow methodology in sample analysis.

The commissioner shall restore the certification when the laboratory demonstrates it is in compliance with parts 4740.2010 to 4740.2040.

During the time of suspension, the laboratory must notify clients who request analysis of the analyte for which the certification has been suspended of the suspension.

Subp. 8. **Revocation of certification.** The following are grounds to revoke a base certification or analyte certification of the laboratory:

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A. failure to comply with applicable standards of parts 4740.2010 to 4740.2040;

B. failure to correct deficiencies noted in the inspection report within the specified time frame;

C. use of another laboratory to analyze performance evaluation samples and reporting the results as the laboratory's own;

D. use of fraudulent or deceptive practices in the laboratory's analysis or reporting of data;

E. failure to produce acceptable results on an initial and follow-up performance evaluation sample; or

F. revocation of certification by a certifying authority with which the commissioner has a reciprocity agreement.

Within 30 days after the revocation, the laboratory must notify all clients for which it is presently analyzing samples that it is not certified. The laboratory must also notify new clients that it is not certified. The laboratory shall provide verification of this notice to the commissioner. The laboratory shall not advertise itself as certified and shall remove or replace any advertisements that indicate that it is certified.

A laboratory that has had its certification revoked may not reapply for certification until it has corrected all deficiencies. It may reapply according to subdivision 1 and, with the application, must provide documentation of the steps taken to correct the deficiencies.

Subp. 9. **Certification of laboratories in other states.** A laboratory in another state may request certification in Minnesota. In addition to following the application process described in subpart 1, the laboratory shall submit with its application an out-of-state inspection fee unless a reciprocity agreement exists.

The commissioner may enter into agreements with federal agencies and agencies of other states for reciprocal recognition of laboratory certification programs or portions of programs as substantially equivalent.

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When such an agreement exists, the commissioner shall certify an out-of-state laboratory that completes the application form under subpart 1, submits the appropriate fees, provides a copy of current certification from the reciprocal state, private or federal agency, and provides a copy of the certifying authority's most recent inspection report. The laboratory shall notify the commissioner within 30 days after any action relevant to certification that is taken by the reciprocal certifying authority.

Subp. 10. **Variance.** The commissioner may grant a variance from a requirement of parts 4740.2010 to 4740.2040. However, no variance shall be granted from an EPA approved method required for analysis under the Safe Drinking Water Program. To request a variance, a laboratory shall indicate in writing:

A. the rule part and language from which the variance is sought;

B. reasons for the request;

C. alternate measures that will be taken if the request for a variance is granted;

D. length of time of the variance; and

E. data to assure analytical results of equal reliability.

The commissioner shall review information submitted with the variance request. If the laboratory proposes alternatives equivalent or superior to those requirements in the rule and shows that strict enforcement of the rule would cause undue hardship, and that the variance will not adversely affect the reliability of the data produced by the laboratory, the commissioner shall grant the variance, provided the variance does not conflict with statutory provisions. The commissioner shall grant or deny the variance within 60 days after receipt of the request, giving the laboratory written justification for the decision.

Subp. 11. **Appeal of administrative decision.** The commissioner shall notify the laboratory in writing of the reasons for a decision to deny a variance or to deny, suspend,

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revoke, or refuse to renew a certification. The laboratory shall have 30 days from the date of receiving the decision to appeal the decision. A request to appeal the decision must be in writing, must indicate the facts the laboratory disputes, and must be signed by the laboratory director. Upon receipt of an appeal request, the commissioner shall initiate the procedure for a contested case hearing according to Minnesota Statutes, chapter 14, and the rules of the Office of Administrative Hearings.

4740.2030 REQUIREMENTS FOR BASE CERTIFICATION.

Subpart 1. **Methodology.** The laboratory shall specify the analytical methodology, sample collection, and preservation procedures used for each analyte for which it seeks certification. The analytical methodology, collection, and preservation procedures used for samples required to be analyzed under a permit, program, or rule administered by a state agency must meet the requirements specified by that permit, program, or rule. The analytical methodology, collection, and preservation procedures used to analyze samples for the Safe Drinking Water Program must comply with the Code of Federal Regulations, title 40, sections 141.21 to 141.24, and Minnesota Rules, chapter 4720. The analytical methodology, collection, and preservation procedures used to analyze samples under the Clean Water Program must comply with the Code of Federal Regulations, title 40, section 136.3.

Alternative methodology may be used if the EPA approves the methodology and the laboratory submits a copy of the EPA approval to the commissioner.

Subp. 2. **Performance evaluations.** The laboratory shall analyze a performance evaluation sample for each certified analyte at least once during the term of certification. The laboratory shall handle and analyze the performance evaluation samples with its usual analysts, equipment, and methods. The laboratory shall obtain the performance evaluation samples from an approved provider. The commissioner shall publish at least

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annually in the State Register a list of approved providers of performance evaluation samples. If the commissioner determines performance evaluation samples are not available for an analyte, the commissioner may review the laboratory's quality control data to evaluate precision and accuracy for that analyte.

The laboratory must show acceptable performance as determined by the approved provider on each performance evaluation sample.

The laboratory shall provide the commissioner with the results of performance from the approved provider within 14 days after the laboratory receives them. When a provider notifies the laboratory that a performance evaluation sample result falls outside acceptable results, the laboratory must promptly take corrective action. Within 14 days after receiving notice of the unacceptable results, the laboratory must submit to the commissioner documentation of the corrective action planned and taken. Within 30 days after receiving notice of unacceptable results, the laboratory must request a follow-up performance evaluation sample from an approved provider. The laboratory shall provide the commissioner with the results of the follow-up performance evaluation within 14 days after receiving them.

The commissioner may supply blind performance evaluation samples to certified laboratories on a randomly chosen basis and to a specific laboratory if the commissioner receives a complaint about the laboratory's performance or suspects fraud in the generation of reporting or test results. A blind performance evaluation sample is one that is not distinguishable as a performance evaluation sample.

Subp. 3. **Records.** The laboratory shall maintain records according to items A to E for each sample processed.

A. The laboratory shall maintain the records in items B, C, and D for three years from the date of analysis for the Clean Water Program and ten years from the date of analysis for the Safe Drinking Water Program.

B. Each sample must be labeled with a number, bar code, or other identification affixed to the sample and to the

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accompanying paperwork. The paperwork must contain the collector's name, the date, the time of collection, and special remarks relevant to the sample. The laboratory shall record the date the sample was analyzed, the analyst, the method used, and any deviation from specified procedures.

