Minnesota Pollution Control Agency

520 Lafayette Road North | St. Paul, Minnesota 55155-4194 | 651-296-6300

800-657-3864 | 651-282-5332 TTY | www.pca.state.mn.us | Equal Opportunity Employer

December 24, 2014

Legislative Reference Library
645 State Office Building
100 Constitution Avenue
St. Paul, Minnesota 55155

Re: In The Matter of the Proposed Rules of the Pollution Control Agency about Wastewater laboratory certification and fee rules; Revisor's ID Number 4290

Dear Librarian:

The Minnesota Pollution Control Agency (MPCA) intends to adopt rules to govern a certification program for wastewater laboratories and associate fees. We plan to publish a Notice of Intent to Adopt Rules without a Public Hearing in the December 29, 2014 *State Register*.

The MPCA has prepared a Statement of Need and Reasonableness. As required by *Minnesota Statutes*, sections 14.131 and 14.23, the MPCA is sending the Library an electronic copy of the Statement of Need and Reasonableness at the same time we are mailing our Notice of Intent to Adopt Rules.

If you have questions, please contact me at 651-757-2597.

Yours very truly,

Carol Nankivel
Minnesota Pollution Control Agency
Rule Coordinator

CN:jlr

Enclosure: Statement of Need and Reasonableness

Minnesota Pollution Control Agency

Environmental Analysis and Outcomes Division

STATEMENT OF NEED AND REASONABLENESS

In the Matter of Proposed Revisions of Minnesota Rule Chapters 7001 and 7002, relating to certification of water and wastewater laboratories and laboratory certification fees

Revisor's # 4290

Alternative Format:

Upon request, this Statement of Need and Reasonableness (SONAR) can be made available in an alternative format, such as large print, Braille, or audio. To make a request, contact Carol Nankivel at the Minnesota Pollution Control Agency, Resource Management and Assistance Division, 520 Lafayette Road North, St, Paul, MN 55155-4194; telephone 651-757-2597; (toll free at 800-657-3864);fax 651-297-8676 or e-mail carol.nankivel@state.mn.us. TTY users may call the Agency at 651-282-5332

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Acronyms or abbreviations

Chapter	ch.
Code of Federal Regulations	CFR
Hazardous & Solid Waste Amendment	HSWA
Minnesota Rules	Minn. R.
Minnesota Statutes	Minn. Stat.
Minnesota	MN
Minnesota Department of Health	MDH
Minnesota Pollution Control Agency	MPCA or Agency
National Environmental Laboratory Accreditation Program	NELAP
National Pollutant Discharge Elimination System	NPDES
Notice of Intent to Adopt Rules Without a Public Hearing	Notice
Part(s)	Pt(s).
Quality Assurance/Quality Control	QA/QC
Section	§
Standard Operating Procedures	SOP
State Council on Affairs of Chicano/Latino People	CLAC
State Disposal System	SDS
Statement of Need and Reasonableness	SONAR
United States Environmental Protection Agency	EPA

1. Introduction and statement of general need

A. Executive summary

In 2013, the Minnesota legislature authorized the Pollution Control Agency (MPCA or agency) to administer a laboratory certification program and to collect fees for specific types of laboratories. *Minnesota Statutes* (*Minn. Stat.*) Section (§)115.84. The purpose of the statute was to provide a certification program for laboratories that provide water and wastewater analyses solely to support MPCA permits, programs or regulatory requirements.

The same statute also gave the MPCA the authority to adopt rules if necessary. The MPCA has determined that rules are necessary. In this rulemaking the MPCA is proposing rules to govern a certification program and to establish a formula for calculating applicable fees. Only certain types of laboratories are eligible to participate in the MPCA's proposed certification program and their participation is optional. Although laboratories must be certified to provide data to the MPCA, they are not required to be certified through the MPCA's program.

Participation in the MPCA's certification program, and therefore, the application of the proposed rules and fees, is limited to laboratories performing wastewater analytical work that is used to determine compliance with National Pollutant Discharge Elimination System (NPDES) or State Disposal System (SDS) permits and laboratories performing water analytical work in support of other regulatory documents issued by the MPCA.

The proposed rules do not:

Apply to any of the following laboratories excluded under *Minn. Stat.* § 115.84:

1. Laboratories that are private and for-profit;
2. Laboratories that perform drinking water analyses; and
3. Laboratories that perform analyses for land remediation programs, such as the Superfund or petroleum remediation programs.
    - Require any laboratory to obtain certification through the MPCA's program. The MPCA's proposed certification program is offered as an alternative to existing laboratory certification programs, including the certification program currently administered through the Minnesota Department of Health (MDH).

The proposed rules:

- Establish the administrative process for obtaining and maintaining certification.
- Incorporate by reference the federal regulations and state documents that establish the protocols and procedures necessary to conduct analyses and ensure laboratory quality.
- Provide a formula for the calculation of certification fees.

The MPCA has conducted a stakeholder notification process and has met or will meet all applicable requirements of *Minn. Stat.* chapter (ch.) 14.

B. Statement of need

The need for the MPCA to have authority to develop an alternative to the existing certification program administered by MDH was discussed in the development of that legislation and will not

be repeated for this rulemaking. In accordance with the statute, the MPCA developed and implemented a laboratory certification program and has collected fees since 2014. The same legislation also gave the MPCA the authority to, if needed, adopt rules to administer the certification and fee programs. The MPCA believes that formalizing the existing program and fee calculation formula into rules is needed for the following reasons:

- **Clarity and detail.** The MPCA believes it can more effectively administer the certification program if it provides additional detail to the legislatively authorized program. The regulated community needs to clearly know what is required to obtain and maintain certification. The level of detail to administer a certification program is most appropriately addressed through rules.
- **Transparency.** The laboratory community that is currently being certified by the MPCA expects to know the justification and basis for the requirements with which it must comply. The programs and permittees who rely on certified laboratories, and the public in general, expect that the MPCA's certification program will ensure that valid and reliable environmental data is submitted to meet permit conditions. Minnesota's rulemaking process provides public review, transparency and technical justification.
- **Program improvement.** The rulemaking process provides opportunities for public input and comment. The MPCA believes that the result of an open and engaged process will identify deficiencies and reveal solutions that will strengthen the existing certification program.
- **Improvement in quality of data.** The rulemaking process formalizes and standardizes the approach used by the MPCA in oversight of wastewater laboratories, which ensures consistency and improvement in data quality through a program tailored for small laboratories and the application of established methods.

C. Scope of the proposed rules:

The proposed changes affect two chapters of *Minnesota Rules*.

- *Minnesota Rules (Minn. R.)* ch. 7001 (MPCA Permits and Certifications). This chapter establishes the general requirements for the MPCA's permits and certifications[1] as well as specific requirements relating to hazardous waste facility permits, NPDES permits, 401 certification, solid waste management facility permits and major facility substance storage permits. The proposed rules will add a new section to address analytical laboratory certification. *Minn. R.* 7001.4310 to 7001.4390. No other permit or certification programs are being added or amended in this rulemaking.
- *Minn. R.* ch. 7002 (MPCA Permit Fees). This chapter establishes the conditions and fees applied by certain MPCA programs. The proposed rules will add a new section, to establish fees applicable to laboratories seeking certification. *Minn. R.* 7002.0400 to 7002.0430.

The scope of the proposed rules is limited to that established in *Minn. Stat.* §115.84, which authorizes the MPCA to develop rules governing the certification program and fees applicable to a very narrow sector of analytical laboratories. The proposed rules apply only to wastewater laboratories that provide analytical services to facilities that are permitted under the NPDES or

[1] Minn. R. ch. 7001 does not include the requirements for the MPCA's air emission permits which are located in Minn. R. ch. 7007.

SDS programs and water analytical laboratories that produce data in support of other regulatory documents issued by the MPCA.

The proposed rules do not extend to any other aspects of *Minn. R.* chs. 7001 or 7002, although minor administrative changes to existing rule language to those or other chapters may be identified by the Revisor of Statutes or Office of Administrative Hearings to support the addition of the proposed rules. These additional changes, if any, will be in the nature of cross references or clarifications.

2. Background

A. SONAR information

Minnesota's rulemaking process requires the MPCA to explain the facts establishing the need for and reasonableness of the rules being proposed and address specific procedural requirements of *Minn. R.* ch.1400 and *Minn. Stat.* ch. 14. In this rulemaking the MPCA has chosen to address both the proposed rule governing laboratory certification and the proposed rule establishing fees for certified laboratories through the same rulemaking process. This SONAR contains the MPCA's affirmative presentation of facts on the need for and reasonableness of both parts of the proposed rules. This SONAR also provides the MPCA's documentation of how it has met the procedural requirements for the rules up to this point in rulemaking.

In this SONAR the MPCA provides the following information:

Introduction, statement of need, and discussion of scope. In Part 1 the MPCA provides a short summary of the rules being proposed in the form of an Executive Summary. This part also provides the MPCA's statement of the need for the proposed rules and a discussion of the scope.

Background discussion of laboratory certification and fee programs. In Part 2 the MPCA provides a brief discussion of the types of laboratories and laboratory functions that are the focus of this rulemaking. The history of the MPCA's laboratory certification program is also discussed.

Public participation and stakeholder involvement. The activities the MPCA has conducted to notify and engage the public and the regulated community are discussed in Part 3 and also in Part 7 where the MPCA discusses its intent to provide the required and additional notice of this rulemaking.

Statutory authority. The MPCA's statutory authority for the proposed rules is addressed in Part 4.

Statement of reasonableness. A discussion of the general and specific reasonableness of the proposed rules is provided in Part 5.

Regulatory analysis. *Minn. Stat.* ch. 14 requires consideration of a number of questions, including consideration of cumulative effect of a rule. A discussion of these questions and of the cumulative effect of the proposed rules is provided in Part 6.

Notice plan: A number of statutory and policy requirements such as notification to the Governor and review by the Office of Management and Budget must be completed for every rulemaking.

In Part 7 the MPCA provides a discussion of how it has met those requirements and how it intends to provide additional notice to interested parties.

Statutory requirements, including consideration of economic factors: Minnesota laws require consideration of a number of factors in SONAR. Parts 6 through 13 provide the MPCA's response to those requirements.

Exhibits: The SONAR includes citations to specific exhibits. The exhibits are those documents that are either required as part of the rulemaking process or that are especially pertinent to the proposed rules. A list of the MPCA's Exhibits is provided in Part 14. The exhibits are not attached to this SONAR but are available for viewing on the rulemaking webpage (http://www.pca.state.mn.us/xwrhffa) and by request.

B. Laboratory processes and certification programs.

The MPCA is authorized by United States Environmental Protection Agency (EPA) to implement the federal NPDES program by issuing permits to industrial and municipal sources to discharge wastewater into surface waters (lakes and streams). The MPCA also administers the SDS program, which is a state-only permit program that issues permits for wastewater land spreading activities. NPDES and SDS permits contain specific requirements that limit the levels of regulated pollutants present in the discharge or effluent from the permitted facility. The types of analyses required by permits range from simple pH and temperature testing to very complicated organic compounds detected through sophisticated analytical procedures. The MPCA also conducts programs to monitor water quality unrelated to NPDES or SDS discharge permits, such as the lake and stream monitoring programs and Surface Water Assessment Grants program. These non-permit programs are referred to in the proposed rules as "agency regulatory or program requirements" and are often conducted in cooperation with local governments, universities, or local organizations that are responsible for submitting valid data to the MPCA.

