



ADMINISTRATIVE RULES OF MONTANA



37.12.320 PROFICIENCY TESTING

- (1) For a laboratory to become approved and to maintain approval for conducting analyses for an analyte or an interdependent analyte group by a specific method, the laboratory must, at its own expense, meet the proficiency testing requirements of this rule.
- (2) In order to initially obtain and to maintain approval, the laboratory must:
 - (a) whenever required by the EPA, enroll and participate in a proficiency testing program approved by the environmental laboratory for each analyte or interdependent analyte group, or, for each analyte or interdependent analyte group and method for which proficiency testing is not available or required, the laboratory must establish, maintain, and document the accuracy and reliability of its procedures through a quality assurance plan;
 - (b) successfully participate in at least two proficiency tests annually;
 - (c) prior to obtaining approval, notify the department of the authorized proficiency testing program or programs in which it has enrolled for each analyte or interdependent analyte group and method approved under its license to analyze;
 - (d) follow the proficiency testing provider's instructions for preparing the proficiency testing sample and must analyze the proficiency testing sample as if it were a client sample;
 - (e) direct the proficiency testing provider to send, either in hard copy or electronically, a copy of each evaluation of the laboratory's proficiency testing audit results to the department; and
 - (f) authorize the proficiency testing provider to release to the department all information necessary for the department to assess the laboratory's compliance with this rule.
- (3) In addition to the requirements of (2), in order to remain approved for testing an analyte or interdependent analyte group, a laboratory must:
 - (a) in each calendar year, successfully complete at least two separate proficiency testing audits for each analyte or interdependent analyte group and method;
 - (b) maintain a paper or electronic copy of all proficiency testing records, including analytical data and worksheets and a copy of the proficiency testing provider report forms authorized by the environmental laboratory and used by the laboratory to record proficiency testing results for a period of five years;
 - (c) for every proficiency test, ensure that the director of the laboratory signs and retains an attestation statement stating that the laboratory followed the proficiency sample provider's instructions for preparing the proficiency sample and analyzed the proficiency testing sample as if it were a client sample; and

- (d) analyze and report to the provider the results of the proficiency test by the deadline set by the proficiency testing provider.
- (4) A laboratory may not:
- (a) perform multiple analyses (such as replicates or duplicates) that are not normally performed in the course of analysis of a routine sample;
 - (b) average the results of multiple analyses for reporting when not specifically required to do so by the analytic method in question;
 - (c) permit anyone other than bona fide laboratory employees who perform the analyses on a day-to-day basis for the laboratory to participate in the generation of data or reporting of results;
 - (d) discuss the results of a proficiency testing audit with any other laboratory until after the deadline set for receipt of results by the proficiency testing provider;
 - (e) if the laboratory has multiple testing sites or separate locations, discuss the results of a proficiency testing audit across sites or locations until after the deadline set for receipt of results by the proficiency testing provider;
 - (f) send proficiency testing samples or portions of samples to another laboratory to be tested; or
 - (g) knowingly receive a proficiency testing sample from another laboratory for analysis and fail to notify the department of the receipt of the other laboratory's sample within five business days of discovery.
- (5) Results of proficiency tests must be within the control limits established by the EPA as specified in the EPA laboratory certification manual (EPA 815-R-05-004) "Manual for the Certification of Laboratories Analyzing Drinking Water," January 2005) for each analysis for which the laboratory requests approval.
- (a) Specific chemistry acceptance criteria are listed in Table IV-10. "MCL and Proficiency Testing Sample Acceptance Criteria in the CFR, Primary and Secondary Drinking Water Regulations" of the EPA laboratory certification manual.
 - (b) Specific microbiology acceptance criteria is correctly analyzing a minimum of nine of ten samples, with no false negative result (i.e., a single false positive result would be considered acceptable).
- (6) The department may require the testing of other samples, such as blind samples or split samples, as needed to evaluate laboratory performance.
- (7) The laboratory must participate in an authorized proficiency testing program for at least 12 months before changing to another proficiency testing provider for the analyte or interdependent analyte group, unless there are extenuating circumstances.
- (8) A laboratory must notify and have approval from the department before changing enrollment in an authorized proficiency testing program, and if the reason for changing providers is a result of extenuating circumstances, the laboratory must also delineate the reasons for the requested change.

- (9) The department adopts and incorporates by reference the acceptance limits for regulated parameters in chapter IV of the EPA laboratory certification manual (EPA 815-R-05-004, "Manual for the Certification of Laboratories Analyzing Drinking Water," January 2005), which contains the critical elements for chemistry that a laboratory must meet, including the acceptance limits required by the EPA for metals, inorganics, volatile organic compounds and synthetic organics in drinking water samples. A copy of chapter IV may be obtained from the Department of Public Health and Human Services, Laboratory Services Bureau, 1400 Broadway, Cogswell Building, P.O. Box 4369, Helena, MT 59604-4369, telephone (406)444-3444, or may be downloaded at the EPA web site: <https://www.epa.gov/dwlabcert/laboratory-certification-manual-drinking-water>.

Authorizing statute(s): 50-1-202, MCA

Implementing statute(s): 50-1-202, 75-6-106, MCA

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