C. The laboratory shall maintain a record of quality control data generated as part of its quality assurance plan and quality control activities specific to each analysis.

D. The laboratory shall maintain records of equipment. The records must include the name of the item of equipment, the manufacturer's name, the serial number, the date the item was placed in service, and the date it was removed from service. The laboratory shall maintain records of maintenance and repair on each item of equipment.

E. The laboratory shall supply any analytical, quality control, or equipment and maintenance data requested by the commissioner within the timeframes in item A. The laboratory shall maintain records for an additional period of time if the commissioner specifies the records and the time period in writing to the laboratory.

Subp. 4. **Quality assurance plan.** The laboratory shall possess and follow a written plan of quality assurance actions. The plan may incorporate documents by reference. The plan must contain a table of contents and numbered pages. Unless the laboratory states why an item is not applicable, the plan must describe policies and procedures used to:

A. collect samples, including containers and preservatives;

B. track samples from the time the laboratory receives them to the time they are disposed, including chain of custody procedures for samples requested to be processed for possible legal action;

C. calibrate instruments, including frequency;

D. check internal quality control;

E. maintain functional equipment, including routine maintenance procedures and schedules;

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F. determine data accuracy and precision for each certified analysis, according to subpart 5;

G. validate data conversion, transcription, and reporting;

H. correct unacceptable performance evaluation results or internal quality assurance checks; and

I. record changes in training and education of laboratory personnel, including on-the-job training relevant to analysis tasks.

Subp. 5. **Minimum quality control practices.** The laboratory shall use at a minimum the quality control practices described in items A to G. The laboratory must record and maintain all quality control data in this subpart according to subparts 3 and 4.

A. At least one reagent blank must be analyzed on each analysis day for those tests for which reagent blanks are considered good laboratory practice.

B. A duplicate must be run as part of every analysis set and at least ten percent of all samples run must be duplicates.

C. Duplicate samples must be collected in the field at least ten percent of the time for methodologies requiring extraction when the laboratory is doing the collection.

D. A spiked sample must be analyzed as a part of every analysis set, and at least ten percent of all samples run must be spiked when spiking is applicable to the method.

E. When 20 or more samples are run in an analysis set, the standard curve must be verified by running an additional working standard within the range of the standard curve.

F. When the verification value of the working standard is not within ten percent of the value indicated by the standard curve, appropriate corrective action must be taken.

G. When available, external reference standards for each analyte must be run periodically.

Subp. 6. **Laboratory procedures manual.** The laboratory

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shall possess a written manual of procedures used by laboratory personnel to analyze samples. Actual practice must conform to the written procedures. The manual must have a table of contents and numbered pages. The manual must be reviewed annually and changes must be initialed by the laboratory director or the director's designee. The description of each test procedure must include sections describing the sample used for the analysis, the sample acceptance and rejection criteria, the reagents, supplies, and materials and equipment used, step-by-step analysis procedures, methods of calculation, detection limits, reporting limits, safety precautions, and limitations of the procedure.

Subp. 7. **Reagents.** The laboratory shall use analytical chemicals meeting or exceeding minimum standards required in the methodology. The chemicals must be dated at time of receipt and removed before expiration of shelf life.

Subp. 8. **Equipment.** Instruments must meet the specifications of the methodology required for the analyte and program and must be maintained, monitored, and calibrated to assure accuracy.

Subp. 9. **Sample reporting.** The laboratory shall indicate on the data sheet a sample that is:

A. incorrectly collected or preserved as determined by inspection; or

B. not analyzed within the holding time specified in the methodology.

Subp. 10. **Duty to notify.** The laboratory shall notify the commissioner in writing within 30 days of changes in:

A. laboratory location;

B. laboratory ownership;

C. major analytical equipment;

D. test methodology; and

E. professional staff performing or responsible for the analyses.

4740.2040 CERTIFIED TEST CATEGORIES.

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Subpart 1. **Scope.** The commissioner shall certify the analytes in subparts 2 to 4 for a specific program. The programs for which the commissioner shall certify an analysis are:

A. the Clean Water Program, Code of Federal Regulations, title 40, part 136; and

B. the Safe Drinking Water Program, Code of Federal Regulations, title 40, part 141.

To be certified for a specific program, the laboratory shall use the sample collection, preservation, and handling techniques required in the methodology meeting the conditions of the specific program.

Subp. 2. **Inorganic analytes.**

A. Inorganic analytes eligible for certification under the Clean Water Program are:

(1) Acidity;

(2) Alkalinity;

(3) Biochemical Oxygen Demand, 5 day;

(4) Biochemical Oxygen Demand, carbonaceous;

(5) Chemical Oxygen Demand;

(6) Chloride;

(7) Color;

(8) Cyanide;

(9) Nitrogen, Ammonia;

(10) Nitrogen, Total Kjeldahl;

(11) Nitrogen, Nitrate;

(12) Nitrogen, Nitrite;

(13) Oil and Grease;

(14) Oxygen, dissolved;

(15) Phenol, Total Compounds;

(16) Phosphorus, Ortho;

(17) Phosphorus, Total;

(18) Residue (Solids), total;

(19) Residue (Solids), filterable (dissolved);

(20) Residue (Solids), nonfilterable (TSS);

(21) Residue (Solids), volatile;

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(22) Specific Conductance;

(23) Sulfate;

(24) Sulfide; and

(25) Surfactant.

Total residual chlorine, pH, and turbidity analyses under the Clean Water Program need not be done by a certified laboratory as long as the analyses are performed as soon as practicable but not later than one hour after collection and the methodology used is that specified under the Code of Federal Regulations, title 40, section 136.3.

B. Inorganic analytes eligible for certification under the Safe Drinking Water Program are:

(1) Cyanide;

(2) Fluoride;

(3) Nitrogen, Nitrate;

(4) Nitrogen, Nitrite; and

(5) Sulfate.

Subp. 3. **Bacteriology.**

A. Bacteriological analytes eligible for certification under the Clean Water Program are:

(1) Fecal Coliform Bacteria;

(2) Total Coliform Bacteria; and

(3) Fecal Streptococci Bacteria.

B. Bacteriological analytes eligible for certification under the Safe Drinking Water Program are:

(1) Fecal Coliform Bacteria;

(2) Total Coliform Bacteria; and

(3) Escherichia coli.

