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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by Revisor _____

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 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

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

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

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

Approved
by Revisor _____

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

Approved
by Revisor _____

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.

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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