NPDES and SDS permittees may contract with commercial laboratories do the testing required by permits. Commercial laboratories are not the subject of this rulemaking. This rulemaking is limited to the certification of laboratories that are public or not for profit. These are usually laboratories that are operated by NPDES or SDS permittees themselves, either municipal or industrial, and entities that submit water data to the MPCA for other covered programs. In order to fulfill permit conditions, or the requirements of an MPCA regulatory program, these types of laboratories must be certified. Before the development of the MPCA's certification program, these laboratories were usually certified through the MDH under the requirements of *Minn. R.* Parts (pts.) 4740.2050 to 4740.2120. The MPCA's certification program began in 2013 when the Minnesota Legislature granted authority to the MPCA to conduct a certification program as an alternative to the MDH laboratory certification program.

The MPCA began its initial laboratory certification program by establishing a steering committee, composed of the persons associated with NPDES/SDS permits and the operators of various types of laboratories and consultants for those laboratories. This steering committee was extensively involved with the development of an MPCA certification manual. The MPCA's manual established the requirements for submitting data to the MPCA to meet permit conditions including Quality Assurance/Quality Control (QA/QC) procedures, Standard Operating Procedures (SOP) and recordkeeping and documentation procedures. Because the manual was the result of a collaborative effort by persons with extensive knowledge of this type of

laboratory work, many of the administrative aspects of the MPCA's manual are being incorporated into the proposed rules. The portions of the manual that continue to be relevant to the procedures necessary to provide valid data in support of permit conditions and water programs have been retained in a document called "*MPCA Laboratory Certification Program Manual*" that is being incorporated by reference in this rulemaking.

In order to produce reliable data, laboratories must conduct their analyses according to specific protocols and procedures. These protocols and procedures are extensive and very complex. Two sets of federal regulations that identify analytical procedures and methods are proposed to be incorporated by reference. The third document being incorporated by reference, the *MPCA Laboratory Certification Program Manual* provides additional detail for the implementation of the federal analytical procedures incorporated by reference.

3. Public participation and stakeholder involvement

The MPCA conducted public participation activities to comply with the requirements of Minnesota's rulemaking process and also to provide a useful exchange of information between MPCA staff and other parties with knowledge and experience regarding laboratory processes. Electronic notifications through the MPCA's GovDelivery system formed the basis of the MPCA's public participation and stakeholder involvement process.

A. Early stakeholder engagement

1. When the MPCA published the Request for Comments, the MPCA provided GovDelivery notice to a number of entities. This notice was sent to:
   - 3,884 persons who had registered their interest in either MPCA rulemaking in general or the MPCA's wastewater laboratory certification program.
   - Members of the steering committee. More than 10 people participate on the MPCA's Laboratory Certification steering committee. The steering committee was formed in 2012, when the MDH laboratory certification program agreed with the MPCA that certification of the small industrial and not for profit wastewater laboratories would be a better fit for the MPCA. The steering committee members participate in the MPCA's implementation of the certification program. Although it was not specifically organized to assist in the development of the rules, the steering committee has been kept notified of MPCA's rulemaking activities.
2. **Steering committee.** A small community of laboratories identified the need for and requested the development of an MPCA certification program. Due to their efforts the MPCA's statutory authority to adopt rules was obtained. A steering committee was formed from the community including small, medium, and large laboratories as well as consultants and other interested parties. Since the passage of the authorizing legislation in 2013, the MPCA has worked with these very committed stakeholders to develop the certification program. The steering committee provided insight into the needs of the program and assisted in building the original MPCA laboratory certification policy that is a basis for the proposed rules. The steering committee reviewed and commented upon the MPCA's recommended costs, documentation, and requirements throughout the building of the program that has been implemented up to this point.

   Because of the limited number of affected entities, and the fact that the steering committee is composed of representatives of many of these affected laboratories, the MPCA is

confident that the parties who will be most affected by the proposed rules have had ample notice and opportunity to be involved in the development of the program and the rulemaking process.

3. **Additional outreach.** In addition to its communications with the steering committee and GovDelivery notices to reach the entities interested in receiving notification about the proposed rules, the MPCA conducted the following additional activities to notify and engage potentially interested parties:
   - Posted information regarding the proposed rules on its rulemaking docket http://www.pca.state.mn.us/index.php/view-document.html?gid=16321. The docket is updated monthly and available online.
   - Posted a rulemaking webpage in September 2014 (http://www.pca.state.mn.us/xwrhffa) with information about the rulemaking.
   - Participated in a 2012 public meeting of the wastewater laboratory community in Fergus Falls, Minnesota to outline the concept of an MPCA program. MPCA staff was invited to discuss the program and take input.
   - Presentations made at the Minnesota Wastewater Operator's Association annual and section meetings, Minnesota Rural Water Association annual and section meetings, and the MPCA Wastewater Operations annual conference.

B. Administrative procedures act notices

The MPCA has provided the required notifications to the public and the entities identified in statute. The MPCA published a Request for Comments in the October 6, 2014 State Register and a provided a comment period until November 7, 2014. At the same time the Request for Comments was published, the MPCA provided the following additional notice:

- Sent a notice through GovDelivery to 3,884 entities. These included persons registered to receive notice of information regarding the MPCA's laboratory certification program and also all persons who had registered to receive notice of any MPCA rulemakings.
- Posted the Request for Comments on the MPCA's Public Notices webpage for the term of the comment period.
- Posted the Request for Comments, plus a simplified Request for Comments in plain English and a "Concept Document" that provided more detail about the MPCA's plans for developing the certification and fee rules, on the rulemaking webpage (http://www.pca.state.mn.us/xwrhffa).

The MPCA did not receive comments in response to the Request for Comments.

The MPCA will provide additional notifications, as required under *Minn. Stat.* Ch. 14, at the time the rules are proposed. The MPCA intends to publish a Notice of Intent to Adopt Rules Without a Hearing in the *State Register* and to provide additional notice of its activities to all parties who have registered their interest in receiving such notice (as described in Part 7).

C. Webpage information

The use of a topic-specific webpage is an important mechanism for informing interested parties of the MPCA's rulemaking activities. There are two webpages that are relevant to this rulemaking. The first is the MPCA's public notice webpage found at http://www.pca.state.mn.us/yrwc6a9. On this webpage the MPCA publishes official notices of rulemaking activity, including the Request for Comments published in the *State Register* on October 6, 2014 and the Notice of Intent to Adopt Rules Without a Hearing that will be published in the *State Register* when the rules are proposed for public comment. The notices that are published on the public notice webpage remain available for viewing during the entire term of the comment period.

The second relevant webpage is the page that has been developed for the use of keeping the public informed specifically about this rulemaking (http://www.pca.state.mn.us/xwrhffa). The MPCA created this webpage at the start of the rulemaking process and will periodically update it to include more detailed information about the proposed amendments and to provide access to rulemaking documents. This SONAR, the proposed rule language, and supporting rulemaking documents (e.g. comments and the MPCA's Response to Comments) will be posted on this webpage for public review as they become available.

The MPCA also provides a rulemaking docket at http://www.pca.state.mn.us/index.php/view-document.html?gid=16321 which is updated monthly to provide easy web access to current information about all active rulemakings.

D. GovDelivery notice

When the MPCA published its Request for Comments, it sent a GovDelivery notice to all persons who had registered their interest in being notified of MPCA rules. This notice described the MPCA's intention to propose wastewater laboratory certification rules and encouraged persons to view the webpage and to register to receive further notices specifically related to this rule. The list developed as a result of this early-phase effort will be used to disseminate rule-related information to interested and affected parties throughout the rulemaking process. The MPCA will send a GovDelivery notice to this list of self-registered interested parties when it publishes the Notice of Intent to Adopt Rules Without a Hearing and proposed rule language.

4. Statutory authority

State authority for the MPCA to adopt the proposed rules is found in *Minn. Stat.* § 115.84, subd.2.

115.84 WASTEWATER LABORATORY CERTIFICATION.

Subdivision 1. ***Wastewater laboratory certification required.***

(a) Laboratories performing wastewater or water analytical laboratory work, the results of which are reported to the agency to determine compliance with a national pollutant discharge elimination system (NPDES) or state disposal system (SDS) permit condition or other regulatory document, must be certified according to this section.

(b) This section does not apply to:

(1) laboratories that are private and for-profit;

(2) laboratories that perform drinking water analyses; or

(3) laboratories that perform remediation program analyses, such as Superfund or petroleum analytical work.

(c) Until adoption of rules under subdivision 2, laboratories required to be certified under this section that submit data to the agency must: (1) register with the agency by submitting registration information required by the agency; or (2) be certified or accredited by a recognized authority, such as the commissioner of health under sections 144.97 to 144.99, for the analytical methods required by the agency.

*Subd. 2.**Rules.***

The agency may adopt rules to govern certification of laboratories according to this section. Notwithstanding section 16A.1283, the agency may adopt rules establishing fees.

*Subd. 3.**Fees.***

(a) Until the agency adopts a rule establishing fees for certification, the agency shall collect fees from laboratories registering with the agency, but not accredited by the commissioner of health under sections 144.97 to 144.99, in amounts necessary to cover the reasonable costs of the certification program, including reviewing applications, issuing certifications, and conducting audits and compliance assistance.

(b) Fees under this section must be based on the number, type, and complexity of analytical methods that laboratories are certified to perform.

(c) Revenue from fees charged by the agency for certification shall be credited to the environmental fund.

*Subd. 4.**Enforcement.***

(a) The commissioner may deny, suspend, or revoke wastewater laboratory certification for, but is not limited to, any of the following reasons: fraud, failure to follow applicable requirements, failure to respond to documented deficiencies or complete corrective actions necessary to address deficiencies, failure to pay certification fees, or other violations of federal or state law.

(b) This section and the rules adopted under it may be enforced by any means provided in section 115.071.

Under this statute, the MPCA has the necessary authority to adopt the proposed laboratory certification requirements and fees into *Minnesota rules*.

5. Reasonableness of the rules

A. General reasonableness

The reasonableness portion of the SONAR provides the discussion of the MPCA's basis for the proposed rules. The proposed rules are generally reasonable because they are based on:

- The MPCA's experience implementing the certification program since 2013;
- A review of the MDH rules that govern a similar certification program;
- The fact that the certification program was requested by and tailored specifically to wastewater laboratories;
- MPCA's programs that issue permits and perform inspections on wastewater facilities;
- The federal regulatory programs, which provide the analytical procedures and methods that are being incorporated by reference.

The proposed amendments provide a reasonable balance between the need to establish clear and concise laboratory procedures and the understanding that analytical methods are complex and continue to evolve, therefore the rules must incorporate methods as they are kept up to date.

Structure of the proposed rules

The proposed rules first establish the scope of regulated entities, which corresponds to the statutory authority granted in *Minn. Stat.* § 115.84. Throughout the proposed rules the MPCA imposes conditions on a "certified laboratory." Because the purpose of the rules is to provide a simpler certification program for laboratories that provide information to the MPCA programs, the proposed rules only apply to a specific sector of laboratories and are not applicable to any laboratories outside of that scope. A laboratory that is excluded under the scope is not subject to any of the requirements of the proposed rules, although they may be a certified laboratory through certification granted under an authority other than the MPCA. Nothing in the proposed rules prevent laboratories certified through an authority other than the MPCA from submitting analytical data to the MPCA to fulfill NPDES or SDS permit requirements. It is also important to emphasize that none of the requirements of the proposed rules apply to laboratories that are certified through other certification programs, the requirements of the proposed rules are alternative, not cumulative, and only apply to those entities that choose to participate in the MPCA's certification program.