Subp. 4. **Metal chemistry.** The analysis of lead is eligible to be certified for the Clean Water Program and the Safe Drinking Water Program.

REPEALER. Minnesota Rules, parts 4717.4600, 4717.4700, 4717.4800, 4717.4900, 4717.5000, 4717.5100, 4717.5200, and 4717.5300 are repealed 60 days after the effective date of parts 4740.2010 to 4740.2040.

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Office of the Revisor of Statutes

Administrative Rules

TITLE: Proposed Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories

AGENCY: Department of Health

MINNESOTA RULES: Chapters 4717 and 4740

The attached rules are approved for publication in the State Register

Craig E. Fridelie

for Kathleen M. Traxler
Assistant Revisor

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of
Proposed Permanent Rules
Relating to Certification
Procedures for Environmental
Testing Laboratories, Proposed
Parts 4740.2010 to 4740.2040

FINDINGS OF FACT,
CONCLUSIONS, AND
ORDER ADOPTING RULES
WITHOUT A PUBLIC HEARING

(1) Notice of the Department of Health (hereinafter "Department") intent to adopt the above-entitled rules was published in the State Register on July 24, 1989, and was sent by United States mail to all persons on the list maintained by the Department pursuant to Minn. Stat. §§ 14.14, subd. 1(a) and 14.22 on July 20, 1989. (2) The statement of need and reasonableness was prepared before the Notice of Intent to Adopt Rules Without a Public Hearing was mailed to all persons on the rulemaking mailing list and published in the State Register and was available to the public. (3) Before the notice was submitted to the State Register, a copy of the notice of intent to adopt rules without a public hearing and the proposed rule was sent to the chairs of the house appropriations committee and the senate finance committee.

(4) All persons were given the opportunity to submit comment on the rules for 30 days after notice of proposed rulemaking. The Department received five comments on the rules within the comment period. (5) The Department received three requests for a public hearing on the rules. Therefore, the Department did not receive 25 requests for public hearing which

were not withdrawn. (7) No requests for notice of submission to the Attorney General were received by the Department.

The Department carefully reviewed all comments submitted within the 30-day period. The following requested changes were not incorporated at this time for the reasons stated.

Part 4740.2020, subparts 1C(2) and (3): A proposal was made to delete both these subparts because of concern that quality control and laboratory procedures manuals contain trade secrets which would become public upon their submission to the Department. No change was made because Minnesota Statutes § 13.37 (1988) allows classification of trade secret information as nonpublic and/or private data if the procedures and standards specified therein are satisfied.

Part 4740.2020, subpart 1C(4): A proposal was made that laboratories be required to submit all performance evaluation results obtained within the year prior to application. No change was made because the Department determined that the most recent performance evaluation results are the best indicator of a laboratory's competency at the time of original application.

Part 4740.2020, subpart 6: A proposal was made that the Department assume the burden of notifying laboratories that their certification is to expire 90 days prior to the expiration date. No change was made because the Department determined that the cost and difficulty of administering such a

rule warrants placing the responsibility upon laboratories desiring certification.

Part 4740.2020, subpart 7: A proposal was made that a laboratory whose certification is suspended by the Commissioner be permitted to subcontract with a certified laboratory to perform certified analyses during the period of suspension. No change was made because the rule as drafted permits subcontracting certified analyses to another certified laboratory, except that a laboratory may not subcontract analysis of performance evaluation samples to another laboratory.

Part 4740.2020, subpart 8: A proposal was made to delete the requirement that a revoked laboratory remove or replace advertisements stating the laboratory possesses certification. No change was made because the Department determined that such advertisements pose a danger of misleading both existing and potential clients, whether intentional or not.

Part 4740.2020, subpart 10: A proposal was made to allow the Commissioner to grant a variance if either strict enforcement of the rule would cause undue hardship, or the variance would not adversely affect the reliability of the data produced. No change was made because the Department determined that both criteria should be satisfied before a variance is warranted from the standards the Department was directed to establish by Minn. Stat. § 144.98 (1988).

Part 4740.2030, subpart 2: A proposal was made that the Department not require submission of performance evaluation sample results for every analyte for which the laboratory is certified during the certification period. No change was made because the Department determined that since certification is analyte-specific, a laboratory can only demonstrate adequate performance by analyzing a performance evaluation sample for each analyte for which is certified.

Part 4740.2030, subpart 2: A proposal was made that the Department itself provide performance evaluation samples to laboratories under the certification program. No change was made because it was determined that at this time the Department has inadequate resources to provide such materials.

Part 4740.2030, subpart 3B: A proposal was made to eliminate the requirement to record information about samples where the laboratory does not itself collect the sample. No change was made because the federal programs for which this certification procedure has been developed, the Clean Water Program and the Safe Drinking Water Program, require that sample collection data be maintained.

Part 4740.2030, subpart 5A-E: A proposal was made to reduce the minimum quality control requirements specified in these subparts. No change was made because the Department was not persuaded at this time that reducing the kinds or amounts of quality control practices from those presently specified in the rule would adequately assure the quality of the data generated by the laboratory.

Part 4740.2030, subparts 10C and D: A proposal was made to delete these provisions, which require a laboratory to notify the Department when the laboratory changes major analytical equipment or test methodology. No change was made because changes in major analytical equipment affect a laboratory's ability to execute analyses, and changes in test methodology affect the adequacy of the laboratory's analyses under the two federal programs for which this certification procedure was developed.

Part 4740.2040, subparts 2-4: Proposals were made to add additional analytes to those eligible for certification under these rules. No change was made because the remaining analytes in both the Clean Water Program and the Safe Drinking Water Program will be added to the list eligible for certification in a subsequent rulemaking process to be commenced during 1990. The absence of some relevant analytes from the program does not affect a laboratory's ability to obtain certification for any or all analytes which are included.

Part 4740.2040, subpart 2A: A proposal was made to delete several analytes listed in subpart 2A(1)-(25) and add them to those for which analyses under the Clean Water Program need not be done by a certified laboratory. No change was made because the analytes at issue all may have harmful environmental effects, whereas those excluded from the requirements for analysis by a certified laboratory do not have such effects.

