Minnesota Pollution Control Agency

Proposed Permanent Rules Relating to Wastewater Laboratory Certification

7001.4310 SCOPE.

Subpart 1. **Applicability.** Parts 7001.4310 to 7001.4390 apply to laboratories required to be certified under Minnesota Statutes, section 115.84, except as excluded in subpart 2.

Subp. 2. **Exclusions.** Certification under parts 7001.4310 to 7001.4390 does not apply to:

A. laboratories that are private and for-profit;

B. laboratories that perform drinking water analyses;

C. laboratories that perform analyses for agency programs under Minnesota Statutes, chapters 115B and 115C; or

D. laboratories that are certified under another similar program, such as that of the Minnesota Department of Health.

7001.4320 DEFINITIONS.

Subpart 1. **Scope.** The terms used in parts 7001.4310 to 7001.4390 have the meanings given them in this part.

Subp. 2. **Agency.** "Agency" means the Minnesota Pollution Control Agency.

Subp. 3. **Agency program.** "Agency program" means a program or rule administered by the agency that requires submission of water data from a certified laboratory, such as the watershed program.

Subp. 4. **Analyte.** "Analyte" means the chemical substance, physical property, or organism analyzed in a sample.

Subp. 5. **Analyte group.** "Analyte group" means a set of analytes that can be determined using the same method or technology.

Subp. 6. **Certified laboratory.** "Certified laboratory" means a laboratory that has:

A. met the requirements of parts 7001.4310 to 7001.4390;

B. received a notice of certification from the agency;

C. not voluntarily discontinued certification; and

D. not been notified by the agency that certification is suspended or revoked.

Subp. 7. **Client.** "Client" means an entity that has arranged with a laboratory to perform tests and analyses to meet the requirements of an NPDES or SDS permit or other agency program or regulatory requirement.

Subp. 8. **Initial application.** "Initial application" means an application submitted by a laboratory that either has never had certification or has not met the requirements for either a renewal or revised application under part 7001.4360.

Subp. 9. **Laboratory.** "Laboratory" means a facility that performs analyses on water or wastewater to support demonstrations of compliance with agency program or regulatory requirements.

Subp. 10. **Method.** "Method" means a published scientific technique for performing a specific measurement. Method includes instructions for sample preparation, sample preservation, and sample analysis.

Subp. 11. **National pollutant discharge elimination system or NPDES.** "National pollutant discharge elimination system" or "NPDES" means the federal program authorized under subchapters III and IV of the Clean Water Act, United States Code, title 33.

Subp. 12. **Parameter.** "Parameter" means the chemical substance, physical property, or organism being measured.

Subp. 13. **Proficiency test.** "Proficiency test" means a test performed by a laboratory for a specific analyte or analyte group to determine the ability of a laboratory to employ applicable analytic methods and to produce an accurate measurement of the concentration of the analyte or analyte group in the sample.

Subp. 14. **Renewal application.** "Renewal application" means an application submitted by a laboratory to renew an existing certification.

Subp. 15. **Reporting limit.** "Reporting limit" means the lowest level of an analyte that can be accurately recovered from the matrix of interest, for example, the level of quantitation.

Subp. 16. **Revised application.** "Revised application" means an application that is submitted to make changes to an existing certification as specified in part 7001.4360, subpart 6.

Subp. 17. **State disposal system permit or SDS.** "State disposal system permit" or "SDS" means a state-only permit issued by the agency for the construction, installation, or operation of a disposal system that does not discharge a pollutant into the waters of the state from a point source.

7001.4330 CERTIFICATION REQUIRED.

A laboratory that performs tests and analyses, the results of which must be reported to the agency to meet permit conditions or other agency program or regulatory requirements, must be certified for the parameters or methods required by the permit or agency program, unless the permit or agency program specifically exempts the parameters or methods from certification requirements.

7001.4340 REQUIRED METHODS.

Subpart 1. **General requirements.**

A. The laboratory's analytical methods, sample collection, and preservation procedures must meet the requirements specified by the NPDES/SDS permit or agency program. The analytical methods, sample collection, and preservation procedures used to analyze samples for programs required by a federal agency must meet the requirements specified in the relevant parts of Code of Federal Regulations.

B. Laboratories must conduct analyses according to the methods in subparts 2 to 4.

Subp. 2. **Clean water methods.** For analysis of water or wastewater samples required by state and federal clean water rules and regulations, laboratories must use the methods and test procedures in Code of Federal Regulations, title 40, part 136, as amended.

Subp. 3. **Biosolids methods.** For analysis of sewage sludge samples required by state rules and federal regulations, laboratories must use the methods and test procedures in Code of Federal Regulations, title 40, part 503, as amended, and "Test Methods for Evaluating Solid Waste: Physical/Chemical Methods," Publication SW-846, United States Environmental Protection Agency (2007 and as subsequently amended and as published as final). Publication SW-846 is incorporated by reference, is not subject to frequent change, and is available at http://www.epa.gov/epawaste/hazard/testmethods/sw846/online/index.htm.

