CHAPTER 4740
DEPARTMENT OF HEALTH
LABORATORIES; ACCREDITATION REQUIREMENTS

4740.0100 PURPOSE AND SCOPE.

The rules in chapter 4740 contain accreditation procedures and standards for laboratories that perform tests or analyses as required by state or federal law.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2867*

4740.0110 DEFINITIONS.

Subpart 1. **Scope.** The terms used in parts 4740.0100 to 4740.0170 have the meanings given them in this part.

Subp. 2. **Accreditation.** "Accreditation" means licensure or certification of a laboratory to perform specific tests.

Subp. 3. **Certification.** "Certification" means written acknowledgment of the laboratory's demonstrated capability to perform tests for a specific purpose.

Subp. 4. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 4a. **Etiologic agent.** "Etiologic agent" means a viable microorganism, or its toxin, which causes or may cause human disease.

Subp. 4b. **Histologic.** "Histologic" means a body tissue.

Subp. 5. **Laboratory.** "Laboratory" means a person, corporation, or other entity, including a governmental entity, which examines, analyzes, or tests samples.

Subp. 6. **Licensure.** "Licensure" means authorization to perform laboratory tests for a purpose defined by statute.

Subp. 7. **Out-of-control quality control result.** "Out-of-control quality control result" means a result from an internal quality control sample that does not fall within a statistically acceptable range.

Subp. 8. **Sample.** "Sample" means a substance derived from a nonhuman source and collected for the purpose of analysis or a tissue, blood, excretion, or other bodily fluid specimen obtained from a human for the detection of a chemical, etiologic agent, or histologic abnormality.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2867*

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

4740.0120 APPLICATION PROCEDURES.

Subpart 1. **Standards.** To obtain accreditation, the laboratory must comply with subparts 2 to 5 and with the technical standards that apply to the specific laboratory test for which accreditation is sought, as specified in rule.

Subp. 2. **Contents.** The application shall include:

A. the address of the principal place of business or headquarters;

B. the address and phone number of the laboratory that seeks accreditation, if different than in item A;

C. the names of officers and the laboratory director;

D. written assurance that the laboratory meets the standards of parts 4740.0100 to 4740.0170 and the standards that apply to the specific test for which laboratory accreditation is sought, as specified in rule;

E. the signatures of two officers or managing agents of the laboratory and proof of the signatories' authority to bind the laboratory; and

F. other reasonable information necessary to determine compliance with accreditation requirements.

Subp. 3. **Documentation.** At the time of application, the laboratory shall submit or have available for inspection the following documents:

A. a current laboratory manual;

B. criteria for accepting and rejecting samples for testing;

C. proficiency testing results;

D. internal quality assurance records;

E. corrective action for out-of-control quality control results;

F. sample receipt and storage records;

G. equipment calibration and standardization records;

H. equipment repair and preventive maintenance records;

I. personnel education and training requirements;

J. laboratory safety policies; and

K. written chain-of-custody procedures.

Subp. 4. **Fee.** The laboratory shall submit with its application a nonrefundable fee, in the amount established by the specific rule for the purpose or type of test for which accreditation is sought.

Subp. 5. **Inspection.** The laboratory must demonstrate compliance with accreditation requirements through an inspection conducted by persons designated by the commissioner. Inspections may be unannounced and at a frequency established by the rule specific to the purpose or type of test for which accreditation is sought.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2867*

4740.0130 PROVISIONAL ACCREDITATION.

A laboratory that meets accreditation application requirements shall receive written provisional accreditation until an on-site inspection is completed. Upon demonstration, through inspections, of compliance with standards specific to the purpose or type of testing for which accreditation is sought, full accreditation shall be granted in writing showing the date of expiration.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2867*

4740.0140 TERM OF ACCREDITATION.

Laboratories shall be accredited for a term of one year, which shall include any period of provisional accreditation. Unless a laboratory submits a timely

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

application for renewal of the accreditation, the accreditation expires without notice at the end of the term.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2867*

4740.0150 COMPLIANCE.

All accredited laboratories shall immediately inform the commissioner of any changes to the information required by part 4740.0120 and the rules specific to the laboratory test for which accreditation is sought. The laboratory director must inform the commissioner in writing of any changes in test methodology, instrumentation, key personnel, or laboratory ownership and submit revisions to the documents listed in part 4740.0120, subpart 3, within 14 calendar days of the change.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2867*

