



ADMINISTRATIVE RULES OF MONTANA



37.12.305 PROCEDURE FOR LICENSURE

- (1) Any laboratory not currently licensed but desiring licensure under this subchapter must:
 - (a) submit a completed application to the Department of Public Health and Human Services, Laboratory Services Bureau, 1400 Broadway, Cogswell Building, P.O. Box 4369, Helena, MT 59604-4369, on forms provided by the department. The application must include:
 - (i) the legal name of the laboratory;
 - (ii) the name of the laboratory owner;
 - (iii) the laboratory mailing address;
 - (iv) the full address of the physical location of the laboratory;
 - (v) the laboratory hours of operation;
 - (vi) a description of qualifications of key personnel and technical employees;
 - (vii) the name and daytime phone number of the laboratory director;
 - (viii) the name and daytime phone number of the laboratory's quality assurance officer;
 - (ix) the name and daytime phone number of the laboratory contact person; and
 - (x) the laboratory's quality assurance plan and documentation of the laboratory's implementation and adherence to the quality assurance plan.
 - (b) be enrolled in a proficiency testing program;
 - (c) apply for approval to analyze at least one analyte or interdependent analyte group by a method the department approves under ARM 37.12.333;
 - (d) pay all applicable fees prescribed by ARM 37.12.310 prior to the department's processing of the application; and
 - (e) submit a statement of assurance of compliance signed and dated by the laboratory owner, director, and quality assurance officer, which shall include:
 - (i) an acknowledgment that the applicant understands that, once licensed, the laboratory must continually comply with the requirements for licensure in this subchapter in order to remain licensed;
 - (ii) an acknowledgment that the department may make unannounced inspections of the laboratory for the purpose of assessing compliance with these rules and that a refusal

to allow entry to the laboratory premises by the department's authorized representatives is grounds for denial or revocation of its license;

- (iii) a statement that the applicant laboratory will perform all proficiency testing audits according to acceptable methods, in accordance with department requirements, and at their own expense; and
 - (iv) a statement that there is no misrepresentation in the information provided in the application.
- (2) When the laboratory submits the documentation required by ARM 37.12.333, the department shall conduct an on-site assessment at a date and time agreed to by the laboratory director to determine whether the laboratory complies with the minimum requirements of this subchapter and that the laboratory can produce valid results.
- (3) At the time of scheduling the assessment, the department's certification officer shall specify what staff, equipment, and supplies need to be on hand during the evaluation and what tests need to be run in order to determine whether the laboratory can meet the licensure requirements set out in this subchapter.
- (4) If possible, the evaluations will be scheduled to occur within 45 days after the department determines the application is complete, except in the case of applications received in May, June, July, or August, which will be scheduled for evaluation no later than October 31 of the same year.
- (5) The certification officer shall provide the laboratory director with a written report of the department's findings from the on-site assessment.
- (6) If the department determines that the laboratory does not meet the requirements for licensure:
 - (a) the department will send the laboratory written notice of that fact, the grounds for the decision, and the right to submit a plan of correction within 30 days after receipt of the notice for minor deficiencies and within 15 days after receipt of the notice for major deficiencies;
 - (b) if a plan of correction is not received by the deadline or if the plan of correction is inadequate to correct the deficiencies, the department will issue a written denial of the license, the grounds for denial, and the right to an appeal pursuant to the Montana Administrative Procedure Act.
- (7) If the on-site assessment is satisfactory or, if it is not, if implementation of the plan of correction successfully eliminates the deficiencies cited, the department shall issue a final decision in writing granting the type of license requested and stating which analyte(s) or interdependent analyte group(s) the laboratory is approved to analyze.
- (8) A license expires on the expiration date listed on the license, unless revoked earlier. To avoid a lapse in licensure, a laboratory must submit, on a form provided by the department, a completed application for renewal and the required fee for licensure prior to the expiration of the license.

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.