

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES
OF THE STATE OF MONTANA

In the matter of the amendment of) NOTICE OF PROPOSED
ARM 37.12.301, 37.12.316,) AMENDMENT
37.12.320, 37.12.338, 37.12.345, and)
37.12.346 pertaining to laboratories) NO PUBLIC HEARING
that conduct analyses of public water) CONTEMPLATED
supplies)

TO: All Concerned Persons

1. The Department of Public Health and Human Services proposes to amend the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on February 2, 2023, to advise us of the nature of the accommodation that you need. Please contact Kassie Thompson, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, MT 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail hhsadminrules@mt.gov.

3. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.12.301 DEFINITIONS For the purpose of this subchapter:

(1) through (9) remain the same.

(10) "Environmental Protection Agency, (EPA)" means the United States Environmental Protection Agency.

(11) and (12) remain the same.

(13) remains the same, but is renumbered (14).

~~(14)~~ (13) "Initial demonstration of analytical capability" means the procedure described in the method cited in 40 CFR part 136, appendix A, ~~July 1998 edition~~ as amended August 28, 2017, for chemistry analysis, used to determine a laboratory's accuracy and precision in applying an analytical method.

(15) and (16) remain the same.

(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, ~~July 2003 edition~~ as amended August 28, 2017.

(18) through (26) remain the same.

AUTH: 50-1-202, MCA
IMP: 50-1-202, 75-6-106, MCA

37.12.316 REISSUANCE OF LICENSE (1) through (3) remain the same.

(4) The department adopts and incorporates by reference the EPA laboratory certification manual (EPA 815-R-05-004, "Manual for the Certification of Laboratories Analyzing Drinking Water,"; January 2005), which contains criteria, procedures, and quality assurance standards required by the ~~Environmental Protection Agency~~ EPA that must be met by laboratories analyzing drinking water to determine compliance with the federal Clean Water Act and its rules. A copy of the manual 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: www.epa.gov/safewater/methods/pdfs/manual_labcertification.pdf
<https://www.epa.gov/dwlabcert/laboratory-certification-manual-drinking-water>.

AUTH: 50-1-202, MCA
IMP: 50-1-202, 75-6-106, MCA

37.12.320 PROFICIENCY TESTING (1) through (4) remain the same.

(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) through (8) remain the same.

(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:

www.epa.gov/safewater/methods/pdfs/manual_labcertification.pdf
<https://www.epa.gov/dwlabcert/laboratory-certification-manual-drinking-water>.

AUTH: 50-1-202, MCA
IMP: 50-1-202, 75-6-106, MCA

37.12.338 LABORATORY EQUIPMENT AND SUPPLIES (1) through (4) remain the same.

(5) The department adopts and incorporates by reference the standards contained in the EPA laboratory certification manual (EPA 815-R-05-004, "Manual for the Certification of Laboratories Analyzing Drinking Water,"; January 2005) for sources of distilled, deionized water, or reagent grade water. A copy of the manual

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: www.epa.gov/safewater/methods/pdfs/manual_labcertification.pdf
<https://www.epa.gov/dwlabcert/laboratory-certification-manual-drinking-water>.

AUTH: 50-1-202, MCA
IMP: 50-1-202, 75-6-106, MCA

37.12.345 CRITICAL ELEMENTS FOR CHEMISTRY LABORATORY LICENSURE (1) through (4) remain the same.

(5) The department adopts and incorporates by reference 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 establishes qualifications for staff training and experience and conditions for approval of laboratories conducting chemical analyses of public drinking water. 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>.

AUTH: 50-1-202, MCA
IMP: 50-1-202, 75-6-106, MCA

37.12.346 CRITICAL ELEMENTS FOR MICROBIOLOGY LABORATORY LICENSURE (1) through (5) remain the same.

(6) The department adopts and incorporates by reference chapter V of the EPA laboratory certification manual (EPA 815-R-05-004, "Manual for the Certification of Laboratories Analyzing Drinking Water," January 2005), which establishes qualifications for staff training and experience and conditions for approval of laboratories conducting microbiological analyses of public drinking water. A copy of the above chapter V 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: www.epa.gov/safewater/methods/pdfs/manual_labcertification.pdf
<https://www.epa.gov/dwlabcert/laboratory-certification-manual-drinking-water>.

AUTH: 50-1-202, MCA
IMP: 50-1-202, 75-6-106, MCA

4. STATEMENT OF REASONABLE NECESSITY

The department is proposing to amend ARM 37.12.301, 37.12.316, 37.12.320, 37.12.338, 37.12.345, and 37.12.346 pertaining to laboratories that conduct analyses of public water supplies.

ARM 37.12.301

The department is proposing to amend this rule to update Code of Federal Regulations (CFR) references to refer to the most current version of each CFR. These updates to the CFR revise the Method Detection Limit procedure. The new procedure is already being utilized by water testing laboratories within Montana. Updating these references is necessary to ensure the rules adopt by reference the current federal regulations.

ARM 37.12.316, 37.12.320, 37.12.338, 37.12.345, and 37.12.346

The department is proposing to amend these rules to correct the hyperlink where the EPA laboratory certification manual (EPA 815-R-05-004, "Manual for the Certification of Laboratories Analyzing Drinking Water," January 2005) can be accessed. The rules currently reference an outdated and broken hyperlink.

5. The proposed rule changes are intended to be effective upon the day after the date of publication of the adoption notice.

6. Concerned persons may submit their data, views, or arguments concerning the proposed action in writing to: Kassie Thompson, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, MT 59604-4210, no later than 5:00 p.m. on February 24, 2023. Comments may also be faxed to (406) 444-9744 or e-mailed to hhsadminrules@mt.gov.

7. If persons who are directly affected by the proposed action wish to express their data, views, or arguments orally or in writing at a public hearing, they must make written request for a hearing and submit this request along with any written comments to Kassie Thompson at the above address no later than 5:00 p.m., February 24, 2023.

8. If the agency receives requests for a public hearing on the proposed action from either 10% or 25, whichever is less, of the persons directly affected by the proposed action; from the appropriate administrative rule review committee of the Legislature; from a governmental subdivision or agency; or from an association having not less than 25 members who will be directly affected, a hearing will be held at a later date. Notice of the hearing will be published in the Montana Administrative Register. Ten percent of those directly affected has been determined to be three persons based on 37 laboratories being licensed within Montana to conduct testing of public water supplies.

9. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 6 above.

10. An electronic copy of this notice is available on the department's web site at <https://dphhs.mt.gov/LegalResources/administrativerules>, or through the Secretary of State's web site at <http://sosmt.gov/ARM/register>.

11. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

12. With regard to the requirements of 2-4-111, MCA, the department has determined that the amendment of the above-referenced rules will not significantly and directly impact small businesses.

/s/ ROBERT LISHMAN
Robert Lishman
Rule Reviewer

/s/ CHARLES T. BRERETON
Charles T. Brereton, Director
Department of Public Health and Human
Services

Certified to the Secretary of State January 17, 2023.