After establishing the scope, the proposed rules then define the terms used throughout the rules. The specific reasonableness of each of the definitions is provided in Section B of this part.

In the scope, the MPCA identifies the types of laboratories that are eligible to participate in the MPCA's certification program and the types of laboratories that are not. In part 7001.4330 the MPCA establishes the requirement for certification.

Part 7001.4340 establishes the technical methods that a certified laboratory must use to generate data. Laboratory analysis is an extremely complex and technical operation and the proposed rules cannot reasonably establish all the procedures and processes that apply to all possible analytical methods. The rules therefore incorporate the technical requirements, established in other documents, into the rule by reference.

Part 7001.4350 establishes a section of certification qualifications that every laboratory, regardless of size or the type of analyses it conducts, must meet to maintain certification. The certification qualifications relate to the operation of the laboratory and not to how the analytical processes conducted by the laboratory must be conducted.

Part 7001.4360 establishes the process for applying for certification. The type of application a facility must submit to obtain certification is significant because the fees charged for certification are based on the type of application. The MPCA must commit different levels of effort to the review of different types of applications. A laboratory's initial application will require the most significant review and the MPCA expects that subsequent reapplications will be much less complex. The proposed rules require specific information that must be submitted for an initial application. For a renewal application, the laboratory only needs to include information that has changed since the initial application was submitted. A third type of application, a revised application, anticipates that in some cases a laboratory will need to make changes in its methods after it has been initially certified. This may involve adding additional methods of analysis because the laboratory wants to expand number of methods it performs in-house or in response to new permit requirements. It is reasonable to expect that some laboratories will

need to add methods and it is reasonable to make a provision in the proposed rules to address that need.

Part 7001.4370 establishes the MPCA's process for granting certification. This part reasonably provides the regulated community with the necessary information about what will constitute a "certification."

Part 7001.4380 anticipates the situation where a laboratory chooses to voluntarily withdraw its application or discontinue certification. Although the MPCA does not expect this to be a frequent occurrence, it is reasonable to anticipate the possibility and establish requirements for a laboratory in this situation.

An essential part of the MPCA's evaluation of a laboratory's ability to generate valid data is the process of proficiency testing. Proficiency testing is an accepted industry practice and part 7001.4390 establishes the requirements relating to conducting proficiency testing and a process to address failed testing results.

Finally, Parts 7002.0400 to 7002.0430 establish the formula for calculating fees and for payment of the required fees.

Each part of the proposed rules addresses a piece of a reasonable administrative process that MPCA considers to be essential to conducting a certification program.

General

The authorizing statute establishes the scope of the certification program by specifically describing that the program is for laboratories that do testing *"the results of which are reported to the MPCA to determine compliance with NPDES and SDS permits or other regulatory document"*. The statutory directive regarding laboratories that submit data to fulfill NPDES or SDS permits is very clear and needs no further discussion. However, the phrase "or other regulatory document" requires further explanation. Based on its involvement with the drafting of the statute, the MPCA understands the statute to mean that participation in the MPCA's laboratory certification program is also available to laboratories that are not specifically associated with NPDES or SDS permits. The legislature intended that the option of participating in the MPCA's certification program extend to include laboratories that submit data in support of MPCA regulatory requirements or programs, such as Surface Water Assessment Grants and lake and stream ambient monitoring programs. Throughout the proposed rules, the MPCA makes repeated references to "permit or agency regulatory or program requirement" to recognize that laboratories may be certified to generate data for non-permit reasons. The phrase "agency regulatory or program requirement" includes the types of programs that are neither NPDES nor SDS permits but that meet the statutory intent that certification extend to laboratories that submit data to determine compliance with an "other regulatory document."

B. Specific reasonableness

1. 7001.4310 Scope

The statute authorizing the MPCA's laboratory certification program (*Minn. Stat.* § 115.84) establishes the scope of the program; proposed *Minn. R.* pt.7001.4310, subpart 1, simply identifies that statute as the applicability for these rules. It is reasonable to identify the scope established by the legislature regarding which types of laboratories are eligible to participate in the MPCA's certification program. Although there are as many as 1,100 NPDES/SDS permits in Minnesota, very few permittees operate their own laboratories and

fewer still will seek certification through the MPCA's certification program. Approximately 50 laboratories currently participate in the MPCA's certification program and the MPCA expects that number to remain essentially the same following adoption of the proposed rules.

Subpart 2 restates the statutory exclusion of certain types of laboratories from participation in the MPCA's certification program. The MPCA cannot extend the scope of the rules to apply beyond the statutory authority so it is reasonable to restrict certification to exclude the same types of laboratories as are excluded in the statute.

It is important to clarify that, for purposes of submitting data required by NPDES/SDS permits or for other MPCA programs, laboratories may be certified through programs other than the program established in these rules. The MPCA will accept data from laboratories that are certified through other programs than the MPCA's, such as the program operated by the MDH. Although it is possible that a laboratory may want to maintain dual certification through the MPCA and MDH programs, laboratories that are only certified through a non-MPCA program are not subject to the requirements established in these rules.

2. 7001.4320 Definitions

A number of new definitions are proposed to clarify words and terms used in the proposed requirements. Although most of these terms will be well known and understood by the laboratory community, it is reasonable to provide a clear understanding of the terms used throughout the rules to eliminate confusion regarding their application.

"Agency" is reasonably defined in the proposed rules to identify the entity that the Legislature authorized to operate the certification program.

"Analyte" is reasonably defined as meaning any of several substances, properties or organisms for which a laboratory regulated under these rules may be conducting analyses. Wastewater and water laboratories routinely test for chemical and physical properties, but also conduct analyses of specific biological components of the water or wastewater.

"Analyte group" is another aspect of analyte, as defined in subpart 1, that reflects the standard laboratory practice of analyzing more than one analyte by means of the same method.

"Certified laboratory" is defined by describing the requirements established in the proposed rules for laboratory operation and, also, the administrative steps a laboratory must fulfill to obtain certification and maintain good standing in regard to that certification. These components reasonably constitute the condition of being certified by the MPCA's laboratory certification program.

"Client" is reasonably defined to establish the MPCA's intent when the proposed rule refers to a certified laboratory's responsibilities to entities other than itself. The definition reasonably distinguishes between the laboratory and the client by stating that a client is an entity that has arranged with a laboratory to receive analyses to meet the requirements of an NPDES or SDS permit or MPCA program.

"Initial Application" is reasonably defined to distinguish it as one of three types of applications that may be submitted for certification. The proposed rules establish requirements that apply differently depending on the type of application being submitted. It is reasonable to provide this definition, as well as the definitions of renewal application and revised application to clearly identify what is meant.

"Laboratory" is a term used throughout the rules. For these rules, MPCA is providing a definition that is limited to the scope of the rules. The definition of laboratory for purposes of these rules is limited to laboratories that fit the statutory criteria for participation in the MPCA's certification program.

"Method" is a term in common usage at analytic laboratories. It is reasonably defined here in a manner limited to the way in which analytic laboratories use it. The definition is similar to the definition provided in the MDH laboratory certification rules (*Minn. R.* pt. 4740.2010).

"National pollutant discharge elimination system or NPDES" is reasonably defined by reference to the applicable sections of the federal Clean Water Act that establish the NPDES program.

"Parameter" is a term of use by laboratories and will be understood by the regulated community. The definition reasonably includes all of the categories of parameters the MPCA expects laboratories of the types of governed by the proposed rules to conduct.

"Proficiency test" is a term that is well understood by the laboratory community and the definition provides a reasonable explanation of the basic purpose of the test.

"Renewal application" is reasonably defined for the same reasons discussed for "initial application."

"Reporting Limit" is a term of use by laboratories and the proposed definition will be reasonably understood by the regulated community.

"Revised application" is reasonably defined for the same reasons discussed for "initial application."

"State disposal system or SDS" is not defined in either rule or statute and is reasonably defined for purposes of these rules by a description of the types of activities for which the MPCA issues SDS permits.

3. 7001.4330 Certification required

This part states that a laboratory must be certified specifically for the parameters or methods required by the permit or covered program for which it will be submitting data. This requirement addresses two concerns.

First, the requirement that the certification address specific parameters or methods reflects the fact that laboratories may conduct a wide range of analyses. A blanket certification cannot address all possible scenarios and all laboratories do not have the equipment, staff or need to conduct analyses for all parameters or methods. The certification is reasonably tied to specific parameters or methods and is not granted to the laboratory in general.

Secondly, the requirement clearly identifies that the laboratory must be certified for the specific parameters or methods that are required by the permit or agency program for which the laboratory is submitting data. An NPDES/SDS permit will contain very specific analytical requirements. It is reasonable for the MPCA to require assurance, in the form of a specific certification, that the laboratory is conducting the same analyses as are required to meet the conditions for which the data is required.

The last sentence in this part recognizes the fact that some permits allow the submission of certain data without requiring that the analysis be done by a certified laboratory. Permits may allow analysis of pH, temperature, dissolved oxygen, specific conductance, and total

residual oxidants to be conducted by facility staff without use of a certified laboratory. This part reasonably clarifies that where a permit or covered program provides an exemption from laboratory certification requirements for a parameter or method, no certification is required.

4. **7001.4340 Required methods**

This part establishes the sources of acceptable methods, procedures, sample collection and preservation procedures that a certified laboratory must use to conduct analyses. Three sources of laboratory procedures are cited and incorporated by reference in this part.

Subpart 1, item A requires that a laboratory must use the procedures that are specified in either the permit or by the MPCA program. Federal and state permits (NPDES/SDS) contain very specific information about the compounds and reporting limits required to meet effluent or monitoring limits. Federal regulations allow multiple methods for each parameter because there may be many ways to measure a specific compound in the environment. Laboratories choose a method that will allow them to have reporting limits that are equal to or lower than the limit specified by their permit or program. In the case of a permit that includes an arsenic limit, for example, a laboratory must choose a sufficiently sensitive method to measure arsenic at levels lower than the limit on its permit.

Subpart 1, item B establishes that the procedures in the documents identified in subparts 2 to 4 are the procedures that must be used by a certified laboratory. This is reasonable to clearly identify the acceptable procedures and identify the process to be allowed to use alternative procedures not specified.

Subpart 2 identifies the methods and test procedures for water and wastewater analyses. EPA adopted these water analytical procedures into the Code of Federal Regulations, title 40, Part 136. This subpart includes all future amendments to those regulations in the incorporation by reference. It is reasonable to incorporate the EPA-approved methods for use in Minnesota. Further, it is reasonable to adopt future amendments to ensure that the laboratories use the most current versions of the methods and will thereby remain consistent with the requirements of the federal water program. The federal rule promulgation process will provide the MPCA, the regulated community and the public with the opportunity to review and comment on future changes before they become effective through this rule.

Subpart 2 also provides a reference in the form of a web link to where the clean water program regulations incorporated by reference can be viewed. It is reasonable to provide access to the electronic version of these rules to ensure access to the most current version.