Subp. 4. **MPCA Laboratory Certification Program Manual.** The MPCA Laboratory Certification Program Manual, Minnesota Pollution Control Agency (2014 and as subsequently amended), is incorporated by reference, is not subject to frequent change, and is available at http://www.pca.state.mn.us/4p44whk.

7001.4350 CERTIFICATION QUALIFICATION.

Subpart 1. **Personnel.** A laboratory must have staff with the education, training, or experience to meet the requirements of certification. At least one staff person must be identified as the laboratory administrator and that person's contact information must be

provided with the certification application. The laboratory administrator must notify the agency when there are changes in contact information for the laboratory administrator no later than 30 days after the change occurs.

Subp. 2. **Quality system.** The laboratory must have a quality assurance and quality control program that meets the criteria specified in the agency's Laboratory Certification Program Manual, incorporated by reference under part 7011.4340, subpart 4, that includes:

A. a quality assurance manual;

B. standard operating procedures; and

C. traceability, documentation, record keeping, and reporting.

Subp. 3. **Access to premises.** The laboratory must allow the agency and its members, employees, and agents access to the laboratory for inspection and evaluation purposes and must produce such information and records as the agency requests to determine compliance with this part.

Subp. 4. **Access to records.** The laboratory must maintain all records used to demonstrate the laboratory's compliance with certification requirements. If a laboratory analyzes samples from a client, records that support the client's test results must be made available to the client. Upon request, records must be made available to the agency.

Subp. 5. **Proficiency testing.** A laboratory must conduct proficiency testing as required under part 7001.4390.

Subp. 6. **Subcontracting.** A laboratory that has samples analyzed by another laboratory must use laboratories that have valid agency certification or similar certification.

Subp. 7. **Cease reporting.** A laboratory must not report analytical results after its certification has expired or been discontinued, suspended, or revoked.

Subp. 8. **Fees.** A laboratory must pay the fees required in part 7002.0430 within 30 days of receiving the invoice.

Subp. 9. **Response.** A laboratory must respond in writing to any written communication from the agency.

7001.4360 APPLICATION FOR CERTIFICATION.

Subpart 1. **Application contents.** To apply for initial or renewal of certification, a laboratory's application must include the following information on a form provided by the agency:

A. identifying information:

(1) the name of the laboratory;

(2) the physical location and postal mailing address of the laboratory;

(3) the owner or legally responsible party of the laboratory;

(4) the name, telephone number, and electronic mailing address of the laboratory administrator; and

(5) the name of at least one managing agent and the agent's signature attested by a notarial officer;

B. the parameters and methods for which the laboratory seeks certification. A laboratory must apply for at least one parameter or method;

C. a quality assurance manual meeting the standards of the agency's Laboratory Certification Program Manual. For a certification renewal, if the quality assurance manual was revised during the current certification year, the most recent version must be submitted;

D. laboratory standard operating procedures for each parameter or method that meet the standards of the agency's Laboratory Certification Program Manual. For a certification renewal, if the standard operating procedures were revised during the current certification year, the revised version must be submitted;

E. if the application is an initial request for certification, the most recent proficiency testing result for each parameter or method for which the laboratory is requesting certification. The proficiency testing must have been completed no more than 12 months prior to the date that the application is received by the agency and must meet the requirements of part 7001.4390;

F. if the application is an initial request for certification, a list of the laboratory's detection limits and reporting limits for each parameter or method for which the laboratory is requesting certification; and

G. any other additional information requested by the agency as necessary to determine compliance with parts 7001.4310 to 7001.4390.

Subp. 2. **Multiple locations.** The owner of laboratory facilities with multiple locations must submit a separate application for each laboratory location.

Subp. 3. **Change of address.** The laboratory administrator must notify the agency of changes in address no later than 30 days before the change occurs.

Subp. 4. **Application period.**

A. Initial applications and revised applications may be submitted to the agency at any time.

B. Renewal applications must be submitted between November 1 and November 30. If a certified laboratory fails to submit a renewal application by November 30, the certification expires on December 31.

Subp. 5. **Initial application.** An initial application must be submitted by a laboratory:

A. that has never been certified under parts 7001.4310 to 7001.4390;

B. that has had its certification revoked in total;

C. with a certification that has expired for more than one year; and

D. that has submitted an application that has remained incomplete for more than one year.

Subp. 6. **Revised application.** A laboratory with a valid certification must submit a revised application, including the information required in subpart 1, items D to F, to the agency to:

A. add a category for which the laboratory does not currently have certification; or

B. add a test method in a category for which the laboratory is already certified.

Subp. 7. **Conditions for reapplication.** A laboratory involved in an active enforcement action or with a suspended or revoked certification is not eligible to seek or renew certification for the affected parameters or methods until the laboratory receives confirmation from the agency that the corrective action associated with the enforcement action, suspension, or revocation is complete.