Based on the comments and evidence in the record before the Department, the Department now makes the following

FINDINGS OF FACT

(b) 1. Part 4740.2010, subpart 2 has been modified to clarify the definition of "acceptable performance" or "acceptable results";

2. Part 4740.2020, subpart 1 has been modified to renumber and reorganize the text into more subparagraphs;

3. Part 4740.2020, subpart 1B(5) (previously numbered subpart 1E) has been modified so that a laboratory must provide background information only about key professional staff in its application, since requiring such information about subordinate staff is burdensome and appears less relevant to the certification program;

4. Part 4740.2020, subpart 6 has been modified to provide that the performance evaluation results submitted for certification renewal must meet the standards of part 4740.2030, subpart 2, rather than part 4740.2020, subpart 1. With this change, a laboratory seeking renewal must submit acceptable performance evaluation results obtained within the prior year for each analyte, but need not necessarily submit its most recent results. The change allows a laboratory whose most recent performance evaluation results were unacceptable, but had previously during the certification period obtained acceptable results, to renew certification while it takes the corrective action and performs the follow-up analysis required by part 4740.2030, subpart 2;

5. Part 4740.2020, subpart 7D has been added so that the Department may suspend a certified laboratory when the laboratory has been suspended by another certifying authority with which the Department has a reciprocity agreement, since that action is evidence of a need for the laboratory to correct deficiencies under Minnesota standards;

6. Part 4740.2020, subpart 7 has been modified to require that a suspended laboratory notify new clients of the suspension, since new as well as existing clients may rely on the fact of the laboratory's certification;

7. Part 4740.2020, subpart 7 has been modified to allow a suspended laboratory to notify only those new and existing clients who require certified analyses of the suspension, since the utility of the tests to those clients depends upon the laboratory possessing current certification;

8. Part 4740.2020, subpart 8G has been added to allow the Department to take action against a laboratory which fails to cooperate with the Department's inspector, since the integrity of the certification program depends on the ability to make timely and comprehensive inspections;

9. Part 4740.2020, subpart 8 has been modified to require that a revoked laboratory notify new clients of the revocation, since new as well as existing clients may rely on the fact of the laboratory's certification;

10. Part 4740.2020, subpart 8 has been modified to allow a require laboratory to notify only those existing and new clients who require certified analyses of the revocation,

since the utility of the tests to those clients depends upon the laboratory possessing current certification;

11. Part 4740.2020, subpart 9 has been modified to make the identities of agencies with whom the Department has reciprocal certification programs available to the public;

12. Part 4740.2030, subpart 1 has been modified to make terminology consistent throughout the paragraph;

13. Part 4740.2030, subpart 1 has been modified to allow a laboratory to perform certified testing on samples collected by the laboratory client, if certain conditions are met, since some clients collect their own samples and some laboratories do not collect samples. The condition that the laboratory must inform the client about proper collection procedures reduces the likelihood of improper collection. The condition that the laboratory must report deviations on a data sheet ensures that relevant information which may affect test results is preserved for inspection;

14. Part 4740.2030, subpart 2 has been modified to allow the laboratory a longer period of time in which to (1) provide performance evaluation results to the Department, (2) take corrective action when the laboratory receives unacceptable results, and (3) provide follow-up performance evaluation results to the Department, since the original fourteen-day period may in each case be difficult to comply with if key personnel are away from the laboratory for any period of time;

15. Part 4740.2030, subpart 2 has been modified to clarify the circumstances under which the Department may supply blind performance evaluation samples to certified laboratories;

16. Part 4740.2030, subpart 3A has been modified to reflect the addition of new subpart 3C;

17. Part 4740.2030, new subpart 3C has been added to clarify that laboratories must retain the raw data generated in performing tests under this certification program, which was previously implicit in former subpart 3E;

18. Part 4740.2030, subpart 3C, D and E have been renumbered to reflect the addition of new subpart 3C;

19. Part 4740.2030, new subpart 3F has been modified to reflect the addition of new subpart 3C, and to clarify the records to be retained under this subpart;

20. Part 4740.2030, subpart 5A has been modified to require use of reagent blanks where the approved methodology used by the laboratory so specifies, and also to require their use for tests where the methodology does not so require but a reagent blank exists. The changes made clarify and make more specific the laboratory's obligations under this subpart;

21. Part 4740.2030, subpart 5F has been modified to allow any verification value defined in an acceptable testing method to constitute an acceptable verification standard, since some acceptable testing methods use values other than ten percent;

22. Part 4740.2030, subpart 6 has been modified to clarify the format of the required laboratory procedures manual;

23. Part 4740.2030, subpart 9 has been modified to clarify the circumstances under which a laboratory must report incorrect sample collection or preservation and the form that report must take;

24. Part 4740.2030, subpart 10E has been modified to allow laboratories to notify the Department of changes in testing staff only with respect to key professional staff, since requiring such notification with respect to subordinate staff is burdensome and appears less relevant to the certification program; and

25. The Statement of Need and Reasonableness for parts 4740.2010 to 4740.2040 is hereby incorporated as the findings of fact except where inconsistent with the above.

Based on the above findings of fact, the Department makes the following

CONCLUSIONS

1. Parts 4740.2010 to 4740.2040, as modified, are needed and reasonable.

2. The modifications are not substantial changes because the modifications do not affect classes of people who could not reasonably have been expected to comment on the proposed rule as originally noticed, do not add significant new subject matter which a reasonable person, on the basis of the proposed rule as originally noticed, would not have anticipated

would occur during the rulemaking proceeding, and make no major substantive change, the possibility of which was not raised by the proposed rule as originally noticed.

NOW THEREFORE, IT IS HEREBY ORDERED that the rules identified as Rules Relating to Certification Procedures for Environmental Testing Laboratories, Proposed Parts 4740.2010 to 4740.2040 are adopted this 15 day of December, pursuant to authority vested in the Department by Minn. Stat. §§ 144.97 and 144.98 (1988).

S. Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health



twin city testing
corporation

662 CROMWELL AVENUE
ST. PAUL, MN 55114
PHONE 612/645-3601

August 21, 1989

Mr. Al Tupy
Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440

Subject: Request for Public Hearing on Minnesota Department of Public Health rules proposed parts 4740.2010 to 4740.2040

Dear Mr. Tupy:

I have reviewed the "Proposed Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories" and the associated "Statement of Need and Reasonableness." My review has underscored several issues requiring resolution prior to the implementation of the laboratory certification rules.

While I strongly support the need for data with a known level of confidence, I am concerned that the proposed rule may not accomplish its stated need "...to ensure reliability and comparability of data produced by laboratories for programs or permits designed to protect the public health and environment." and at the same time represents an unreasonable hardship for the impacted businesses of the state. For this reason I am requesting that a public hearing be held to consider the impact of the proposed rules.