Subpart 3 identifies the methods and test procedures established under the federal program governing sewage sludge use and disposal. The test methods and procedures for water analyses, cited in subpart 2, do not establish procedures for all possible analyses that may be required to fulfill the requirements of all permits. In some cases a laboratory will need to comply with the additional procedures established in the federal biosolids regulations that govern sewage sludge. Subpart 3 identifies two sources of federal biosolids methods. One of them, the Code of Federal regulations, title 40, Part 503, is similar to the methods incorporated to address wastewater analyses. These federal methods are incorporated as amended, which is reasonable for the same reasons discussed above for the wastewater methods. The proposed rules also incorporate a federal document called "*Test Methods for Evaluating Solid waste: Physical/Chemical Methods, publication number*

SW-846" (SW-846). The procedures established in that document are published in a "phased" manner, which is different from the way in which other methods are published. Sewage sludge procedures in SW-846 are adopted and published at different states of completeness. A sewage sludge procedure may be published for limited application, but not yet be considered "final". Subpart 3 establishes that only those procedures in SW-846 that are "published as final" are incorporated by reference and therefore applicable to the MPCA's certification program. The proposed rule incorporates those "published as final" federal methods, including all future amendments to those methods. The MPCA believes it is reasonable to adopt the methods in SW-846 "as amended" to ensure that the laboratories will use the most current versions of the methods and will thereby remain consistent with the requirements of the federal program. The federal update process will provide the MPCA, the regulated community and the public with the opportunity to review and comment on future changes before the incorporation by reference becomes effective in this rule.

Subpart 3 also provides a reference in the form of a web link to where the federal biosolids regulations and SW-846 methods can be viewed. It is reasonable to provide access to the electronic version of these methods to ensure access to the most current version.

Subpart 4 identifies a manual developed by the MPCA as the acceptable source of laboratory procedures. The MPCA's Laboratory Certification Program Manual may be used when neither of the federal documents incorporated by reference in subparts 2 and 3 provides sufficient detail to satisfy the permit or agency program requirements. The MPCA's Laboratory Certification Program Manual is especially important for establishing the requirements for Quality Assurance/Quality Control, Standard Operating Procedures and recordkeeping requirements at certified laboratories. This document was developed with extensive input from the Laboratory Certification Steering Committee and has been used since the MPCA began its laboratory certification program in 2013. The MPCA's Laboratory Certification Program Manual is adopted by reference "as amended" because the MPCA reasonably expects that laboratory processes and the needs of the regulated community will continue to change. The MPCA considers that adopting the manual as amended is the most reasonable way to ensure that it remains current and relevant to the certified laboratory community. The MPCA's Laboratory Certification Program Manual is available online and the web link is provided in the rule to ensure that it is readily available.

5. **7001.4350 Certification qualifications**

Subpart 1 establishes the requirement that a certified laboratory must be staffed in a manner that will allow it to meet the requirements of the certification. Because laboratories will be certified for a broad range of procedures, it is reasonable to require that the level of staffing and staff ability meet the requirements of certification.

Subpart 1 also requires that a laboratory designate a contact person and provide contact information for that person. It is reasonable to require that this person be identified because the MPCA relies on being able to contact a specific individual with questions. It is also reasonable to require that the MPCA be notified of changes to that information. Although the MPCA expects that this information will be provided as soon as possible after a change, the MPCA considers that 30 days is the longest time that can reasonably be allowed for a laboratory to submit updated contact information.

Subpart 2 requires a facility to have a Quality System in place that meets the requirements in the MPCA's Laboratory Certification Program Manual, which is incorporated by reference

in Part 7001.4340. A Quality System is composed of three parts: QA/QC procedures, documentation of SOP and procedures for documenting data and maintaining laboratory records. A Quality System ensures that a laboratory will generate valid, reproducible data. Having a Quality System is an essential element for meeting that standard. The requirements for each of the components of a Quality System will vary according to the type of analyses being conducted by the laboratory. A laboratory that is certified for an extensive range of analyses and the use of sophisticated equipment will necessarily have a more complicated Quality System. The rule reasonably cites to the requirements of the MPCA's Laboratory Certification Manual to provide the details to ensure that a laboratory's Quality System will meet the minimum standards required for permits or regulatory programs.

Subpart 3 addresses access to premises and reasonably requires that the laboratory provide the agency with access to the laboratory facility and access to the information and records needed to determine compliance. Without access to premises, information and records, the MPCA cannot enforce the rule.

Subpart 4 establishes the requirements for maintaining and providing access to the records that document a laboratory's activities. A laboratory must maintain written records that describe its procedures for recording analytical results. Whether the records are maintained electronically or in paper form, the MPCA expects that they will be accessible and organized in a manner that allows for ready review. The requirements for record keeping are specified in the MPCA Laboratory Certification manual that is incorporated by reference in Part 7001.4340.

A laboratory that only conducts analyses for the facility with which it is associated must be able to provide the agency with records of the results of those analyses and how it obtained those results. For laboratories that conduct analyses for other entities, the rule requires that the records be made available to those clients as well as to the agency. It is reasonable to require a laboratory to document when, how, and what it has analyzed for any client for which it has conducted analyses. The rule also reasonably requires that laboratory records be made available to clients and to the agency. This is a broader requirement than the requirement in subpart 3 which requires that records be made available to the agency for purposes of inspection and evaluation.

Subpart 5 requires a laboratory to conduct proficiency testing and cites to the proposed rule part that establishes the proficiency testing requirements. Proficiency testing provides an essential assurance that a laboratory is generating accurate data. It is a standard industry practice that requires a laboratory to conduct a test analysis on an unknown sample obtained from a proficiency test sample vendor. The vendor knows the analyte or analytes in the sample and the amounts. The proposed rules require that proficiency testing must be done before certification is granted and repeated annually. The requirements that apply to proficiency testing are complicated and subpart 5 reasonably cites to the specific proficiency testing rule part for the details of what is required.

Subpart 6 addresses the situation in which a laboratory may need to send samples to a different laboratory for analysis. There may be a number of reasons for this to occur. A laboratory may have staff or equipment issues or may be required to submit data for which it does not have certification. It is acceptable for a laboratory to subcontract to another laboratory to obtain necessary data. However, the laboratory must ensure that the subcontracting laboratory is either certified through the MPCA's certification program or a similarly acceptable program. In the SONAR discussion of Part 7001.4310, (Scope) the MPCA

establishes that data obtained from laboratories certified through alternative certification programs can fulfill the conditions of MPCA permits and other programs.

Subpart 7 states that a laboratory is not allowed to report results for analyses for which its certification has either expired or been discontinued, suspended, or revoked. This is a reasonable corollary of the requirement in Part 7001.4330 that a laboratory must be certified to conduct the specific analyses required by the permit. A laboratory is not considered to be certified if its certification has expired, been discontinued, suspended, or revoked.

Subpart 8 requires that a laboratory must pay the fees required in Part 7002.0400 to 7002.0440. Payment of fees is required to obtain and maintain certification. A discussion of the reasonableness of the fees is provided in section 10 of Part 5 of this SONAR. A requirement that a fee be paid within 30 days of receiving the invoice is a reasonable expectation based on standard fiscal practices.

Subpart 9 requires a laboratory to respond to all written communications from the agency. The MPCA expects there will be a number of points of communication between the agency and the laboratory. These communications may be associated with proficiency testing or compliance issues. The requirement in subpart 9, establishing the expectation that the laboratory will respond to all written communications from the agency, is reasonable to ensure ongoing communication and timely resolution of issues between the agency and the laboratory.

6. 7001.4360 Application for certification

This part establishes the requirements for submitting an application to the agency to obtain an initial, renewal or revised laboratory certification.

Subpart 1 establishes requirements that apply to the contents of initial and renewal certifications. Item A requires the applicant to provide basic information on a form provided by the agency. It is reasonable to request this information in a standard format to facilitate review and for purposes of comparing initial information to the information submitted in renewal and revised applications. The required information is fundamental to adequately identifying the applicant and the facility. Subitem 5 requires that the application be signed by a managing agent of the laboratory and that the signature be notarized.

Item B requires the applicant to identify all the parameters and methods for which it is applying for certification. A certification is specific to the parameters and methods approved so it is reasonable that the applicant identify the specific parameters and methods for which certification is being sought. Item B also requires that an application must include at least one parameter or method in an application. This is a reasonable requirement because the MPCA's certifications are method-specific. In addition, the MPCA will not issue certification to an "empty" laboratory that is not actually functioning and producing data for a permit or program.

Item C requires the information necessary to determine that the laboratory has a system to ensure the quality of its results. Item D requires submittal of information about SOP for each parameter or method for which certification is requested. The MPCA reasonably requires information about both of these aspects of laboratory management in order to make a determination that the laboratory can meet the requirements of a Quality System as required in 7001.4350, subpart 2.

For both the QA/QC manual required in item C and SOP manual required in item D, it is reasonable to require that both manuals meet the standards established in the MPCA Laboratory Certification Program Manual, which is incorporated by reference in Part 7001.4340. Other documents relating to laboratory procedures are incorporated by reference in 7001.4340 (Clean Water methods and biosolid methods) but neither of them provide QA/QC and SOP standards. Because it is essential that the agency evaluate a laboratory's QA/QC and SOP procedures as part of the application review, it is reasonable to refer to the MPCA Laboratory Certification Program Manual that establishes current and comprehensive criteria for what constitutes acceptable programs.

For both the QA/QC manual in item C and SOP manual in item D, the MPCA reasonably states that for purposes of renewal applications, the applicant only needs to submit a revised manual if it is different from the one submitted for the current certification. If the manual has not been revised, there is no need to re-submit the same manual that was submitted for the initial application.

Item E requires the applicant to submit the results of proficiency testing. Routine proficiency testing is part of an ongoing process of ensuring laboratory function, and the details of proficiency testing are further discussed in this SONAR under the discussion of the requirements of Part 7001.4390. The requirement of item E clarifies the fact that in the case of an initial application, the results of proficiency testing must be provided as part of the application. In the case of a laboratory that is already certified, proficiency testing would have been conducted during the current certification year.

It is reasonable to require proficiency testing as part of an initial application because it will be the basis of the agency's determination that a laboratory can produce consistent and reliable data. Item E requires that the results of proficiency testing be completed within 12 months prior to the date of application. It is reasonable to allow a window of time for a laboratory to conduct their proficiency testing, but it is also reasonable to ensure that the proficiency testing is current and reflective of the actual conditions that exist at the laboratory at the time it applies for certification. The MPCA considers that a 12 month window is reasonable because it is an accepted industry standard for ensuring laboratory quality and it also corresponds to the proficiency testing that is required for renewal or revised applications.

Item F requires submittal of a list of the laboratory's detection limits and reporting limits. As with the requirements for proficiency testing, this information is reasonably required to ensure that the laboratory can generate valid data for the parameters for which it will be certified. This information is only required for initial applications because if a laboratory is only applying for renewal without making any significant change to the procedures or equipment, the detection limits will not change.

Item G allows the agency to require an applicant to provide additional information as needed to determine compliance with the requirements of the proposed rules. This is a reasonable allowance to accommodate the fact that many laboratories and laboratory operations are unique and that the rules cannot anticipate every situation. The MPCA considers that because participation in the MPCA certification program is optional, no laboratory will be subject to unreasonable agency discretion in the application of this requirement. It is in the best interest of the laboratory seeking certification to provide the information that will allow the agency to correctly evaluate the ability of the laboratory to meet certification conditions.

Subpart 2 requires that laboratories at different locations must submit separate certification applications. This is a reasonable requirement to reflect the fact that laboratories at different locations, even if under common control, are separate entities with different capabilities. Application information cannot be generalized over a number of locations.

Subpart 3 requires that the agency be notified if a laboratory changes location. It is possible that a laboratory, especially a simple laboratory, may be moved to a different location. The agency is required to conduct periodic on-site evaluations of the laboratory and it is reasonable that the agency have current information about the location of the laboratory. Because the location of the laboratory is important for the completion of compliance inspections, it is reasonable to require that this information be provided at least 30 days before the laboratory changes location.