Subp. 8. **Alternate methods.** A laboratory must request approval for alternate methods by following the instructions provided in "Alternate Test Procedure Guidance" (document # p-eao2-12), Minnesota Pollution Control Agency (October 2014 and as subsequently amended). The guidance document is incorporated by reference, is not subject to frequent change, and is available at http://www.pca.state.mn.us/index.php/view-document.html?gid=16155. The agency's approval or denial of the request must be based on the requirements of the guidance document.

7001.4370 GRANTING CERTIFICATION.

Subpart 1. **Term of certification.** Certifications are effective on the date of issuance and are valid through December 31 of the year issued unless suspended, revoked, or voluntarily discontinued.

Subp. 2. **Certification documents.** A laboratory must not alter or modify certification documents and must make them available upon the request of a client or regulatory agency.

Subp. 3. **Limit of certification.** Certification of a laboratory is not an endorsement by the agency of the quality or validity of the data generated by a laboratory. Certification does not guarantee the usability of data generated by a laboratory for an intended purpose. The users of laboratory results are responsible for determining whether to accept or reject analytical data from a certified laboratory.

7001.4380 VOLUNTARY WITHDRAWAL OR DISCONTINUATION OF CERTIFICATION.

Subpart 1. **Agency notification.** If a laboratory chooses to withdraw its application for certification or discontinue its current certification, in total or in part, the laboratory must notify the agency in writing and specify the effective date of withdrawal or discontinuation and the parameters or methods for which certification is being withdrawn or discontinued. The laboratory must submit notification at least 30 days before the effective date of withdrawal or discontinuation.

Subp. 2. **Cease reporting.** After the effective date specified in subpart 1, the laboratory must not provide analytical results for compliance reporting or any agency program for the parameters and methods for which certification has been withdrawn or discontinued.

Subp. 3. **Client notification required.** At least 30 days before the effective date of the laboratory's discontinuation of certification, the laboratory must notify clients and

affected regulatory agencies in writing of the discontinuation date and which parameters and methods will be affected. The laboratory must submit a copy of each client notification to the agency at the same time that the notification is sent under subpart 1.

Subp. 4. **No fee refund.** The agency does not refund fees if a laboratory voluntarily withdraws or discontinues its current certification.

Subp. 5. **Recertification.** To be recertified after voluntary discontinuation of certification, a laboratory must submit an application meeting the requirements for:

A. a revised application under part 7001.4360, subpart 6, if reapplying within one year of the date that certification was discontinued; or

B. an initial application under part 7001.4360, subpart 1, if certification has been discontinued for more than one year.

7001.4390 PROFICIENCY TESTING.

Subpart 1. **Requirements.**

A. A laboratory must successfully complete at least one proficiency test for each parameter or method for which it applies for certification. The laboratory must complete the proficiency test no more than 12 months prior to submitting the application. If no proficiency test sample is available for an analyte, the laboratory is exempted from the requirements of this part only for that analyte.

B. Proficiency tests results must be included with the initial or revised certification application required under part 7001.4360.

C. Proficiency test samples that are analyzed as a part of a discharge monitoring report-quality assurance study required under federal regulations must meet the requirements of item A.

Subp. 2. **Laboratory testing of proficiency test study samples.** To ensure valid proficiency test results, the laboratory must:

A. obtain all proficiency test study samples as unknowns from a nationally recognized accreditation program approved vendor;

B. manage, analyze, report, and otherwise handle all proficiency test samples in the same manner as routine samples, including the same staff, procedures, equipment, and facilities used for routine analysis for the tested parameter or method;

C. employ the same calibration, quality control, acceptance criteria, sequence of analytical steps, number of replicates, and other standard operating procedures for proficiency test samples as used when analyzing routine samples; and

D. follow sample preparation steps for the proficiency test sample as instructed by the proficiency test sample provider.

Subp. 3. **Reporting results.**

A. A laboratory must submit the results of all proficiency tests to the agency no later than 30 days after the laboratory receives the results from the proficiency test sample provider.

B. A laboratory conducting proficiency testing as part of an initial or revised application must submit the results of proficiency testing as part of the application.

C. A laboratory must either provide a copy of the original results to the agency or authorize the proficiency test sample provider to provide all results directly to the agency.

D. Proficiency testing samples analyzed or reported to the proficiency test sample provider after the provider's study closing date are not valid for compliance with the proficiency testing requirements under this part.

