

7001.4390 PROFICIENCY TESTING.**Subpart 1. Requirements.**

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

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

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

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

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

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

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

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

Subp. 3. Reporting results.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) if the third proficiency test result is unacceptable, the laboratory may not provide analytical results for compliance reporting or any agency program for the parameters and methods for which the laboratory failed to demonstrate acceptable proficiency test results. The laboratory may resume providing analytical results when the laboratory passes two proficiency tests in a row. These proficiency tests must be conducted at least 15 days apart. The laboratory must submit a corrective action report to the agency within 30 days of passing the second of the two proficiency tests.

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

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

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