Subpart 4 establishes the time frame for submittal of certification applications. Item A allows the submittal of initial or revised applications at any time. This is reasonable because a laboratory cannot be expected to wait for the November application window if it is just starting operation or if it is making a significant change to an aspect of its certification. In these cases, a laboratory is allowed to submit its revised application at any time for the agency's review.

Item B requires that all renewal applications must be submitted during the month of November. It is reasonable to establish a specific application period so that the MPCA will be able to focus the necessary effort to grant certification effective January 1st. The laboratories that are currently participating in the MPCA's certification program are aware of the annual renewal cycle and this requirement will not be unexpected. Applications that are submitted earlier than November 1st will be returned to the applicant with a suggestion that when they re-apply in November, they verify that the information is correct and current as of the November re-submittal date. Item B provides clarification that a laboratory that submits a late application is not assured of being recertified by the December 31st expiration of its current certification. Although the MPCA is committed to issuing renewal certifications in a timely manner so as not to not disrupt laboratory functions, in the case of late submittal of renewal applications, this may not be possible.

Subpart 5 identifies additional conditions that require the submittal of an initial application.

Item A addresses a laboratory that has not been previously certified. The need for this type of facility to submit an initial application is evident.

Item B states that an initial application is required for a laboratory that has had its certification revoked in total. This is a reasonable response to a compliance issue serious enough to result in revocation of certification. The MPCA expects that a laboratory that has had its certification revoked in total will need to make significant changes to its operation. The type of information required to verify that a laboratory has returned to full compliance and operating correctly is more similar to what is required for an initial application than a renewal application. The MPCA's review effort will be correspondingly more complex. The MPCA is not requiring an initial application from a laboratory that has had its certification revoked in part. A laboratory that is seeking certification for those parameters or methods for which certification has been partially revoked, may reapply for certification for those parameters in the course of its normal renewal application.

Item C states that a laboratory that has let their certification expire for more than one year must submit an initial application. After a year of inactivity, it is reasonable to assume that a

laboratory must make significant changes to its application information and this information is equivalent to that required of an initial application rather than a renewal.

Item D states that a laboratory that has allowed its application to remain incomplete for more than one year must re-apply as an initial applicant. Applying for certification is a complicated process and the MPCA expects that some applications will be missing certain information. The MPCA will work with the applicant to identify the information required, but it is reasonable to establish a time limit after which the MPCA will consider the application to be too out of date to continue the review process. An applicant that cannot complete the application within one year is reasonably required to begin the process from the start with an initial application.

Subpart 6 establishes the requirements that apply to a laboratory that is already certified but is seeking to significantly revise that certification in a way that cannot be addressed through a simple renewal. Laboratory certification is specific to the parameters and methods approved in its certification and the agency must review and approve changes to parameters and methods.

Subpart 7 establishes certain conditions for reapplication that apply to laboratories that are involved in an active enforcement action or that have had their certification suspended or revoked. In these cases, the laboratory must wait to seek or renew certification until the enforcement issue is resolved. This is a reasonable condition because the outcome of the enforcement action could affect recertification and the condition will ensure that the laboratory is able to meet the conditions of certification.

Subpart 8 addresses situations where a laboratory may need to request to use an alternative test method. The MPCA expects that in most cases, the documents incorporated by reference in Part 7001. 4340 will address the methods and procedures required by permits or agency programs. However, it is reasonable to anticipate that there may be situations where a particular requirement is not addressed. Subpart 8 allows a laboratory to request approval of an alternative method and directs the laboratory to the process for submitting the request to the agency. The process for approving alternative methods, as established in the document incorporated by reference, is based on EPA protocols for the approval of alternative methods. The EPA requires that MPCA review alternative methods and make recommendations for their acceptance to EPA Region 5. The document that establishes the process is incorporated by reference in this part. Subpart 8 provides a web link to the document that identifies the administrative process a laboratory must use to obtain approval for the use of an alternative method. The cited web link provides step by step directions for preparing and submitting a request to the MPCA to use an alternative method and will remain accessible on the MPCA's website.

7. **7001.4370 Granting certification**

Subpart 1 establishes the term of certification. Certification is valid through December 31 unless it is suspended, revoked or voluntarily discontinued. In the case of a renewal application, the MPCA expects that renewed certifications will become effective on January 1. This maximum term of one year is the same length of certification that the MPCA has used in implementing the program since 2013 and the same term used by MDH in its certification program. The MPCA believes it is very important to issue certifications on a regular schedule and to continue the practice that certifications must be renewed at the same time every year. One year is a reasonable time for a laboratory to operate before

requiring renewal and ensures that laboratory practices and procedures are regularly reviewed. In some cases, the certification will be for a term of less than one year, such as a laboratory that submits an initial or revision application at mid-year, or a renewal applicant that fails to submit an application within the November application window. In these cases the certification effective date may be later than January 1 and the term of the certification will be valid for less than one year. The MPCA believes it is reasonable to require standardization of the expiration date of laboratory certification and this is an established expectation of the currently certified laboratory community.

Subpart 2 establishes conditions relating to the certification documents, which laboratories will consider their "certificate". The document the MPCA issues upon approving certification is intended to provide tangible evidence of the certification status of the laboratory. Subpart 2 imposes reasonable conditions on the laboratory regarding the use or misuse of the document.

Subpart 3 provides a disclaimer of the limits of the MPCA's certification. The MPCA issues the certification based on the information provided by the laboratory and the MPCA's evaluation and oversight. However, subpart 3 clarifies that the possession of certification does not guarantee that the laboratory will produce valid data and does not in itself provide assurance to any client of the laboratory that the laboratory is operating as certified. This is a reasonable clarification of the scope of the certification and its associated responsibilities.

8. **7001.4380 Voluntary withdrawal or discontinuation of certification.**

The MPCA's reasonably expects that there will be circumstances under which a laboratory will voluntarily discontinue certification. This may occur when permit requirements change or when it becomes apparent that the responsibilities of maintaining certification cannot be met. A laboratory may also initially apply for certification but decide to withdraw its application before certification is granted.

Subpart 1 requires a laboratory to provide written notification to the agency 30 days in advance of when it intends discontinued operations or withdraw its application for certification. A laboratory may choose to withdraw certification for only some parameters or methods, while maintaining certification for others. Therefore, this is a reasonable requirement to initiate the process of terminating the certification and ensure that both the MPCA and the laboratory are informed about the certification status of the laboratory.

Subpart 2 requires the laboratory to stop reporting results effective on the date that certification is discontinued. This is reasonable because, in the case of a voluntary discontinuation, there will be no need to grant a period of negotiation or corrective action in order to resolve differences as there may be in the case of suspension due to a compliance issue. Part 7001.4330 requires that a laboratory must be certified to submit data; a laboratory that discontinues its certification no longer meets that requirement. The rule specifies that a laboratory may not report data for compliance reporting or any other MPCA program for all parameters and methods affected by the discontinuation of certification. It is possible that a laboratory will discontinue its certification for certain parameters or methods but can continue to report data for other parameters or methods or reporting for purposes not covered by these rules.

In some cases, a laboratory may provide analytical services to entities other than itself. In these cases, subpart 3 requires the laboratory that has discontinued its certification to provide notice to its client laboratories that it is no longer certified. It is reasonable that the

MPCA also be informed when the notification is provided to the clients so that the MPCA can be assured that the clients, who will in most cases be MPCA permittees or MPCA programs, know that the laboratory is no longer certified.

The MPCA charges fees to cover the costs of reviewing applications and conducting laboratory evaluations. A laboratory that withdraws or discontinues its certification has already caused the MPCA to expend staff time on its certification. It is reasonable that a laboratory cannot be refunded the fees it has paid for the services that the MPCA has already provided. Subpart 4 establishes that the MPCA will not refund the fees paid by a laboratory when the laboratory voluntarily withdraws or discontinues certification.

Subpart 5 addresses how a laboratory would apply for recertification following a voluntary discontinuation. It is the MPCA's intent that a laboratory can re-apply for certification at any time and resume operation as soon as the application is completed and the certification is granted. It is reasonable that the rules facilitate the return of a laboratory to certified status as soon as possible. The only difference addressed in the rule is that if the certification has been discontinued for more than year, it is reasonable to assume that there have been so many changes to the original certification application that submittal of an initial application is most appropriate. A laboratory that re-applies for certification within a short time frame after discontinuing certification can reasonably be expected to be able to demonstrate its ability to be recertified through a revised application.

9. 7001.4390 Proficiency testing

This part requires a laboratory to provide evidence that it is capable of conducting the analyses for which it is certified or has applied to be certified. Proficiency testing is an accepted practice of laboratories and the process will be familiar to all laboratories seeking MPCA certification. The proposed requirements for proficiency testing are based on commonly accepted industry practices which require that a laboratory provide proficiency test results at the time of initial and renewal of certification for all the parameters for which it is certified.

A proficiency test consists of a laboratory obtaining a sample from a provider that contains an unknown quantity of a parameter or analyte. The laboratory then runs its usual analyses on that sample, and reports those results to the provider of the sample. The provider then reports whether the laboratory has correctly analyzed the sample. There are a number of specific conditions associated with proficiency testing such as time limits, repeating analyses and maintaining sample anonymity, but the process is essentially a system to verify that a laboratory is generating accurate data.

Subpart 1, item A establishes the requirement that a laboratory must successfully complete one proficiency test for each parameter or method for which it is applying to be certified. The effect of this requirement, though phrased in terms of the certification application process, is that a certified laboratory must conduct proficiency testing at least once a year for every parameter and method for which it is certified to generate data. The last sentence in item A recognizes that for some parameters and methods, no vendor provides the samples necessary to conduct proficiency testing and reasonably provides an exemption from all the proficiency testing requirements for those analytes for which no sample is available.

Item B states that the results of the proficiency testing must be submitted as part of the laboratory's application. The results of proficiency testing is required in Part 7001.4360 to be included as part of initial and revised applications for certification.

Item C allows a laboratory that has conducted proficiency testing to fulfill the requirements of the MPCA's Discharge Monitoring Report Quality Assurance program to use the same proficiency test results to meet the requirements for certification. The MPCA believes it is reasonable to allow results that show that the laboratory is functioning correctly to be submitted to meet more than one program requirement.

Subpart 2 establishes the requirements that apply to a laboratory as they conduct the proficiency test. Items A to D are standard industry practices that ensure that proficiency testing accurately characterizes the operation of the laboratory and that the results of the tests are valid and representative of the data the laboratory generates.

Subpart 3 requires the laboratory to submit the results of its proficiency testing to the agency within 30 days of the laboratory receiving the results from the provider. Proficiency test results must be included with the laboratory's application, whether it is an initial or revised application, but in the case of a laboratory that is already certified, the MPCA expects that the results will be submitted during the operating year as well as with the laboratory's renewal application. It is reasonable that the MPCA receive the results of proficiency testing as soon as they are available to provide the assurance that the laboratory is operating correctly. It is not reasonable for a laboratory to hold the results until a renewal application is submitted in November.

Item C provides the laboratory with the option of either providing the results to the MPCA or authorizing the provider to submit the results to the agency. The MPCA believes that either source will provide a reasonably prompt and accurate report of the results. The MPCA intends that if the laboratory submits the results itself, it submit the information as received directly from the provider and do not incorporate the results into a report or document of its own. It is important that the agency receive the provider's results in the same format as they are received from the provider to ensure accurate reporting.