Subp. 4. **Restrictions on exchanging information.** Prior to the time the results of the proficiency test are submitted to the agency:

A. a laboratory must not communicate proficiency test results to another laboratory, including intercompany communication; and

B. a laboratory must not attempt to obtain the assigned value of any proficiency test sample from a proficiency test sample provider or another laboratory.

Subp. 5. **Evaluation of results.**

A. A laboratory must demonstrate passing performance to the agency, as determined by the proficiency test sample provider, for each parameter or method reported.

B. A laboratory may use one proficiency test sample for multiple methods.

C. A laboratory must not request a revised report from the proficiency test sample provider when the requested revisions are the result of error on the part of the laboratory.

Subp. 6. **Repeat proficiency tests.**

A. A laboratory may repeat proficiency tests after obtaining unacceptable results as follows:

(1) if the first proficiency test result is unacceptable, the laboratory must resolve the suspected cause and complete a second proficiency test within 30 days of receiving the unacceptable result;

(2) if the second proficiency test result is unacceptable, the laboratory must:

(a) resolve the suspected cause and submit a corrective action report to the agency within 30 days of receiving the second unacceptable result; and

(b) order and complete a third proficiency test within 30 days of receiving the unacceptable result of the second proficiency test;

(3) if the third proficiency test result is unacceptable, the laboratory may not provide analytical results for compliance reporting or any agency program for the

parameters and methods for which the laboratory failed to demonstrate acceptable proficiency test results. The laboratory may resume providing analytical results when the laboratory passes two proficiency tests in a row. These proficiency tests must be conducted at least 15 days apart. The laboratory must submit a corrective action report to the agency within 30 days of passing the second of the two proficiency tests.

B. The Laboratory Certification Program Manual, incorporated by reference in part 7001.4340, subpart 4, governs when a portion of a multiple analyte group proficiency test is unacceptable.

C. The agency may request additional information necessary to validate sample results generated during the testing period covered under this subpart.

7002.0400 SCOPE; DEFINITIONS.

Subpart 1. **Scope.** Parts 7002.0400 to 7002.0430 apply to laboratories required to be certified according to parts 7001.4310 to 7001.4390.

Subp. 2. **Definitions.** The terms used in parts 7002.0400 to 7002.0430 have the meanings given under part 7001.4310.

7002.0410 FEE DETERMINATION.

A. Certification fees under parts 7002.0410 to 7002.0430 are based on the number, type, and complexity of analytical methods that a laboratory is certified to perform.

B. The fee formula is designed to collect revenue equal to the certification program's expenses by using a system of points to equitably distribute the fees among all laboratories certified by the agency. Each fee item is assigned a point value under part 7002.0430. Once the dollar per point value is determined under part 7002.0420, it is multiplied by the total number of points for each application.

C. The agency must annually establish the fee target in an amount necessary to cover costs of reviewing applications, issuing certifications, conducting laboratory evaluations, training, collecting fees, and providing compliance assistance and other anticipated costs of administering the certification program. After the first year of the program, the fee target must be based on the actual costs to administer the certification program in the previous calendar year, with any necessary adjustments to cover costs according to this item.

7002.0420 COMPUTATION OF DOLLAR PER POINT VALUE.

The agency computes the dollar per point value for each year as follows:

$$\$ \text{ per point} = T/B$$

where:

$ per point is the dollar amount applied to each point;

T is the fee target calculated according to part 7002.0410, item C; and

B is the sum of all points for participating laboratories during the previous calendar year.

7002.0430 LABORATORY CERTIFICATION APPLICATION FEES.

Subpart 1. **Payment of fees.**

A. Certification for a calendar year is provisional until the laboratory's certification application is paid.

B. Fees are nonrefundable once an invoice has been issued.

Subp. 2. **Application points.** The points assessed for certification application or category types designated in this subpart are multiplied by the dollar per point value determined under part 7002.0420 to calculate the appropriate fee.

Application or category type		Points
A.	Initial application	6
B.	Renewal application	4

C.	Voluntary field tests	0
D.	Oxygen utilization	1
E.	Nitrogen	1
F.	Phosphorus	1
G.	Physical	1
H.	Microbiology	1
I.	General I	1
J.	General II	2
K.	General III	4
L.	Metals	4
M.	Organics, purgeable, Gas Chromatograph, and Gas Chromatograph Mass Spectrometer	4
N.	Organics, semivolatile, Gas Chromatograph Mass Spectrometer	4
O.	Organics, organochlorine compounds	4

Subp. 2. **Revised applications.**

A. A laboratory submitting a revised application to add a new test category to the laboratory's certification must pay:

(1) the full category fee if the application is submitted to the agency on or before July 1; or

(2) 50 percent of the category fee if the application is submitted to the agency after July 1.

B. A laboratory submitting a revised application to add a test method for a parameter in a category for which the laboratory is already certified must pay 25 percent of the total category fee for the parameter.