4740.0160 ACCREDITATION RENEWAL.

A laboratory shall submit an application for renewal of accreditation with the applicable renewal fee, no later than 30 days before the expiration date of the current accreditation. The renewal application shall contain the same information required for an initial application in part 4740.0120, subpart 2. At the time of application for a renewal of its accreditation, the laboratory shall also submit or have available for inspection the documents listed in part 4740.0120, subpart 3. Unless a laboratory submits a timely application for accreditation renewal, the accreditation expires without further notice at the end of the term.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2867*

4740.0170 ACCREDITATION; SUSPENSION AND REVOCATION.

The commissioner may, pursuant to Minnesota Statutes, chapter 14, suspend, revoke, refuse to renew, condition, or limit the accreditation of a laboratory upon finding that the laboratory has violated provisions of parts 4740.0100 to 4740.0160 or has failed to meet standards defined under the rule applicable to the specific laboratory test for which the laboratory is accredited.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2867*

DRUG AND ALCOHOL TESTING OF EMPLOYEES

4740.1010 DEFINITIONS.

Subpart 1. **Scope, application.** The following terms used in parts 4740.1020 to 4740.1080 have the meanings given them in this part.

Subp. 2. **Alcohol.** "Alcohol" means ethyl alcohol.

Subp. 3. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 4. **Confirmatory test.** "Confirmatory test" means a drug or alcohol test, run on a sample that was positive on the initial screening test. Techniques for a confirmatory test are described in part 4740.1070, subparts 5 and 6.

Subp. 5. **Department.** "Department" means the Department of Health.

Subp. 6. **Drug.** "Drug" means a controlled substance as defined in Minnesota Statutes, section 152.02, and as updated yearly by rules of the Board of Pharmacy.

Subp. 7. **Employee.** "Employee" means a person, independent contractor, or person working for an independent contractor who performs services for compensation, in whatever form, for an employer.

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

Subp. 8. **Employer.** "Employer" means a person, independent contractor, or entity located or doing business in this state and having one or more employees, and includes the state of Minnesota and all political or other governmental subdivisions of the state.

Subp. 9. **Initial screening test.** "Initial screening test" means a drug or alcohol test, the results of which indicate presumptive presence of a drug, drug metabolite, or alcohol in a sample. Techniques for an initial screening test are described in part 4740.1070, subparts 5 and 6.

Subp. 10. **Initial screening test minimum detection level.** "Initial screening test minimum detection level" means the level at which a laboratory is capable of detecting a drug or drug metabolite using a screening test. The values are derived from the NIDA initial cutoff levels in Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines; Notice, paragraph 2.4(e)(1), as provided by the Federal Register, Volume 53, Number 69, page 11983, Monday, April 11, 1988.

Subp. 11. **Job applicant.** "Job applicant" means a person, independent contractor, or person working for an independent contractor who applies to become an employee of an employer, and includes a person who has received a job offer that is contingent on the person passing drug or alcohol testing.

Subp. 12. **Laboratory.** "Laboratory" means a person, corporation, or other entity, including a governmental entity, that examines, analyzes, or tests samples.

Subp. 13. **NCCLS.** "NCCLS" means the National Committee for Clinical Laboratory Standards, Villanova, Pennsylvania.

Subp. 14. **NIDA.** "NIDA" means the National Institute on Drug Abuse, of the Alcohol, Drug Abuse, and Mental Health Administration, United States Health and Human Services Department.

Subp. 15. **Positive test result.** "Positive test result" means a finding of the presence of drugs, alcohol, or their metabolites in the sample tested by a confirmatory test in levels at or above the threshold detection levels set by the commissioner under part 4740.1080.

Subp. 16. **Presumptive presence.** "Presumptive presence" means some indication of the presence of a drug, drug metabolite, or alcohol that, in the judgment of the laboratory director or the laboratory director's designee, provides a reasonable basis for conducting a confirmatory test. The presumptive presence of a drug, drug metabolite, or alcohol is not a positive test result.

Subp. 17. **Sample.** "Sample" means a substance derived from a nonhuman source and collected for the purpose of analysis or a tissue, blood, excretion, or other bodily fluid specimen obtained from a human for the detection of a chemical, etiologic agent, or histologic abnormality.