Attached is a list of some of my concerns with, in many instances, recommendations for their resolution. Please contact me if you have any questions.

Sincerely,

Richard S. Alberg

Richard S. Alberg
Quality Assurance Coordinator

RSA/llq

MNLABCER.LTR

Attachment

AN EQUAL OPPORTUNITY EMPLOYER

CONCERNS AND RECOMMENDED RULE CHANGES

1. Chapter 4740.2010 Subp. 2. (Editorial): For clarity change "...analytical test results generated by a laboratory that fall..." to "...analytical test results generated by a laboratory on performance evaluation samples that fall..."

2. Chapter 4740.2020 Subp. 1. F. (2) and (3): This is a significant concern for several reasons. Both our quality assurance plan and our procedures manual are controlled documents for which revisions are issued as required. With over 300 standard operating procedures, manuals issued to sources external to the TCT laboratories make it more difficult to assure that every copy of the manual is current. Furthermore, these documents represent a significant amount of effort by TCT staff members. In many instances, we consider the procedures developed within TCT to be proprietary. I anticipate the application information submitted to meet the requirements of this subpart would become a public record. If so, a competitor could obtain information of a confidential nature due to the requirement to submit a laboratory procedures manual. For these reasons it is TCT's corporate policy restrict the issue of procedures manuals. It is not important for the Department of Health to have copies of a laboratory's procedures. The significance of procedures is for the laboratory's staff performing the analyses to have and to follow current valid procedures. Other states and the Safe Drinking Water Act do not require laboratories submit copies of their laboratory procedures to the certifying agency. I strongly recommend that the requirement for submission of a quality assurance plan and laboratory procedures manual be deleted.

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4. Chapter 4740.2020 Subp. 8. F.: Change "The laboratory must also notify new clients that..." to "The laboratory must also notify new clients for testing programs described in part 4740.2040 that..." for the same reason as stated in #2.

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6. Chapter 4740.2020 Subp. 10.: In the second paragraph change "...requirements in the rule and shows that..." to "...requirements in the rule or shows that...". As I understand this subpart it is referring to two specific but exclusive reasons to grant a variance which will not adversely affect data reliability.

7. Chapter 4740.2030 Subp. 2.: The requirement for the analysis of "...a performance sample for each certified analyte at least once during the term of certification." goes well beyond a reasonable need for a laboratory to demonstrate its ability to perform a specific type of analysis. In addition, this requirement will be a significant handicap to expansion of the program to other analytes such as organic analyses by GC/MS.

8. Chapter 4740.2030 Subp. 2.: The 14 day time limit after receipt for reporting performance evaluation sample results is too short. In the situation that the laboratory director or the director's designee were out of the laboratory for training, technical meetings, vacation or some similar cause, performance sample results may not even be reviewed for 14 days after receipt by a laboratory. I recommend this period be increased to 30 days.

9. Chapter 4740.2030 Subp. 3. B.: The way this subpart reads; if a client submits a sample without specifying "the collector's name, the date, the time of collection" a commercial laboratory must either refuse to perform the analysis or be in violation of the rules. Sampling information is the responsibility of the person(s) performing the sampling and the individual/company/agency required to report data to meet regulatory requirements. Since we cannot force our clients to provide this information, I recommend that this section be reworded so sampling information is not an absolute requirement when the analyzing laboratory is not responsible for and does not perform the sampling.

10. Chapter 4740.2030 Subp. 5. A.: Who has or will define what is "good laboratory practice" for reagent blanks? This requirement is not adequately defined and a potential source of future dispute.

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12. Chapter 4740.2030 Subp. 6.: The section detailing items required in the description of each test procedure includes information not included in the EPA reference procedures for the certified analytes. This is not reasonable or justified! What is the definition of "sample acceptance and rejection criteria"? I have not been able to find a definition of this requirement. Change the wording to: "The description of each test procedure should include relevant information such as sections ...".

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14. Chapter 4740.2040: The limited scope of analytes covered by this program presents a serious problem to Minnesota Laboratories certified and doing business in other states with programs that include a more exhaustive list of parameters. Under these conditions it appears that reciprocity will not be feasible. Thus Minnesota's program would cause an increased financial load for state laboratories doing business in other states such as Wisconsin. I recommend that this concern be addressed before the program is implemented.



twin city testing
corporation

662 CROMWELL AVENUE
ST. PAUL, MN 55114
PHONE 612/645-3601

August 21, 1989

Mr. Al Tupy
Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440

SUBJECT: Request for Public Hearing on Minnesota Department of Public Health rules proposed parts 4740.2010 to 4740.2040

Dear Mr. Tupy:

I have reviewed the "Proposed Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories." Based on my review, several issues require resolution prior to the implementation of the laboratory certification rules.

Since the rules, as proposed, represent a hardship for the affected businesses of the state, I am requesting that a public hearing be held to consider the impact of the proposed rules.

Attached is a list of concerns with recommendations for their potential resolution. Please contact me if you have any questions.

Sincerely,

W. J. Nosek Jr.

W. J. Nosek Jr.
Quality Assurance Manager

WJN/llq

MNLABCER.LJN

Attachment

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twin city testing
corporation

662 CROMWELL AVENUE
ST. PAUL, MN 55114
PHONE 612/645-3601

August 21, 1989

Mr. Al Tupy
Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440

Subject: Request for Public Hearing on Minnesota Department of Public Health rules proposed parts 4740.2010 to 4740.2040

Dear Mr. Tupy:

My review of the "Proposed Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories" has resulted in a number of concerns about the impact of the proposed rules on Minnesota's service laboratories. The proposed rules, if implemented as published, would not accomplish their intended purpose and would impose unnecessary additional expense and effort on the state's affected industries. I am requesting that a public hearing be held to consider the impact of the proposed rules.

Attached is a list of concerns with recommendations for their potential resolution. Please contact me if you have any questions.

Sincerely,

William F. Welbes
Vice President
Chemistry/Environmental Division

WFW/llq

MNLABCER.LWW

Attachment

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Research and Engineering Department

Conoco Inc.
P.O. Box 1267
Ponca City, OK 74603
(405) 767-3456

July 28, 1989

Al Tupy
Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440

Dear Mr. Tupy:

I have read, with interest, your proposed certification rules relating to lab certification. Thanks for sending the information. I certainly wish to obtain certification for "Conoco Analytical Laboratory" when your system is in operation.

