567—83.5(455B) Laboratory recertification. Laboratories shall be recertified every two years after initial certification. Applications for recertification must be on department form 542-0492 (June 2021) and must be submitted at least 60 days prior to the renewal date. Applications shall be accompanied by the nonrefundable fee specified in 83.3(2). To be recertified, laboratories must meet the following requirements.

83.5(1) *Approved methodology.* Laboratories must use methods promulgated or approved by the EPA or by the department. Notwithstanding an approval by the EPA, the department may use discretion in determining which methods may be used in Iowa. A laboratory may not analyze and report data from samples collected for an environmental program area until certified in that area. The laboratory shall submit supporting documentation such as calibration curves, MDL studies, LOQs, or other information upon request. The following are adopted by reference:

a. Drinking Water – 40 CFR Part 141 Subpart C (Monitoring and Analytical Requirements) as amended February 5, 2024; 40 CFR §141.74 (Filtration and Disinfection) as amended February 13, 2013; 40 CFR §141.89 (Control of Lead and Copper) as amended January 15, 2021; 40 CFR §141.131 (Disinfection By-Products) as amended February 13, 2013; 40 CFR §141.402 (Groundwater Rule) as amended February 13, 2013; 40 CFR §141.704 (Enhanced Treatment for Cryptosporidium) as amended June 29, 2009; 40 CFR §141.852 (Revised TCR) as amended February 26, 2014; 40 CFR Part 901 (PFAS) as amended through June 25, 2024; 40 CFR §143.4 (Secondary Regulations) as amended June 29, 2009.

b. Wastewater (nonpotable water) – 40 CFR Part 136, June 17, 2024.

c. Municipal biosolids (sewage sludge) – 40 CFR Part 136, as amended June 17, 2024, and Test Methods for Evaluating Solid Waste: Physical/Chemical Methods (SW-846 Update VII) as amended July 30, 2021.

d. Solid waste and contaminated sites – Test Methods for Evaluating Solid Waste: Physical/Chemical Methods (SW-846 Update VII) as amended July 30, 2021.

e. Underground storage tanks – Iowa Methods OA-1 and OA-2, December 10, 2019, and EPA method 8260 – Test Methods for Evaluating Solid Waste: Physical/Chemical Methods (SW-846 Update VII) as amended July 30, 2021.

83.5(2) *Proficiency testing samples.* Certified laboratories must satisfactorily analyze PTs at least once every 12 months for each analyte by each method in each program area for which the laboratory intends to retain certification unless a PT sample is not available for the particular analyte, method, or program area. Results must be submitted electronically by the PT provider to the department at labcert@dnr.iowa.gov along with a statement of the method used once the study is published. The laboratory must maintain records of all PT samples including summary pages, explanations, and footnotes, pursuant to the recordkeeping requirements in 83.5(8)*"b."*

a. Test requirements.

(1) PT samples shall be analyzed in accordance with the laboratory's routine standard operating procedures using the same quality control, acceptance criteria, and staff as used for the analysis of routine environmental samples. PT samples may not be analyzed multiple times for the purpose of averaging results to be reported to the PT provider.

(2) The PT sample shall be analyzed by a different analyst(s) or analytical team in following years, if there are multiple analysts in the laboratory.

(3) Once the results of a PT sample are submitted to the PT provider, remaining PT samples may be used as check samples or for demonstration of capability of analysts.

(4) Laboratories that receive unacceptable PT result(s) shall notify the department within 10 days of the unacceptable result(s). This does not include the required corrective action report.

b. Performance testing providers and acceptance limits. All PT samples must be obtained from a NELAP accredited provider. Performance test results shall be evaluated using criteria from NELAP field of proficiency tables except where noted otherwise. If there is a difference between the NELAP field of proficiency tables and federal rules, the rules shall prevail. Approved PT vendors and fields of proficiency tables may be found at nelac-institute.org.

83.5(3) *Notification of major changes.* Laboratories must notify the department, in writing, of major changes in critical or essential personnel, equipment, laboratory location, or other major change that might alter or impair analytical capability. The department may issue a notice of violation based on cause.

a. Major equipment. Laboratories must notify the department 90 days, whenever possible, prior to installation of major equipment when the technology is not currently being utilized by the laboratory. This includes, but is not limited to, inductively coupled plasma spectrophotometers, mass spectrometers, gas chromatographs, liquid chromatographs, and continuous spectrophotometers. The installation of a new water bath or incubator does not need to be reported. If requested, the laboratory must submit the DOC to the department for review and approval prior to reporting compliance data using the new equipment.

b. Laboratory relocation. Laboratories must notify the department 90 days prior to a laboratory relocation. Laboratories must complete a DOC for each major piece of equipment once it has been relocated to the new laboratory. If requested, the laboratory must submit the DOC to the department for review and approval prior to reporting compliance data.