Item D does not allow a laboratory to submit proficiency test data that is generated after the closing date of the sample period. For many analytical processes, such as biological parameters, samples have an expiration date after which results will not be valid. To successfully complete the proficiency tests, the laboratory must complete the process within the specified times.

Subpart 4 establishes restrictions that ensure that proficiency testing samples remain unknown and that the results of the testing remain confidential. These are reasonable restrictions to ensure that the analyses are conducted on blind samples and accurately reflect the capabilities of the laboratory.

Subpart 5 establishes additional restrictions and provisions for the conduct of the proficiency test. Item A clarifies that a laboratory must pass the proficiency testing *required by the provider* for each parameter or method for which it reports data. This is similar to the requirement of subpart 1, item A which requires that the laboratory must successfully complete proficiency testing. Item A of subpart 5 adds the requirement that passing the proficiency test is based on meeting the conditions established by the provider. The MPCA does not attempt in these rules to establish all the conditions relating to proficiency testing

for all parameters and methods. Those details are reasonably left to the provider of the proficiency test samples.

Item B allows a laboratory to use one proficiency test sample for multiple methods. Proficiency test samples are an expense to a laboratory and it is reasonable to allow savings where the use of multiple samples does not impair the results obtained.

Item C prohibits a laboratory from trying to affect the results that the provider will report. This is a reasonable prohibition to protect the integrity of the testing protocol.

Subpart 6 The operation of a laboratory is complicated and it is possible that a laboratory may fail proficiency testing. Subpart 6 establishes a protocol for conducting follow up proficiency tests. Subpart 6 reasonably allows a laboratory to address the reason for the failure and conduct repeated proficiency tests until the laboratory's procedures demonstrate its ability to competently conduct specific test methods.

10. 7002.0400 to 7002.0430 Fees applicable to certified laboratories.

Minnesota Rule (Minn. R.) pts. 7002.0400 to 7002.0430 establish the requirements for the fees the MPCA will charge to certified laboratories. The authorizing statute (*Minn. Stat.* § 115.84) allows the MPCA to collect fees from certified laboratories *"in amounts necessary to cover the reasonable costs of the certification program, including reviewing applications, issuing certifications, and conducting audits and compliance assistance.* In addition, the statute requires that the fees the MPCA collects must be based on the *"number, type, and complexity of analytical methods that laboratories are certified to perform."* The final condition of the statute is that *"revenue from fees charged by the agency for certification shall be credited to the environmental fund."*

In Parts 7002.0400 to 7002.0430 the MPCA reasonably meets the legislative directive by establishing a process that will generate the amounts necessary to conduct the certification program. The critical element of the proposed fee rules is the fee formula established in Part 7002.0420. This part establishes the factors that will determine what a laboratory will pay for certification. One of these factors is the fee target. The fee target is the actual amount it costs the MPCA to administer the certification program from the previous year. The amount available to the MPCA to conduct the program is established by the legislature in the budget process. In FY15, the MPCA budget was $105,000, which, being the previous year's expenses, is the fee target for the fees assessed in 2015.

The fee is based upon a point system where methods that are more difficult and require additional MPCA review and quality assurance work have a higher point value assigned than a more straight forward method of analysis. For example running volatile organics by gas chromatography and mass spectrometer (valued at 4 points) is more complex than a total nitrogen test (valued at 1 point). The MPCA expects that each laboratory will apply for a number of methods with an application. A laboratory will receive a total number of points based upon the analyses for which the laboratory requests certification. The total amount needed for the MPCA to run the program (the fee target) is divided by the total points for all applying laboratories and this determines the cost the MPCA will charge per point.

The proposed formula is as follows:

$ per point = T/ B, where:
$ per point = dollar amount applied to points.
T = fee target, last year's actual cost to administer the program.
B = the sum of all points for all participating laboratories during the previous year.

The proposed rules reasonably provide fee reductions for laboratories adding a new method of analysis half way through calendar year to accommodate laboratories that have requirements added to permits or wish to add methods to keep more of their analytical work within their own laboratory.

The proposed rules specify that fees will not be refunded once the invoice has been sent. This is reasonable to ensure the MPCA is not required to refund fees if laboratories wish to change or drop certification after completing the application process. After a laboratory submits an application, work is performed by the MPCA to review the application, applicable methods, and quality assurance from the laboratory which reasonably requires reimbursement to ensure that the agency's costs are covered by the fees.

6. Regulatory analysis

This part addresses the requirements of Minn. Stat. § 14.131(a), which compel state agencies to address a number of questions in the SONAR.

A. Description of the classes of person who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

Participation in the MPCA's laboratory certification program is optional. Although all laboratories that submit data to the MPCA to meet permit conditions must be certified by an approved certification program, no laboratory is required to obtain certification through the MPCA's program. All laboratories eligible to be certified through the MPCA's program also have the option of seeking certification through the existing MDH laboratory certification program or through other private, state or national laboratory certification programs. Because the MPCA's proposed certification program and associated fees will be an alternative to existing certification programs, no entity will be required to bear any new costs associated with the certification.

Because of the statutory limits regarding eligibility for MPCA certification, there is a limited universe of potentially regulated laboratories. The laboratories eligible for participation in the proposed MPCA certification program only include laboratories associated with NPDES/SDS permitted wastewater dischargers, either municipal or industrial, and laboratories that conduct water analyses that are submitted to the MPCA for regulatory documents other than an NPDES/SDS permit. These water laboratories are usually operated in support of park, natural resources, or recreation organizations. All laboratories that are eligible to participate in the MPCA's certification program are currently required to be certified by an alternative organization and to pay the fees associated with their chosen certification program. At the time of developing this SONAR, 52 laboratories are certified through the MPCA's program and the MPCA expects that with the adoption of the proposed rules, a similar number will continue to choose the MPCA certification option.

The classes of persons that will bear the costs, in the form of the laboratory application costs and certification fees, will be the same persons who benefit from the proposed certification program. Those will be the laboratories that choose the option of being certified through this program in lieu of an alternative certification program. The MPCA expects that the MPCA's certification program will result in decreased certification costs as compared to current options.

B. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

The probable costs to the agency are identified in *Minn. Stat.* § 115.84 which states, at the point that the establishment of fees is discussed, that the agency is allowed to collect fees *"in amounts necessary to cover the reasonable costs of the certification program, including reviewing applications, issuing certifications, and conducting audits and compliance assistance."* Those costs are discussed in part 5, section B, 10 of this SONAR, which describes the reasonableness of the proposed fee formula. The MPCA has conducted certification activities since 2013 and has charged fees as provided in the statute. The MPCA does not expect that there will be any new cost to the MPCA as a result of the proposed rules other than those costs already accounted for in the proposed fee formula.

Minn. Stat. §115.84 requires that revenues generated by the fee program be credited to the environmental fund. The MPCA estimates that for 2014-2015 the fee program will generate annual revenue of approximately $ 96,000.

C. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

First, the MPCA does not consider that the development of an optional certification program is intrusive. A certification program and associated fees are by their nature intrusive in that they dictate conditions that must be met and the amounts that must be paid. However, the fact that the proposed certification process and fees are an optional alternative to other certification programs means that no entity will be required to seek MPCA certification or pay fees to the MPCA unless they so choose.

The MPCA has considered the steps that must be conducted to maintain laboratory quality assurance and quality control and determined that they are the minimum necessary to implement a valid certification program that will meet the expectations of the permit programs it is intended to support. Similarly, the MPCA has reviewed its administrative expenses to implement a certification program and determined that there are no less costly methods to meet the minimum level of review and oversight that ensures that the program is valid.

D. A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the Agency and the reasons why they were rejected in favor of the proposed rule.

The nature of laboratory operation provides little discretion about what constitutes acceptable laboratory procedures and protocols. In the areas of procedures, methodology, and QA/QC, no alternatives were considered. The required procedures, methodology and QA/QC are specified in facility permits and the MPCA must propose the technical requirements that are minimally necessary to provide valid data to meet those permit conditions. In developing the administrative requirements the MPCA carefully considered

numerous alternatives to best ensure that the administrative requirements were the minimum necessary to conduct a valid program. As part of this process the MPCA relied on its own experience in conducting a certification program since 2013.

An additional aspect of this question is whether the MPCA considered any alternatives to adopting rules in order to achieve the purpose of the proposed rules. The MPCA is authorized to implement a certification program without adopting rules and has done so, by the application of policy, since 2013. *Minn. Stat.* §115.84 only requires the MPCA to adopt rules if the MPCA determines that rules are necessary. The MPCA carefully considered whether the existing alternative, implementation of the program without rulemaking, would achieve the purpose of conducting an acceptable laboratory certification program. In Part 1, section B of this SONAR the MPCA discusses why the MPCA's certification program needs to be adopted into rules. The needs identified in that discussion are why the MPCA considered, but rejected the alternative of continuing to implement the program without adopting rules.

E. The probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals.

In considering the costs of the proposed rules, it is important to note that the costs of complying with the proposed rules must be considered in relation to the costs of obtaining certification through an alternative certification program. The proposed rules do not increase the operating costs of a laboratory because, regardless of whether it participates in the MPCA's certification program, in order to submit data to the MPCA every laboratory must:

1. conduct its analyses according to specific standards
2. be certified

The MPCA does not consider that the cost of running a laboratory in a manner that generates valid data is a cost that can legitimately be attributed to adoption of the proposed rules. In order to operate a laboratory that generates valid data, the correct analytical procedures must be followed and the laboratory must operate according to specific standards. These laboratory operational standards, which are incorporated into the rule by reference, will apply regardless of whether the proposed rules are adopted.

Similarly, a laboratory that is certified through a program other than the MPCA's certification program will also be required to pay costs associated with that alternative certification, including application fees, audit costs and the costs of documentation and recordkeeping. Laboratories already incur costs to operate and be certified; the proposed rules do not add to these costs. In fact, the adoption of this certification program will reduce some costs to laboratories.

The amount of fees charged to a laboratory will depend on the extent of the laboratory's operations and the status of the laboratory's certification. The proposed fee formula is based on the complexity of the laboratory and the type of certification application submitted. The costs are based on a multiplier that is applied to each parameter. In Part 5, section B, 10 of this SONAR, the MPCA provides a discussion of how the fee formula works; an estimate of the costs to a particular laboratory can be derived from that discussion. Once the fee formula is adopted, the actual fee charged to a laboratory may change from year to year by application of the base program variable. As the MPCA's costs to implement the program change, the base program variable will make adjustments to either increase or

decrease the rate at which each of the fee formula factors is multiplied. Applying the formula based on the base program variable established for 2015 will result in a range of fees, from $1,025 for a laboratory renewing certification for a few parameters to as much as $3,000 for a laboratory seeking initial certification for a broad range of parameters. The legislature establishes the budget for the laboratory certification and the fee formula reflects that budget.

F. The probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

There will be no cost associated with not adopting the proposed rules. If the proposed rules are not adopted, there will be no loss of revenue or change in the costs that regulated laboratories currently pay. Without rules, the laboratories that choose to participate in the MPCA's certification program will continue to obtain certification and pay fees under the MPCA's existing program. The MPCA expects that the costs and fees, based on the legislative appropriation for the MPCA's certification program, will be similar regardless of the adoption of these rules. Laboratories that choose to not participate in the MPCA's program have the option of being certified through the MDH or other accreditation programs.

There will be consequences though to not adopting the rules. *Minn. Stat.* §115.84 directs the MPCA to establish an alternative certification and fee program and the MPCA has addressed that mandate by implementing a certification program since 2013. The need to adopt rules to support that program is discussed in part 1 of this SONAR and not adopting the proposed rules will mean that those needs will not be met.