Subp. 18. **Threshold detection level.** "Threshold detection level" means the level at which the presence of a drug, drug metabolite, or alcohol can be reasonably expected to be detected by a confirmatory test performed by a laboratory that meets the standards of parts 4740.1010 to 4740.1090. The threshold detection level is neither meant to indicate impairment nor any relationship between the time of the test and the time of use of a drug or alcohol by the employee or applicant. The threshold detection level simply indicates the level at which a valid conclusion can be drawn that the drug or alcohol is present in the employee's or applicant's sample.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2860*

4740.1020 LICENSE REQUIRED FOR LABORATORIES PERFORMING DRUG AND ALCOHOL TESTING FOR EMPLOYERS.

A laboratory that performs drug and alcohol laboratory tests of employees and job applicants for Minnesota employers must possess a valid license to do

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

so. A laboratory must obtain a license according to the procedures in parts 4740.0100 to 4740.0170, as proposed at 13 State Register 1079 and as subsequently adopted. In addition to the information required on an application for a license, a laboratory that performs only initial drug and alcohol screening tests must disclose on its application the name of the licensed laboratory that performs its confirmatory tests.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2860*

4740.1025 EXCEPTION.

A medical clinic, hospital, or other medical facility need not be licensed under parts 4740.1010 to 4740.1080 to perform a breath test as an initial screening test for alcohol if:

A. the medical clinic, hospital, or other medical facility is not owned or operated by the employer; and

B. the results of the breath test are confirmed by a blood test performed by a laboratory licensed under parts 4740.1010 to 4740.1080.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2860*

4740.1040 RECIPROCITY.

A license shall be granted to a laboratory located in another state, if the requirements of Minnesota Statutes, section 181.953, subdivision 1, paragraph (d), are met.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2860*

4740.1050 TERM OF LICENSE.

Laboratories shall be licensed for a term of one year. Unless a laboratory submits a timely application for license renewal, the license expires without further notice at the end of the term.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2860*

4740.1060 FEES.

Subpart 1. **Annual license fee required.** The laboratory must pay an annual license fee and other required costs with the initial application for license and with each renewal application. The amount of the fee and other required costs is determined under subpart 3. A laboratory must pay the fees and costs required under this part before a license is issued.

Subp. 2. **Information required to determine fee.** The laboratory must submit an estimate of the laboratory annual receipts during the current accounting year with the application for a license or license renewal. The laboratory must submit to the department quarterly reports of the laboratory annual receipts and the results of proficiency testing results for the past quarter. The statistics from these reports are used to adjust the license fee collected from the laboratory on its next license renewal application to reflect actual laboratory annual receipts.

Subp. 3. **License fee schedule.** The annual license fee is made up of an application fee and inspection fee as described in items A and B. The fees are nonrefundable.

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

A. The application fee is determined as follows:

Laboratory Annual Receipts	License fee
less than $500,000	$ 600
$500,000 to $2,000,000	1,200
$2 million to $10 million	1,800
more than $10 million	2,400; and

B. The inspection fee is $1,200 per year per lab.

C. Laboratories located outside Minnesota are assessed actual cost of additional labor, travel, and lodging expenses the department incurs in the laboratory inspection.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2860*

4740.1065 ANNUAL INSPECTION.

The commissioner shall conduct periodic inspections of laboratories licensed for drug and alcohol testing of employees. Inspections may be unannounced and occur at least annually.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2860*

4740.1070 PERFORMANCE METHODS REQUIRED FOR ISSUANCE OF A LICENSE.

Subpart 1. **Standards required.** To qualify for a license to conduct drug and alcohol testing for Minnesota employees and job applicants, the officers or the owner of a laboratory must use the performance methods described in subparts 2 to 8.

Subp. 2. **Test samples.** The usual sample for drug testing is freshly voided urine. A breath, urine, or blood sample may be used for initial screening tests. When the breath test is used as the initial screening test for alcohol, a blood sample shall be obtained for the confirmatory test. The blood sample shall be collected immediately after the breath test. When an initial positive urine test indicates the presence of drugs, a blood or urine sample shall be used for the confirmatory test.

The sample volume must be adequate to allow for the initial screening test, a confirmatory test, and a confirmatory retest.

Subp. 3. **Collection of urine samples; procedures.** The laboratory must have written procedures for collecting urine samples. The collection procedures must contain paragraphs 6 and 11 to 16 of the specimen collection procedures in Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies, NIDA, as provided by the Federal Register, volume 52, pages 30639 and 30640, Friday, August 14, 1987. Paragraphs 1 to 5 and 7 to 10 of these procedures are optional. The site where the sample is collected must have a stall or partitioned area that allows the individual being tested to provide the individual's urine specimen in privacy. The collection site person must sign and date either the tape sealing the sample container or the sample container label.

