4740.2070 PROFICIENCY TESTING REQUIREMENTS.

Subpart 1. **Use of approved providers.** A laboratory must obtain proficiency testing samples from an approved provider meeting the requirements under part 4740.2075.

Subp. 2. **Certification requirements.** At the time a laboratory applies for certification, the laboratory must provide an appropriate PT sample result for all fields of testing for which it seeks to obtain or maintain certification by the commissioner.

Subp. 3. **Frequency.** To be certified initially and to maintain certification, a laboratory must participate in at least one proficiency testing study per year, where available, for each field of testing for which it seeks to obtain or maintain certification.

Subp. 4. **Laboratory testing of PT study samples.**

A. A laboratory's management and all analysts must ensure that all PT samples are managed, analyzed, reported, and otherwise handled in the same manner as routine samples, including utilizing the same staff, procedures, equipment, facilities, and frequency of analysis as used for routine analysis for that field of testing.

B. When analyzing a PT sample, a laboratory must employ the same calibration, quality control, acceptance criteria, sequence of analytical steps, number of replicates, and other standard operating procedures as used when analyzing routine samples. The laboratory must follow sample preparation steps for the PT sample as instructed by the approved PT provider for which the PT sample was obtained.

Subp. 5. **Reporting results.**

A. A laboratory must ensure that results of all proficiency testing samples are received by the commissioner not later than 30 days after receiving the results from the approved provider.

B. A laboratory may supply results by authorizing the approved PT provider to release all certification and remediation results to the commissioner or by mailing a copy of the original results to the commissioner.

C. Proficiency testing samples analyzed or reported after the study closing date are not valid for compliance with the proficiency testing requirements under this part.

Subp. 6. **Restrictions on exchanging information.** A laboratory must comply with the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study are released:

A. laboratory management or staff must not communicate PT sample results with any individual at another laboratory, including intracompany communication; and

B. laboratory management or staff must not attempt to obtain the assigned value of any PT sample from an approved provider.

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Subp. 7. **Evaluation of results.**

A. A laboratory must demonstrate acceptable performance, as determined by the approved provider, for each field of testing reported.

B. A laboratory may use one PT sample to analyze and report results for multiple methods under multiple test categories.

C. A laboratory may not request from the PT provider a revised report when the revisions to the report are due to any error on the part of the laboratory.

D. For the purpose of initial or continuing certification, the commissioner shall deem unacceptable any reported results not meeting the criteria under this subpart.

Subp. 8. **PT samples to obtain or maintain certification.**

A. A laboratory seeking to obtain certification must successfully complete at least one proficiency testing sample for each requested field of testing no more than 12 months before the date the laboratory submits its application.

B. When a laboratory has been granted certification status, it must continue to complete proficiency testing studies for each field of testing and maintain a history of at least one acceptable evaluation for each field of testing out of the most recent two PT sample results submitted to the PT provider.

C. When a laboratory has attained certification and requests to add a field of testing to its scope of certification, the laboratory must submit acceptable proficiency testing results for that field of testing, analyzed no more than 12 months before the date the laboratory submits its application.

Subp. 9. **Corrective actions for unacceptable results.** When an approved provider notifies a laboratory that a PT sample result for any reported field of testing is unacceptable, the laboratory must:

A. within 30 days after receiving the notification of unacceptable results from the approved provider, submit written documentation to the commissioner indicating corrective actions planned and taken;

B. within 30 days after receiving the notification of unacceptable results from the approved provider, submit written documentation to the commissioner indicating the laboratory's request to purchase a PT sample from an approved provider; and

C. within 30 days after receiving the results of the PT sample under item B, supply a copy of the results to the commissioner.

Subp. 10. **Availability of PT samples.**

A. The commissioner must determine that a PT sample for a particular field of testing is not available if:

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(1) none of the approved providers lists the PT sample through published catalogs, websites, or other widely distributed literature; or

(2) none of the approved providers makes the PT sample available in a form similar to routine samples. For example, PT samples may be considered to be unavailable if the preparation instructions require the laboratory to perform pretreatment steps not normally associated with the requirements of the approved methods. In this context, dilution of the PT sample is not considered pretreatment.

B. If the commissioner determines that no approved provider has PT samples for a field of testing, the commissioner must request written documentation from the laboratory of quality control data meeting the minimum requirements under parts 4740.2010 to 4740.2120 to evaluate the capability of the laboratory to perform testing.

Subp. 11. **Additional samples for compliance.** The commissioner may require certified laboratories to test additional PT samples at any time to determine compliance with parts 4740.2010 to 4740.2120.

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