G. An assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

There is no federal counterpart to the proposed certification program. The MPCA has incorporated certain federal documents establishing laboratory procedures into the rule by reference, but federal regulations do not provide any corresponding certification process.

H. An assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.

> *Minn. Stat. § 14.131 defines "cumulative effect" as "the impact that results from incremental impact of the proposed rule in addition to the other rules, regardless of what state or federal agency has adopted the other rules. Cumulative effects can result from individually minor but collectively significant rules adopted over a period of time."*

In item A of this part the MPCA stated that there is no burden resulting from the proposed rules, because they are an optional alternative to already existing certification programs. Laboratories have the option of meeting either the MPCA's program conditions or the conditions of some other certification program; the programs are alternative, not cumulative. Similarly, in Item G, the MPCA stated that there is no federal certification program so that there is no cumulative effect of the proposed rules in relation to federal regulations.

7. Notice plan

Minn. Stat. § 14.131 requires that an agency include in its SONAR a description of its efforts to provide additional notification to people or classes of people who may be affected by the proposed rule, or explain why these efforts were not made.

The MPCA uses an e-mail self-subscription service, called GovDelivery, for interested and affected parties to register to receive rule-related notices. Upon request, U.S. Mail service of notifications is also available; for this rulemaking, no entities have requested to receive notice by U.S. Mail.

Required notice:

On October 6, 2014, the MPCA published notice requesting comments on planned rules to *Minn. R.* Chapters 7001 and 7002. The notice was placed on the MPCA's Public Notice webpage (http://www.pca.state.mn.us/iryp3c9) and the rule webpage (http://www.pca.state.mn.us/xwrhffa). No comments were received in response to this notice.

The MPCA intends to send the following notices when the Notice of Intent to Adopt Rules Without a Hearing and proposed rule language are published in the *State Register* for comment:

1. ***Minn. Stat.* § 14.14, subd. 1a.** On the date the Notice is published in the *State Register*, the MPCA intends to send an electronic notice with a hyperlink to electronic copies of the Notice, SONAR, and proposed rules to all parties who have registered with the MPCA for the purpose of receiving notice of rule proceedings and those entities who specifically requested to receive notice of this rule. If any parties within this group have requested non-electronic notice, they will receive copies of the Notice and the proposed rules in hard copy via U.S. Mail.
2. ***Minn. Stat.* § 14.131.** The MPCA will send a copy of the SONAR to the Legislative Reference Library when the Notice required under Minn. Stat. § 14.14, subd. 1a is sent.
3. ***Minn. Stat.* § 14.116.** The MPCA will send a cover letter to the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules, the Legislative Coordinating Commission, as required by *Minn. Stat.* § 14.116. The statute also requires, in addition to sending notice to affected/interested legislators, that if the mailing of the notice is within two years of the effective date of the law granting the agency authority to adopt the proposed rules, the agency must make reasonable efforts to send a copy of the notice and SONAR to all sitting House and Senate legislators who were chief authors of the bill granting the rulemaking. The MPCA will send the notice to those legislators because the bill authorizing this rulemaking was passed in 2013. The letter to legislative members will include a link to electronic copies of the Notice, proposed rules, and SONAR. This notice will be sent at least 33 days before the close of the public comment period.

The following notices are required under certain circumstances that do not apply to this rulemaking. These notices will not be sent:

1. ***Minn. Stat.* §14.111**. If the rule affects agricultural land, *Minn. Stat.* §14.111 requires an agency to provide a copy of the proposed rule changes to the Commissioner of Agriculture no later than 30 days before publication of the proposed rule in the *State Register*. These rules will not affect agricultural land or farming operations so notice of this rulemaking will not be sent to the Commissioner of Agriculture in advance of publication. Staff of the Department of Agriculture may have an individual interest in the rules and may have registered to receive

GovDelivery notice; if so, they will be notified through GovDelivery at the time the Notice is published.

2. ***Minn. Stat.* § 3.9223, subd. 4**. If the proposed rules have their primary effect on Chicano/Latino people, *Minn. Stat.* § 3.9223, subd. 4 requires an agency to give notice to the State Council on Affairs of Chicano/Latino People (CLAC) for review and recommendation at least five days before initial publication in the *State Register*. This rule is not expected to have a primary effect on Chicano/Latino people. CLAC will not be notified.
3. ***Minn. Stat.* § 115.44, subd. 7.** If the proposed rule adopts water quality standards, the MPCA must provide notice to every municipality that borders on or through which waters affected by the standard flow. The proposed rules do not adopt water quality standards so the MPCA does not intend to provide this notice.
4. ***Minn. Stat.* § 116.07, subd. 7(i)** requires notification of specific legislators of the adoption of rules that apply to feedlots or feedlot fees. This rule does not relate to feedlots or fees and no notice will be sent.

Additional Notice

The MPCA believes that public interest in this rulemaking will be limited to the owners and operators of the laboratories that will be affected by the proposed rules. Because of the very limited effect of the proposed rules, the MPCA does not intend to provide extensive additional notice or conduct a broad public outreach effort at the time the MPCA publishes a Notice of Intent to Adopt Rules Without a Public Hearing (Notice). Additional support for this decision is the fact that the MPCA is confident that all the persons and entities that are interested in or affected by laboratory certification have been actively engaged with the MPCA's certification program for the past year and have already registered to receive GovDelivery notices on this subject. The MPCA believes that by conducting the notifications described below it will have provided adequate additional notice appropriate to the effect of the proposed rules.

The MPCA's efforts to notify and inform potentially interested parties at the start of the rulemaking are discussed in Part 3 and form the basis for the MPCA's additional notice plan; the GovDelivery notification process. At the time of drafting this SONAR, approximately 1,200 individuals and organizations have registered their e-mail addresses for the purpose of receiving specific notice about laboratory certification. The MPCA's GovDelivery mailing lists meet the requirements of *Minn. Stat.* § 14.14, subd. 1a for maintaining a list of interested parties.

On the same day the Notice is published in the *State Register*, a copy of the Notice and proposed rules will be posted on the MPCA's public notice webpage at: http://www.pca.state.mn.us/yrwc6a9. The MPCA will also post the Notice, a "plain English" version of the Notice, the proposed rules, SONAR and exhibits on the webpage established specifically for this rulemaking http://www.pca.state.mn.us/xwrhffa. The Notice and supporting information will be posted on both these websites for the entire term of the public comment period.

This Additional Notice Plan, and its regular means of public notice, including the early development of an extensive GovDelivery mailing list, publication in the *State Register* and posting on the MPCA's webpages, will adequately provide additional notice of this rulemaking to persons interested in or regulated by the proposed rules.

8. Performance-based rules

Minnesota Stat. §14.002 requires state agencies, whenever feasible, to develop rules that are not overly prescriptive and inflexible but that emphasize achievement of the MPCA's regulatory objectives while allowing maximum flexibility to regulated parties and to the MPCA in meeting those objectives. Fundamentally, the MPCA considers that the proposed rules provide maximum flexibility by being optional. No laboratory is required to participate in the MPCA's certification program; a laboratory may choose to obtain accreditation through organizations other than the MPCA. Because a laboratory has discretion about whether to seek certification though the MPCA's program, the laboratory has complete flexibility about whether they will comply with the proposed requirements and pay the MPCA's proposed fees.

However, the MPCA has also considered how to provide regulatory flexibility while meeting regulatory objectives. For this rule the MPCA's regulatory objectives are:

- to establish a certification program that ensures the production of valid and reliable data; and
- to establish fees that cover the costs of implementing the certification program

The MPCA considers that it has met the first regulatory objective by clearly identifying the requirements that must be met for certification. Meeting that objective through providing flexible, performance based rules is difficult. The nature of laboratory work is very prescriptive, requiring compliance with extremely detailed procedures and rigorous adherence to quality protocols. The processes that ensure the production of valid data that meets quality protocols are extremely prescriptive and the MPCA does not believe a certification program can allow flexibility in those areas. However, the MPCA has allowed for a certain amount of flexibility in providing the opportunity to request the agency's approval of "alternative test methods" (Part 7001.4360, subp. 8).

9. Consideration of economic factors

In exercising its powers, the MPCA is required by identical provisions in *Minn. Stat.* § 116.07, subd. 6 and *Minn. Stat.* § 115.43, subd. 1 to give due consideration to:

> *...the establishment, maintenance, operation and expansion of business, commerce, trade, industry, traffic, and other economic factors and other material matters affecting the feasibility and practicability of any proposed action, including, but not limited to, the burden on a municipality of any tax which may result there from, and shall take or provide for such action as may be reasonable, feasible, and practical under the circumstances...*

The MPCA has given consideration to the economics relative to the proposed rules. The MPCA maintains, as discussed in Parts 6 and 12, that the rules do not impose an economic burden on any municipality or business.

Although there are costs associated with operating a laboratory to meet the requirements of the proposed rules, those costs are part of the existing requirement for being a certified laboratory in the state of Minnesota. The MPCA maintains that the proposed certification rules will result in a savings to laboratories and therefore have a positive economic effect on the affected laboratories. The proposed rules will reduce the amount of day to day paperwork, on-site auditor costs, and registration costs for the laboratory community when compared to the accreditation program currently operated by the MDH or American Association of Laboratory

Accreditation (A2LA). The following cost-related information was compiled by the MPCA to compare the costs of the MPCA's 2014 certification program against the MDH and A2LA certification program in the same year. The MPCA conducted the following economic analysis comparing administrative costs of the MPCA and MDH programs as they would apply to an example laboratory, in this case, a full service wastewater laboratory.

Fees	MPCA 2014	MDH 2013	MDH 2014 est	A2LA 1st yr	A2LA 2nd yr	A2LA 3rd yr.	A2LA 4th yr
Initial application				$800			
Base Fee	$900		$600	$1,300	$1,300	$1,300	$1,300
Billable Time		NA	NA	$4,350	$2,550	$4.350	NA
Sample Preparation		$200	$200				
Oil and Grease	$225	$200	$200	Included	Included	Included	Included
Ammonia as N	$225	Included	Included	Included	Included	Included	Included
Total Phenolics	$450	Included	Included	Included	Included	Included	Included
BOD	$225	Included	Included	Included	Included	Included	Included
COD	Included	Included	Included	Included	Included	Included	Included
TSS	Included	Included	Included	Included	Included	Included	Included
Chromium IV	$900	$500	$500	Included	Included	Included	Included
Sulfide	Included	Included	Included	Included	Included	Included	Included
Fecal Coliform	Included	$200	$200	Included	Included	Included	Included
Total	**$2,925**	**$1700[1]**	**$1,700[1]**	**$6,450[2]**	**$3,850[2]**	**$5,650[2]**	**$1,300**

[1] Does not include the cost of hiring a third party accreditor which varies based on the size and scope of the lab. If a lab chooses to become A2LA accredited as well as MDH accredited the cost can be approximately $1,300 to $6,400/year plus site specific auditor travel costs.

[2] Does not include travel costs paid by laboratory.

The MPCA calculated costs for the 52 wastewater facilities and found that nearly all facilities found a savings in using the MPCA laboratory certification program. This is mainly because the MPCA's program fee is designed to include the cost of an MPCA evaluation that would otherwise have to be paid by the laboratory for an outside audit. A laboratory certified through a program other than the MPCA would have to pay to hire an assessor every two years, which includes travel expenses in addition to paying a base accreditation fee (as all third party assessors are out of state requiring travel and lodging).

