



ADMINISTRATIVE RULES OF MONTANA



37.12.301 DEFINITIONS

For the purpose of this subchapter:

- (1) "Accuracy" means the degree of agreement between an observed value and an accepted reference value.
- (2) "Analyte" means the substance or thing for which a water sample is analyzed to determine its presence or quantity.
- (3) "Bachelor degree or equivalent" means a college degree with the equivalent of 30 semester hours in a biological or physical science program or at least four years of experience in a specific related scientific discipline.
- (4) "Certification officer" means a representative of the department who conducts assessments of laboratories to determine if they should be approved for licensure. The representative may be a third party contractor who acts under the authority of the department.
- (5) "Chemical hygiene plan" means a document written by a laboratory that describes the procedures used to store, handle, and dispose of chemicals in the laboratory.
- (6) "Conditional licensure" refers to a laboratory applying for a license for the first time that is in compliance with most requirements for licensure but has not yet met all of the requirements of this subchapter, but whose deficiencies do not affect the capability of the laboratory to perform valid analyses.
- (7) "Contaminated" means exceeding a maximum contaminant level established in ARM Title 17, chapter 38, subchapter 2.
- (8) "Department" means the Department of Public Health and Human Services.
- (9) "Environmental laboratory" means the environmental laboratory of the Department of Public Health and Human Services that is responsible for the licensing of laboratories performing drinking water analyses in Montana.
- (10) "Environmental Protection Agency (EPA)" means the United States Environmental Protection Agency.
- (11) "EPA laboratory certification manual" means the EPA publication entitled "Manual for the Certification of Laboratories Analyzing Drinking Water," January 2005, 5th edition (EPA 815-R-05-004).
- (12) "Holding time" means the maximum time that a sample may be held prior to preparation or analysis.

- (13) "Initial demonstration of analytical capability" means the procedure described in the method cited in 40 CFR part 136, appendix A, as amended August 28, 2017, for chemistry analysis, used to determine a laboratory's accuracy and precision in applying an analytical method.
- (14) "Interdependent analyte group" means a group of analytes, as determined by the department, for which the ability to correctly identify and quantify a single analyte in the group indicates the ability to correctly identify and quantify other analytes in the group.
- (15) "Interim licensure" refers to a status that may be granted by the certifying agency to a fully licensed laboratory without an on-site inspection for a particular analyte or interdependent analyte group if the certifying agency determines with appropriate documentation that the laboratory has the appropriate instrumentation, is using a previously approved method, has adequately trained personnel to perform the analyses, and has satisfactorily analyzed PT samples, if available for the analytes in question.
- (16) "Key personnel" means a laboratory's director, supervisor, and quality assurance officer, all of whom meet the requirements of the EPA laboratory certification manual.
- (17) "Method detection limit" means the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero as determined from analysis of a sample containing the analyte in a given matrix as described in 40 CFR part 136, appendix B, as amended August 28, 2017.
- (18) "Performance evaluation (PE) sample" means a sample obtained through a source approved by the environmental laboratory whose composition is unknown to the laboratory performing the analysis and which is used to evaluate the ability of the laboratory to produce precise and accurate results.
- (19) "Precision" means the degree to which a set of observations or measurements of the same property, usually obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.
- (20) "Proficiency testing (PT)" refers to testing an unknown sample to evaluate the ability of the laboratory to produce precise and accurate results and is used interchangeably with performance evaluation (PE).
- (21) "Provisional licensure" refers to the downgraded status of a laboratory previously holding full certification due to noted deficiencies, but in the opinion of the certifying agency the laboratory can still demonstrate their ability to consistently produce valid data.
- (22) "Quality assurance plan" means a document written by a laboratory that describes the procedures used to ensure that routinely generated analytical data are scientifically valid and that their precision and accuracy are within defined limits.
- (23) "Safe Drinking Water Act" means the federal law set out in 42 USC 300f through 300j-11, governing drinking water programs.
- (24) "Standard operating procedures (SOPs)" means a laboratory's written document which details the steps of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and is accepted by the laboratory as the procedure for performing certain routine or repetitive tasks.
- (25) "Variance" means written approval from the environmental laboratory allowing a laboratory to use a method, procedure, or equipment other than that required by these rules that meets the

purpose and intent of these rules and that has been shown to have no adverse material effects on the accuracy of analyses.

- (26) "Waiver" means written approval from the environmental laboratory exempting a laboratory from a requirement of these rules if the environmental laboratory finds that the requirement is inapplicable to the particular practice of that laboratory.

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

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

History: NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03; AMD, 2011 MAR p. 2286, Eff. 10/28/11; AMD, 2023 MAR p. 305, Eff. 3/25/23.