It appears that reciprocal certification may be available. Our lab is certified in seven states.

Oklahoma
Arkansas (reciprocal with Oklahoma)
South Carolina (reciprocal with Oklahoma)
Nevada (reciprocal with Oklahoma)
North Dakota (reciprocal with Oklahoma)
North Carolina
Wisconsin (reciprocal with North Carolina

We have the following pending certifications:

Florida (on-site has been performed)
NVLAP (for asbestos, on-site has been performed)
New Jersey

I am sending information that pertains to our Oklahoma certification. If you have your Minnesota applications available, I would be happy to submit the proper forms.

If I can provide any information that would be useful for our certification or for your new program, please call 405-767-2468.

Gary Keen
Associate Director
Analytical II

tmj

Northern States Power Company

414 Nicollet Mall
Minneapolis, Minnesota 55401-1927
Telephone (612) 330-5500



August 10, 1989

Al Tupy, Chief
Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440

Dear Mr. Tupy:

I am writing to propose a change in the proposed permanent rules relating to certification procedures for environmental testing laboratories. I propose that the inorganic analytes, dissolved oxygen and TSS, residue (solids), nonfilterable as specified in Part 4740.2040 Certified Test Categories, Subp 2. Inorganic analytes be included with other analytes (total residual chlorine, pH, and turbidity) that need not be done by a certified laboratory as long as the analyses are performed as soon as practicable but not later than one hour after collection.

Requiring the analytes dissolved oxygen and TSS, residue (solids), nonfilterable to be done by a certified laboratory will mean that all of our small power plant labs be certified because they are required to have NPDES permits according to the Clean Water Act. During discussions held at the health department concerning development of these rules, consensus was reached that there was no basis for requiring small laboratories analyzing only samples for compliance with an NPDES permit to be certified. If the department's position on this matter has changed, please let me know the reason(s) for the change.

Thank you for your consideration.

L W Eberley

L W Eberley, Administrator
Plant Permits and Compliance

sw

Metropolitan Waste Control Commission
Mears Park Centre, 230 East Fifth Street, St. Paul, Minnesota 55101
612 222-8423



August 8, 1989

Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, MN 55440

Attention: Al Tupy

Dear Mr. Tupy:

The Laboratory Services Division of the Metropolitan Waste Control Commission are in full support of a Laboratory Certification Program. We compliment you and your colleagues for the commitment and persistence needed to develop such a program.

In response to the notice concerning "Matter of Proposed Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories, Proposed Parts 4740.2010 to 4740.2040" we respectfully submit the following comments for your review and consideration.

4740.2020 Administrative Procedures Regarding Certification.

1. In Subpart 1.E. (pg 2) it is recommended that only relevant education be submitted.

2. In Subpart 6. (pg 5) it is requested that the Commissioner notify laboratories 90 days before the expiration date of the certification. It is believed that this automatic notification would be less costly for all parties in comparison to time spent in suspension, revocation, and reapplication. If there is an additional cost involved in this notification, we believe Laboratories would be willing to absorb it.

3. In Subpart 7. (pg 5,line 31-33) it is recommended that an option to subcontract analysis to a Certified laboratory be made available in the event of a suspension. This would satisfy the intent of the Rule to ensure accurate data used to evaluate environmental concerns, minimize the impact on the laboratory's customers, and avoid any premature negative ramifications to a laboratory's reputation. If the certification is revoked, notification of the client would then be mandatory. We believe this approach would best serve all parties involved.

4. In Subpart 8.F. (page 3-6) it is recommended that this section include language which specifies that this applies to out-of-state laboratories only. Since the State of Minnesota will not grant reciprocity to it's own laboratories involvement in out-of-state Certification programs, failure in those programs should not result in revocation of the Minnesota Certification.

An alternative would be to grant reciprocity to Minnesota based laboratories which have acquired Certification from an equivalent program.

Line 15 - 21 This paragraph states that the laboratory must notify its clients if certification is revoked. Language may need to be added to address the procedure followed if a laboratory willingly relinquishes its certification. Are they required to notify their clients?

4740.2030 Requirements For Base Certification.

1. In Subpart 2 it is requested that the Commissioner mail the list of approved providers of performance evaluation programs to the laboratory at the time of application and renewal. Any additional copies would then be obtained by the laboratory from the State Register.

2. Line 6 - 8 on page 9 states that the laboratory must show compliance on each performance evaluation sample. Does this mean each Certified parameter in an evaluation sample set, or each set which is analyzed. A laboratory may analyze performance evaluation sample sets quarterly, ie. more than is required for certification. Must they show acceptable performance on all four sets in order to meet this criteria?

3. Line 25 - 26 on page 9 states "... in the generation of reporting or test results." The meaning is unclear. Is it "in generation of reports and test results" or "in the reporting of test results"?

4. In Subpart 5.B. would a dilution constitute a duplicate. In the BOD test, if two different dilutions were made and both were within acceptable limits, would that satisfy the duplicate requirement? If dilutions were made to determine the presence of interferences, would they be considered duplicates (assuming no interferences were found)?

5. In Subpart 5.A. - E. appears to require at least 23 percent QC as a minimum. This is assuming a batch of 20 analyses, running one blank, 2 duplicates, 2 spikes, and a standard curve verification. Thirty percent QC is normal for organic parameter analysis. More than fifteen percent QC for inorganic testings seems excessive. (A blank, 5% duplicates, 5% spikes, and a standard curve verification for each sample batch would provide reasonable quality control measures.) The minimum QC specified in the Rule does not guarantee reliable performance of the laboratory since poor precision and percent recoveries could result from a matrix interference. Once standard reference materials are developed, method performance can be monitored more closely. Using duplicates and/or percent recoveries does not evaluate performance but rather give sample matrix information. Substitution of the matrix information for performance information will result in higher operating costs without improving performance.

6. In Subpart 6., Line 8 the phrases "sample acceptance" and "rejection criteria" are used. Their meaning is unclear and needs to be included in the definition section.

7. In Subpart 7., line 16 states "...expiration of shelf life.". It is requested that it be expanded to state "...expiration of shelf life as specified by the manufacturer."

If we need to clarify our comments any further, please contact either Jim Wyzykowski at 772-7175, Mike Elling at 772-7137 or myself at 772-7110. Thank you for an opportunity to comment on this very important issue.

