



## ADMINISTRATIVE RULES OF MONTANA



### **37.12.333 APPROVAL TO CONDUCT ANALYSES**

- (1) Analyses must be conducted using current EPA approved methods in accordance with the analytical requirements set forth in 40 CFR 141.
- (2) Alternate analytical procedures are not permitted unless such procedures satisfy 40 CFR 141.27 and have been approved by the EPA.
- (3) An applicant laboratory must request approval to analyze for an analyte or interdependent analyte group and the method(s) used as part of its application for licensure or renewal of a license.
- (4) Approval for such analyses will be granted only after an on-site assessment. The applicant laboratory shall submit:
  - (a) documentation that it has the necessary equipment and qualified technical employees to preform the tests;
  - (b) for chemistry analysis, documentation that the laboratory has successfully passed two proficiency testing audits for the analyte and method in question from an approved proficiency testing program;
  - (c) its standard operating procedure for the method used to analyze for the analyte in question;
  - (d) documentation of its initial demonstration of analytical capability; and
  - (e) documentation establishing the laboratory's method detection limit for each chemical analyte.
- (5) If the department is satisfied from its assessment that the applicant laboratory can produce valid results, it shall grant approval for the analyte or interdependent analyte group by a specific method.
- (6) At a time other than when applying for a license renewal, a licensed laboratory may request approval to analyze for an additional analyte or interdependent analyte group by submitting a written request together with the documentation required in (1).
  - (a) If the analyte for which approval is requested is an addition to, or a group similar to, analytes that have already received approval, the certifying agency may grant interim approval for the analyte which shall remain in effect until the next review for license renewal as long as the laboratory continues to successfully complete proficiency testing on the analyte.
  - (b) If the analyte for which approval is requested is unrelated to previously approved analytes, or requires specialized equipment and/or personnel training, the certifying agency shall require a new application packet and an application fee to be submitted, as well as an

update of the laboratory licensure file, and shall perform an on-site assessment prior to approval.

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

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

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**History:** NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2011 MAR p. 2286, Eff. 10/28/11.