Subp. 4. **Collection of blood samples; procedures.** The laboratory must have written procedures for collection of blood samples. The procedure must address identification of the employee or job applicant, necessary collection supplies, seating or positioning of the employee or job applicant during sample collection, cleansing of the skin at the venipuncture site, and verification that the sample and paperwork are from the individual from which the sample was collected. NCCLS Guidelines H3-A2, Procedures for Collection of Diagnostic Blood Specimens by Venipuncture, 2nd Edition, Approved Standard, 1984, is an acceptable guide for the collection of blood samples. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford Building, 117 University Avenue, Saint Paul, Minnesota 55155.

The collection site person must sign either the tape sealing the sample container or the sample container label.

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

Subp. 5. **Techniques for drug testing.** For an initial screening test for drugs or drug metabolites, the laboratory must use a chromatographic technique or an immunoassay method. Samples that show the presumptive presence of a drug or drug metabolite must be confirmed by the gas chromatography/mass spectrometry (GC/MS) technique.

Subp. 6. **Techniques for alcohol testing.** A breath test, alcohol dehydrogenase reaction, microdiffusion, or oxidation of distillate with potassium dichromate may be used as a method to initially test for the presence of alcohol. The presumptive presence of alcohol must be confirmed using gas chromatography.

Subp. 7. **Confirmatory tests required.** A laboratory that performs only initial testing must obtain confirmatory results from a licensed laboratory that performs confirmatory tests.

Subp. 8. **Chain-of-custody procedures for handling samples.** The laboratory must follow written chain-of-custody procedures that, at a minimum, meet the requirements of items A to C.

A. Possession of a sample must be traceable to the employee from whom the sample is collected, from the time the sample is collected through the time the sample is tested, the test result reported, the sample retested, and the sample stored.

B. At all times, the sample must be in the possession of, in view of, or placed in a secured area by a person authorized to handle the sample.

C. A sample must be accompanied by a written chain-of-custody record. Individuals relinquishing or accepting possession of the sample must record the time the possession of the sample was transferred and must sign and date the chain-of-custody record at the time of transfer.

Subp. 9. **Storage of positive samples.** All confirmed positive samples shall be stored frozen for at least six months. The sample container must be sealed and labeled. The freezer must be locked or be located in a secure area.

Subp. 10. **Requirements for directors.** The director of the laboratory must be a full-time employee of the laboratory, must possess a doctoral, medical doctor, or a master's degree in a biological or medical science, and must have at least three years' experience in an analytical toxicology laboratory.

Subp. 11. **Proficiency testing required.** Satisfactory participation in a proficiency testing program is required of a laboratory applying for or renewing a license. The Forensic Urine Drug Testing surveys conducted by the College of American Pathologists and the American Association for Clinical Chemistry and the NIDA Performance Test Program are acceptable proficiency testing programs. The laboratory must participate at the appropriate screening and confirmatory test levels for which an application for license is submitted.

Subp. 12. **Procedures for proficiency testing.** Before applying for or renewing a license, a laboratory must participate in and report the results of three cycles of proficiency testing. The laboratory must mail proficiency testing results to the commissioner.

The procedures for handling and testing proficiency test samples after receipt by the laboratory must be identical to the procedures for normal laboratory samples.

Laboratory personnel shall not be informed that these samples are part of a performance test to the extent possible.

A licensed laboratory may also be subjected to blind proficiency testing. Performance on blind testing samples is required at the same level as for the open proficiency testing.

A false-positive result from a confirmatory test sample is unsatisfactory performance. Two false-positive results from a screening test sample during a one-year period constitute unsatisfactory performance. The laboratory must

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

inform the commissioner, in writing, of any false-positive test result on a proficiency testing sample, with a plan of corrective action. The commissioner will be informed within 14 days of receipt of the proficiency testing report.