Sincerely,

Carol Barnhart

Carol Barnhart
Laboratory Manager
2400 Childs Rd.
St. Paul, MN 55124

CB:dt

pace® laboratories, inc.
PROFESSIONAL ANALYTICAL CHEMISTRY & ENGINEERING

Offices:
Minneapolis, Minnesota
Tampa, Florida
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Novato, California
Leawood, Kansas

1710 Douglas Drive North □ Minneapolis, MN 55422 □ Phone (612) 544-5543 □ FAX (612) 544-3974

AUG 1989
MN Dept. of Health
LABORATORY
SERVICES
SECTION

August 22, 1989

Mr. Al Tupy
Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, MN 55440

Dear Mr. Tupy:

PACE Laboratories, Inc. (PACE) appreciates the opportunity to comment on the proposed rules relating to laboratory certification published in the State Register (July 24, 1989) [CITE 14 S.R. 151]. PACE recognizes the need to assess the reliability of laboratory data and strongly supports all efforts that lead towards a statewide certification program that will assist in that assessment. The following specific comments are provided to you to aid in this process:

1) 4740.2010 Subpart 2 - Defining acceptable performance in statistical terms requires the data belong to the same population (i.e. the data must be generated by the same or equivalent analytical methods). Therefore, a phrase such as "by a laboratory using an acceptable method" should be added to the definition.

2) 4740.2020 Subpart 1.F.4 - To give a better assessment of data, it would be best to provide all performance evaluation results generated for externally submitted samples for the analytes of interest in the last year (not just the most recent data).

3) 4740.2020 Subpart 7 - If the Rule does not require analysis by a certified laboratory, protocols will have to be developed to deal with data that have been generated by a suspended laboratory.

4) 4740.2030 Subpart 2 - The Minnesota Department of Health should supply the performance evaluation samples. This would guarantee that each laboratory that is seeking certification would be analyzing the sample at the same time from a common source. It would also allow for a statistical evaluation of performance in the program.

5) 4740.2030 Subparts 3 and 4 - All methods and quality assurance plans must be produced using a document control format that identifies the time period during which the methods and plans were in use. This will allow historical records to insure that

data are interpreted based on the methods used at the time of data production. Method revisions should be clearly indicated.

4740.2030 Subpart 3 - The subpart does not define the technology allowable for record storage. Does the Commissioner require all information to be in a hard-copy format or will other formats (such as micro-fiche, diskette or nine-track tape formats) be allowed?

6) 4740.2030 Subpart 5.F - The verification value for the working standard may not always be set as "within 10%." Some future method may have a different limit. An alternative approach would be to include the phrase "within the value defined in the acceptable method ....".

7) 4740.2030 Subpart 6 - The manual should also follow a document control format (see Item #4 above).

8) 4740.2040 Subpart 2 through 4 - A major portion of analytes specified for monitoring in both the Safe Drinking Water Program and the Clean Water Program are not addressed in this certification program (i.e. organic analyses and metal chemistry analytes (besides lead)). These analytes should be addressed since many are contaminants of current concern and have potential health impacts.

PACE is interested in providing assistance in the continued development and implementation of the Certification Program. The staff at PACE has been involved in several State and National programs and would be willing to share those experiences to help insure a high quality Certification Program for Minnesota.

If we can be of any help to you, please contact us at (612) 544-5543.

Sincerely,

William H. Scruton
Senior Consulting Chemist
Minnesota Region

Roger C. Splinter, Ph.D.
Vice Pres., Corporate Quality Programs

WHS79:RCS/jb

SERCO Laboratories

St. Paul, Minnesota

1931 West County Road C2
St. Paul, Minnesota 55113
Phone: (612) 636-7173

AUG 1989
MN Dept. of Health
LABORATORY SERVICES SECTION

August 22, 1989

Mr. Al Tupy
Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, MN 55440

Dear Mr. Tupy:

This letter is written in response to the "Proposed Permanent Rules Relating to Certification Procedures for Environmental Testing Laboratories" published in the July 24, 1989 State Register.

The lab certification program is a very positive step toward assuring the quality of the data being generated for use by the citizens of Minnesota. The program should proceed with this data quality goal in mind. I feel strongly about the issues addressed in this letter. It appears that some of these items will make the program unworkable for the Minnesota Department of Health, as well as adversely affect the operation of labs seeking certification. I will address these issues in the order in which they appear in the proposed rules.

Section 4740.2020 Subpart 1 E.
The proposed rule states "E. the names of professional staff performing or responsible for the analyses, their educational level, field of study, and analytical laboratory experience...". It is my understanding that this program is intended to certify laboratories, not individuals. The management of the laboratory is ultimately responsible for the data being generated, and paragraph C requires the names of the officers or managing agents, and the lab director. Paragraph E should be deleted.

Section 4740.2020 Subpart 7.
The proposed rule states "During the time of suspension, the laboratory must notify clients who request analysis of the analyte for which the certification has been suspended of the suspension." These proposed rules are intended to govern Safe Drinking Water Act (SDWA) and Clean Water Act (CWA) samples taken in Minnesota, but the wording of this paragraph indicates that notification regarding suspension from Minnesota's

certification program be given to any client from any state or country requesting analysis of an analyte that happens to be listed as part of Minnesota's certification program. This notification requirement would not apply to all cases and should be written in that manner. Addition of the word "Minnesota" will clarify this point. "During the time of suspension, the laboratory must notify Minnesota clients who request analysis....".

Section 4740.2020 Subpart 8.
The proposed rule states "Within 30 days after the revocation, the laboratory must notify all clients for which it is presently analyzing samples that it is not certified. The laboratory must also notify new clients that it is not certified." A laboratory should not be under obligation to notify those clients whose analyses do not require a certified lab of a certification revocation. This applies to new clients as well. The following wording clarifies this: "Within 30 days after the revocation the laboratory must notify all clients currently under contract or requesting analyses to be performed whose analytical work requires a Minnesota certified laboratory that it is not certified."

Section 4740.2020 Subpart 8.
The proposed rule states "The laboratory shall provide verification of this notice to the commissioner.". This requirement is unrealistic from the stand point of enforcement, as well as compliance. During normal business operation, clients would be notified of the change in certification status when they call to discuss their analytical needs. Of course, we do not want labs to represent themselves in an improper manner, but it is unreasonable to require proof of this to be submitted to the commissioner, and would likely be difficult to enforce. This statement should be deleted from the rule.