Additional savings should be realized with a reduction in laboratory staff time because, under the MPCA's certification program, the laboratories are no longer producing and maintaining paperwork required under the National Environmental Laboratory Accreditation Program (NELAP). The NELAP approach, which was adopted by MDH, was designed for production, for-profit laboratories and is not appropriate for wastewater laboratories supporting permit reporting or wastewater laboratories with a small workforce.

Additional cost savings have been realized in combining permitting activities and the laboratory certification program in the same agency. The combination of these two types of state programs

within the same state agency saves administrative costs and allows coordinated review and communication among MPCA permit staff and MPCA on - site inspectors, ensuring that the data generated by the laboratory meets permit requirements.

10. Consult with Minnesota Management and Budget on local government impact

As required by *Minn. Stat.* § 14.131, the MPCA will consult with the Commissioner of Minnesota Management and Budget to help evaluate the fiscal impact and fiscal benefits of the proposed rule on local government. The MPCA will do this by sending the Director of Minnesota Management and Budget copies of the documents that are sent to the Governor's office for review and approval. The documents will include the Governor's Office Proposed Rule and SONAR Form, the proposed rules, and the SONAR. The MPCA will receive the results of Management and Budget's review before publishing the Notice of Intent to Adopt Rules Without a Hearing. If a hearing is held, the MPCA will submit a copy of the cover correspondence and any response received from Management and Budget to the Office of Administrative Hearing or, if no hearing is held, with the documents it submits for Administrative Law Judge review.

11. Impact on local government ordinances and rules

Minn. Stat. § 14.128, subd. 1, requires an agency to determine whether a proposed rule will require a local government to adopt or amend any ordinances or other regulation in order to comply with the rule. The proposed rules will affect certain municipalities to the extent that they may operate a wastewater treatment facility that may seek certification through the proposed program. However, the MPCA does not anticipate any scenario where the proposed rules will create any need for a municipality to adopt or amend its ordinances or regulations.

12. Costs of complying for small business or city

Minn. Stat. § 14.127, subds. 1 and 2 require an agency to determine whether the cost of complying with a proposed rule in the first year after the rule takes effect will exceed $25,000 for any one business that has fewer than 50 full-time employees, or any one statutory or home rule charter city that has fewer than 10 full-time employees.

The MPCA does not expect the proposed rules to cost any small city or business more than $25,000 in the first year after the rule takes effect. The MPCA cites the following factors it considered in making this determination.

1. Participation in the certification program is optional and no municipality or industry is compelled to obtain certification through the MPCA's program. A small business or municipality that finds the cost of seeking MPCA certification to be prohibitive may choose not to participate and therefor incur no expense as a result of the proposed rules.
2. The expenses associated with operating a laboratory and obtaining certification program are considerable and in some cases could exceed $25,000. However, the MPCA does not consider that those fundamental operation and certification costs can be solely attributed to the proposed MPCA certification requirements and fees. In order to submit data that meets state and federal requirements, a laboratory must incur baseline costs to meet operating standards and also costs to maintain certification through an acceptable certification

program. The underlying cost of operating a laboratory, as well as obtaining and maintaining certification through any certification program, cannot be considered in relation to the statutory $25,000 threshold. The MPCA does not anticipate a scenario where any additional costs associated with meeting the requirements and fees of the MPCA's proposed certification program would amount to more than $25,000 to any entity in the first year after adoption of the proposed rules.

3. The MPCA does not expect that any of the municipalities or industries that operate a wastewater or water analytical laboratory that may seek MPCA certification, meet the statutory criteria of having fewer than 10 or 50 full time employees respectively. The investment in maintaining a certified laboratory is significant and the MPCA believes it is most likely that small businesses and municipalities that meet those limits would use the services of a commercial laboratory rather than maintaining their own certified laboratory. (Note: An exception to this would be small laboratories that may submit water analysis data for programs not associated with NPDES/SDS permits. In the MPCA's experience, these types of laboratories are operated by educational institutions or watershed districts that do not meet the statutory criteria of either a small business or small home rule or charter city. Regardless of their status as a small entity, the MPCA does not expect the rules to cost them more than $25,000 in the first year after adoption for the reasons cited in the prior items.)

13. Comparison to border and EPA Region V states

Minn. Stat. § 116.07 subd. 2 requires that for proposed rules adopting air quality, solid waste, hazardous waste, or water quality standards, the SONAR must include an assessment of any differences between the proposed rule and existing federal standards adopted under the Clean Air Act, title 42, section 7412(b)(2); Clean Water Act, United States Code, title 33, sections 1312(a) and 1313(c)(4); and the Resource Conservation and Recovery Act, United States Code, title 42, section 6921(b)(1); similar standards in states bordering Minnesota; and similar standards in states within the Environmental Protection Agency Region 5; and a specific analysis of the need and reasonableness of each difference.

The proposed rules are not air quality, solid waste, hazardous waste, or water quality standards and do not correspond in any way to the federal regulations cited in the statute so no comparison to similar standards in EPA Region V or states bordering Minnesota is relevant or necessary.

14. Authors, witnesses, and SONAR exhibits

A. Authors and witnesses

The MPCA expects that the proposed rules will be noncontroversial. In the event that a hearing is necessary, the MPCA anticipates having the listed authors testify as witnesses in support of the need for and reasonableness of the rules.

- Sandy McDonald (MPCA Staff) is the technical staff person working with the MPCA's laboratory certification program.
- Luke Charpentier(MPCA Staff) is the supervisor of the MPCA program that is responsible for the MPCA's laboratory certification program.
- Kathleen Winters(MPCA Staff) is General Counsel to the Minnesota Pollution Control Agency and will introduce the required jurisdictional documents into the record.
- Carol Nankivel (MPCA Staff) is the project rule coordinator and responsible for Minnesota Administrative Procedures Act requirements.

B. SONAR exhibits

Exhibit 1. MPCA Laboratory Certification Program Manual, dated December 1, 2014.
Exhibit 2. Alternative Test Methods, dated October 2014.

15. Conclusion

In this SONAR, the MPCA has established the need for and the reasonableness of the proposed rules being added to *Minn. R.* chs. 7001 and 7002. The MPCA has provided the necessary notifications and in this SONAR documented its compliance with all applicable administrative rulemaking requirements of Minnesota Statute and Rules.

Based on the foregoing, the proposed rules are both needed and reasonable.

12/12/2014
Date

John Linc Stine, Commissioner
Minnesota Pollution Control Agency

Minnesota Pollution Control Agency

Environmental Analysis and Outcomes Division

NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING

Proposed Amendment of Rules Governing Wastewater Laboratory Certification and Certification Fees, *Minnesota Rules*, 7001.4310, 7001.4320, 7001.4330, 7001.4340, 7001.4350, 7001.4360, 7001.4370, 7001.4380, 7001.4390, 7002.0400, 7001.0410, 7002.0420 and 7002.0430; Revisor's ID Number 0429.

Introduction. The Pollution Control Agency (MPCA) intends to adopt rules without a public hearing following the procedures in the rules of the Office of Administrative Hearings, *Minnesota Rules*, parts 1400.2300 to 1400.2310, and the Administrative Procedure Act, *Minnesota Statutes*, §§ 14.22 to 14.28. Until February 6, 2015 you may submit written comments on the proposed rules and may also submit a written request that a hearing be held on the rules.

MPCA Contact Person. You must submit comments or questions on the rules and written requests for a public hearing to the MPCA contact person. The contact person is Carol Nankivel, MPCA–RMAD, 520 Lafayette Road North, St. Paul, Minnesota 55155-4194; Telephone: 651-757-2597 or 1-800-657-3864; e-mail carol.nankivel@state.mn.us. TTY users may call the MPCA at 651-282-5332.

Subject of Rules and Statutory Authority. The MPCA is proposing new rules to govern the MPCA's wastewater laboratory certification program and to establish a formula for the calculation of fees applicable to laboratories certified by the MPCA. Participation in the MPCA's certification program is optional and limited to laboratories performing water or wastewater analytical work to determine compliance with National Pollutant Discharge Elimination System (NPDES)/State Disposal System (SDS) permits or in support of other regulatory documents issued by the MPCA.

The proposed amendments establish:

- The analytical procedures and protocols for operating a certified laboratory. The administrative requirements for obtaining and maintaining laboratory certification.
- The formula for calculating fees applicable to certified laboratories.

The statutory authority to adopt the rules is *Minnesota Statutes* §115.84. A copy of the proposed rules is published in the *State Register* and posted on the MPCA's website at http://www.pca.state.mn.us/xwrhffa.

Comments. You have until 4:30 p.m. on February 6, 2015, to submit written comment in support of or in opposition to the proposed rules and any part or subpart of the rules. Your comment must be in writing and the contact person must receive it by the due date. The MPCA encourages your comment. Your comment should identify the portion of the proposed rules addressed and the reason for the comment. You are encouraged to propose any change desired. You must also make any comment about the legality of the proposed rules during this comment period. All comments received will be part of the rulemaking record and will be reviewed by the Office of Administrative Hearings.

Request for a Hearing. In addition to submitting comments, you may also request that the MPCA hold a hearing on the proposed rules. Your request must be in writing and the MPCA contact person must receive it by 4:30 p.m. on February 6, 2015. Your written request for a public hearing must:

- Include your name and address.
- Identify the portion of the proposed rules that you object to or state that you oppose the entire set of rules.

Any request that does not comply with these requirements is not valid, and the MPCA cannot count it when determining whether a public hearing must be held. You are encouraged to state the reason for the request and any changes you want made to the proposed rules.

Withdrawal of Requests. If 25 or more parties submit a valid written request for a hearing, the MPCA will choose to seek the withdrawal of those requests, hold a hearing, or withdraw the rulemaking. If a sufficient number withdraw their requests in writing to reduce the number below 25, the MPCA must give written notice of this to all parties who requested a hearing, explain the actions the MPCA took to effect the withdrawal, and ask for written comments on this action. If a public hearing is held the MPCA will follow the procedures in *Minnesota Statutes*, §§ 14.131 to 14.20.

Alternative Format. Upon request, this information can be made available in an alternative format, such as large print, braille, or audio. To make such a request, please contact the contact person at the address or telephone number listed above.

Modifications. The MPCA may modify the proposed rules as a result of public comment. The modifications must be supported by comments and information submitted to the MPCA, and the adopted rules may not be substantially different from these proposed rules, unless the MPCA follows the procedure under *Minnesota Rules*, part 1400.2110. If the proposed rules affect you in any way, the MPCA encourages you to participate in the rulemaking process.

Statement of Need and Reasonableness. The statement of need and reasonableness contains a summary of the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. It is available for viewing at http://www.pca.state.mn.us/xwrhffa. You may also obtain copies from the MPCA contact person.

Lobbyist Registration. *Minnesota Statutes*, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. You should direct questions about this requirement to the Campaign Finance and Public Disclosure Board at: Suite 190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone 651-296-5148 or 1-800-657-3889.

Adoption and Review of Rules. If no hearing is required, the MPCA may adopt the rules after the end of the comment period. The MPCA will then submit the rules and supporting documents to the Office of Administrative Hearings for review for legality. You may ask to be notified of the date the MPCA submits the rules to the office. If you want to be so notified, or want to receive a copy of the adopted rule, submit your request to the MPCA contact person listed above. To register to receive notice of future rule proceedings, register at http://public.govdelivery.com/accounts/MNPCA/subscriber/new.

Order. I order that the rulemaking hearing be held at the date, time, and location listed above.

12/12/2014
Date

John Linc Stine, Commissioner
Minnesota Pollution Control Agency