Subp. 13. **Laboratory procedure manual.** The laboratory must possess and follow a laboratory procedure manual. The laboratory manual must describe the individual test procedures performed by the laboratory. The manual must have a table of contents and numbered pages. The manual must be reviewed annually. The description of the test procedures must include sections addressing the sample used for the test, reagents, supplies and materials, equipment calibration, quality control, the step-by-step procedure, calculations, reporting results, special notes, safety precautions, limitations of the procedure, references, and flow diagrams. Changes m a procedure must be reviewed and dated. Clinical Laboratory Procedure Manuals; Approved Guidelines, GP2-A, National Committee for Clinical Laboratory Standards, 1984, is an acceptable guide to writing a laboratory manual. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford Building, 117 University Avenue, Saint Paul, Minnesota 55155.

Statutory Authority: *MS s 144 07; 181.953*

History: *13 SR 2860*

4740.1075 INITIAL SCREENING TEST; MINIMUM DETECTION LEVELS.

The minimum levels that need to be detectable by a screening test are as follows:

A. marijuana metabolites, 100 ng/ml;

B. cocaine metabolites, 300 ng/ml;

C. opiate metabolites, 300 ng/ml;

D. phencyclidine, 25 ng/ml; and

E. amphetamines, 1,000 ng/ml.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2860*

4740.1080 THRESHOLD DETECTION LEVELS.

Threshold detection levels for confirmatory tests of drugs and drug metabolites defined in Minnesota Statutes, section 152.02, and rules of the Board of Pharmacy are 1,000 ng/ml, except as listed in items A to K:

A. marijuana metabolite (delta-9 tetrahydrocannabinol-9-carboxylic acid), 15 ng/ml;

B. cocaine metabolite (benzoylecgomne), 150 ng/ml;

C. opiates:

(1) morphine, 300 ng/ml*; and

(2) codeine, 300 ng/ml*;

D. phencyclidine, 25 ng/ml;

E. amphetamines, 500 ng/ml;

F. fentanyl, 5 ng/ml;

G. lysergic acid diethylamide (LSD), 5 ng/ml;

H. 3-4-methylenedioxy amphetamine (MDA), 300 ng/ml;

I. alcohol (urine), .02 gram percent; and

J. alcohol (blood), .02 gram percent.

* 300 ng/ml individually or in combination.

Statutory Authority: *MS s 144 07; 181.953*

History: *13 SR 2860*

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

4740.1090 VARIANCE AND WAIVERS.

A laboratory may request that the department grant a variance or waiver from the provisions of parts 4740.1000 to 4740.1080. A request for a variance or waiver must be submitted to the department in writing. A request must contain the following information:

A. the specific rules for which the variance or waiver is requested;

B. the reasons for the request;

C. the alternative measures that will be taken if a variance or waiver is granted; and

D. the length of time for which the variance or waiver is sought.

The commissioner shall review information submitted with the request for waiver or variance. If the laboratory proposes alternatives equivalent or superior to those prescribed in the rule and shows that strict enforcement of the rule would cause undue hardship, and the variance would not adversely affect public health or safety, the commissioner shall grant the variance, provided however the variance shall not conflict with statutory provisions. The commissioner shall provide the laboratory with a written decision that states the reasons for granting or denying the request for the variance.

Statutory Authority: *MS s 144.07; 181.953*

History: *13 SR 2860*

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 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

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

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.

Statutory Authority: *MS s 144.97; 144.98*

History: *14 SR 1874*

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:

(1) the address and phone number of the laboratory;

(2) the ownership of the laboratory;

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

(4) signatures of two managing agents with authority to bind the laboratory and proof of their authority to bind;

(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

(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

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

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 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. 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;

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

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

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

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 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;

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 whose analytical work requires a certified laboratory 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. The commissioner shall provide a list of reciprocity agreements upon request.

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;

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

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.

Statutory Authority: *MS s 144.97; 144.98*

History: *14 SR 1874*

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.

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

The laboratory shall provide the commissioner with the results of performance from the approved provider within 30 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 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 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 or reporting 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 F for each sample processed.

A. The laboratory shall maintain the records in items B 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.

E. 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.

F. The laboratory shall supply 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;

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

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 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 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 record on the data sheet when a sample:

A. has been incorrectly collected or preserved; 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;

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

B. laboratory ownership;

C. major analytical equipment;

D. test methodology; and

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

Statutory Authority: *MS s 144.97; 144.98*

History: *14 SR 1874*

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

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.

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.

Statutory Authority: *MS s 144.97; 144.98*

History: *14 SR 1874*

Copyright © 1990 Revisor of Statutes, State of Minnesota. All Rights Reserved.