Section 4740.2020 Subpart 8.
The proposed rule states "The laboratory shall not advertise itself as certified and shall remove or replace any advertisements that indicate that it is certified.". It is common for a change in an ad placed in a magazine, professional journal, or telephone directory to take three to fifteen months lead time. The statement should read "The laboratory shall not advertise itself as certified.".

Section 4740.2020 Subpart 9.
It is my understanding, that because a lab is located in Minnesota, they are not eligible to be certified under the same conditions as an out-of-state lab that applies through a reciprocal program. This reciprocity rule potentially favors out-of-state business and may pose potentially significant economic disadvantages for Minnesota businesses. The economic disadvantages of being located in Minnesota have been expounded upon enough over the past few years. It would be unfortunate if this rule added to that problem. The concept of reciprocity should be re-evaluated.

Section 4740.2020 Subpart 9.
The proposed rule states that "The commissioner may enter into agreements with federal agencies and agencies of other states for reciprocal recognition of laboratory certification programs...". Assuming reciprocity remains part of this rule, private organizations should be included here as they are in the paragraph following this one. The rule should state, "When such an agreement exists, the commissioner shall certify an out-of-state laboratory that...provided a copy of current certification from the reciprocal state, private or federal agency...".

Section 4740.2030 Subpart 1.
The proposed rule states "The laboratory shall specify the...sample collection...procedures used...". It may be difficult, if not impossible, for a laboratory to be certain how a sample is collected unless the sample is collected by the laboratory itself. Many samples are collected by non-lab personnel, as must also be the case for the Minnesota Department of Health Lab. Even though sampling is an important part of generating quality data, the lab cannot take the responsibility of losing their certification due to the manner in which their clients collect samples or keep records. The lab cannot certify that a sample was collected according to proper procedures when someone other than their own personnel collected the sample. This is unreasonable and not enforceable. To include responsibility for sampling and related record keeping in the laboratory certification rule, would be to include certification of those who collect samples. Those who collect samples include, not only many of the laboratories themselves, but also many others such as consulting firms, individuals, city agents and sample collection firms. For this reason, all references to sample collection and record keeping related to sample collection should be deleted from the rules for laboratory certification. These references occur in sections 4740.2030 Subpart 1, 4740.2030 Subpart 3, 4740.2030 Subpart 4, 4740.2030 Subpart 5, 4740.2040 Subpart 1, 4740.2040 Subpart 2. If this change cannot be made, then the only alternative is to certify everyone who collects samples. This would make the program unmanageable for the Minnesota Department of Health.

Section 4740.2030 Subpart 1.
The proposed rules state "The analytical methodology...used for samples required to be analyzed under a permit, program or rule administered by a state agency must meet the requirements specified...". With the understanding that the State of Minnesota does not expect to police any other state's permits, programs or rules, the statement should be changed to read as follows: "The analytical methodology...used for samples required to be analyzed under a permit, program or rule administered by a Minnesota state agency must meet the requirements specified...".

Section 4740.2030 Subpart 3 Paragraph E.
The proposed rule states "The laboratory shall supply any analytical, quality control, or equipment and maintenance data requested by the commissioner within the time frames in item A.". This statement compromises the independent third-party nature of independent testing laboratories. A laboratory should have no problem providing the commissioner with QC data relating to the quality of their analytical performance. But, as an independent laboratory, their obligation is to provide accurate laboratory analysis for the requesting party. This means the independent laboratory is free from the potential "conflict of interest" that would be inherent in providing the data to anyone but the requesting party. The rule should be changed to read "The laboratory shall supply any quality control information requested by the commissioner for programs covered in these laboratory certification rules (i.e. CWA and SDWA) within the time frames in item A.". Review of analytical data must be dealt with through the party responsible for submission of the data to the Minnesota Department of Health or the Minnesota Pollution Control Agency, as specified by the pertinent regulation.

Section 4740.2030 Subpart 9.
The proposed rule states "A. incorrectly collected or preserved as determined by inspection". This should be clarified as to the inspection as follows: "A. incorrectly collected or preserved as determined by visual inspection".

Section 4740.2030 Subpart 10.
The proposed rule states "The laboratory will notify the commissioner in writing within 30 days of changes in: ...C. major analytical equipment; D. test methodology; and E. professional staff performing or responsible for the analyses.". It is understandable that the commissioner would require notification of changes in location (address is assumed), ownership or officers or managing agents, and laboratory director. Requiring notification of changes in methodologies, major analytical equipment and staff performing the analyses will likely result in an unmanageable amount of information coming to the Minnesota Department of Health. Since a certified lab is inherently bound to use approved methodologies, proper QC procedures and pass performance evaluation samples, notification of changes in methodologies, major analytical equipment and staff would result in an unmanageable amount of information with little value. If proper methods and proper QC procedures are being followed, then the data should be considered acceptable. The notification requirements should be changed to include only what is necessary, i.e. changes in ownership, location, and manager or lab director.

Section 4740.2040 Subparts 2,3 and 4.
It is not apparent how these lists or parameters were derived. The Safe Drinking Water Act list in the laboratory certification rules, in particular, does not seem to correlate with the parameters listed in the Safe Drinking Water Act (40CFR, 141.11, 141.12, 141.13, 141.14 and 143.3). For example, it is not apparent in the Act where cyanide is either a primary or secondary parameter. Also, there are a number of Safe Drinking Water Act parameters missing from the parameter lists in the proposed rules, particularly a number of organic compounds and metals. These groups of analytes are included in the rules governing the laboratory certification program fee structure. I understand the intention is to add these parameters later, but, since the program is to be phased-in anyway, the entire list of parameters should be included in the rules from the beginning. Future time and effort devoted to rule development and implementation could be avoided. A case in point is the inclusion of lead, but no other metals. It would be relatively easy to include the other metals that are analyzed by technologies and methods similar to lead. The survey officer could cover several parameters at one site inspection. Under the rule as it is written now, it appears that the Minnesota Department of Health will be the only laboratory certified to do Safe Drinking Water Act work. In order for these rules to be workable, all parameters from CWA and SDWA need to be included.

In conclusion, I want to thank you for this opportunity to offer my input regarding these proposed rules for lab certification. I would welcome a discussion of these issues with you and would be more than happy to offer my assistance in the further refinement of these rules to make them more workable for all concerned.

Sincerely,
SERCO Laboratories

Carol A. Kuehn
President

CAK/bja