



ADMINISTRATIVE RULES OF MONTANA



37.12.312 LICENSE

- (1) In the case of a laboratory applying for a license for the first time, the department may grant a conditional license to a laboratory that:
 - (a) is in compliance with all requirements for licensure but has not yet analyzed a second PE sample or does not have records of historical performance; or
 - (b) does not comply with all of the requirements of this subchapter, but whose deficiencies do not affect the capability of the laboratory to perform valid analyses.
- (2) Conditional licensure will be granted only after an on-site inspection and is in effect for one year or until full licensure is granted under provisions of ARM 37.12.311, whichever is earlier.
- (3) In order for a laboratory applying for a chemistry license for the first time to upgrade from conditional licensure status to fully licensed status, it must perform analyses of a minimum of two PE samples over the course of a year that indicate at least two successful analyses of each analyte or interdependent analyte group and method for which they seek licensure to analyze, and undergo a second on-site inspection that shows full compliance with licensure standards.
- (4) In order for a laboratory applying for a microbiology license for the first time to upgrade from conditional licensure status to fully licensed status, a microbiology laboratory must be in continual operation for one year, analyze and successfully pass at least two performance evaluation (PE) sets for each analyte and method, and undergo a second on-site inspection to verify that its methodologies and quality control meet the standards of this subchapter.

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.