c. Personnel changes. Laboratories must notify the department 30 days prior to, whenever possible, but in no circumstance later than ten days after, the departure of critical or essential personnel. If requested, a DOC must be submitted to the department before the laboratory may report environmental data. DOC records for all staff must be maintained on file for review by an auditor. The loss of a critical staff person means the lab will not be able to analyze samples and must subcontract samples for a specific method(s) or program area(s) until another person is hired to perform the particular function or analysis and has completed an initial DOC. The loss of an essential staff person means that existing staff must undergo additional training before they can assume the role.

d. Laboratory shutdown. Laboratories must notify the department within five days if the laboratory has shut down due to a natural or man-made disaster, a cybersecurity incident, or other occurrence that renders the laboratory unable to perform analyses for Iowa clients.

e. Data quality issues. If a laboratory becomes aware that there are systematic data quality issues that affect the result(s) for one or more analytes, the laboratory must notify the department within five days. The laboratory must resolve the issues, submit a corrective action report, and submit an amended analytical report to the client(s) and the department within 30 days.

83.5(4) *Annual requirements.* Laboratories are required to perform the following updates on an annual basis. Documentation of these updates must be maintained in paper or electronic form, or a combination thereof, pursuant to the recordkeeping requirements in 83.5(8)*"b"* and shall be made available during the on-site audit, or if requested by the department.

a. Balance maintenance and weight verification;

b. Working thermometer verification;

c. Review the QA plan and document the date, reviewer, and any changes;

d. Review SOPs, and document the review and any changes to the SOPs. Confirm that QC requirements are performed with each analysis and that additional QC requirements are conducted monthly, quarterly, or annually as needed;

e. Review sample handling, preservation and storage requirements if they are not addressed in the SOP;

f. Conduct a continuing DOC for analysts;

g. Run and document calibration curves;

h. Perform annual PTs;

i. Review manufacturer equipment maintenance schedules, perform scheduled maintenance, and document the maintenance performed;

j. Replace and document the source of reference cultures used for microbiological analyses; and

k. Check spreadsheets annually to determine that calculated results have not changed due to software updates. Spreadsheet calculations may need to be checked manually.

In addition to the above requirements, it is recommended that the laboratory review the safety plan with all employees and conduct an internal audit annually.

83.5(5) *Site audits.*

a. SHL certification. The department has designated the SHL as its appraisal authority for laboratory certification. The SHL is responsible for attaining and maintaining laboratory certification for the SDWA program that is acceptable to the EPA. The SHL shall obtain accreditation from a state NELAP accreditation authority in all department program areas specified in 83.1(3), where available. The SHL shall forward audit reports to the department according to the time frame in 83.3(3). The SHL is not required to pay the fees for laboratory certification.

b. On-site audits. Laboratories must consent to a periodic site audit by the department or its designee, at least every two years. However, on-site audits may be conducted more frequently if the laboratory undergoes a major change that may alter or impair analytical capability, fails a PE sample analysis, or if the department questions an aspect of data submitted that is not satisfactorily resolved. Laboratories certified by reciprocity generally are not required to have an on-site audit conducted by the SHL. However, the department and the SHL reserve the right to conduct an on-site audit.

83.5(6) *Period of validity.*

a. Certification shall be valid for a period not to exceed two years from the date of issuance. Certification shall remain in effect until certification is either renewed or revoked, provided a laboratory has submitted a timely and complete application, and paid the appropriate fee.

b. Laboratories that have not submitted a timely and complete application and have not paid the appropriate fee may not report compliance data if their certification has expired.

83.5(7) *Reporting requirements.* Laboratories may not analyze or report sample results for any analyte, analytical series, or environmental program area until an initial certification status of certified or temporary has been granted by the department. Any data generated before certification status is granted will be considered invalid for compliance purposes. A laboratory with provisional status may analyze and report analyses for compliance purposes. A certified laboratory may contract analyses to another certified laboratory. The responsibility lies with the primary certified laboratory contracting for services to verify that the secondary contracting laboratory is certified by the department and to ensure that reporting requirements and deadlines are met.

a. All program areas. Laboratories that generate data for clients must list all of the following elements on paper or electronic reports provided to clients.

(1) Iowa certified laboratory number;
(2) Laboratory name, address, and phone number;
(3) Laboratory sample ID;
(4) Client sample location ID;
(5) Regulatory ID number, such as a permit number;
(6) Date and time of sample collection;
(7) Date and time of sample receipt and temperature (may be recorded on chain of custody, receiving sheet, or comments);
(8) Sample collector name;
(9) Date and time of analysis;
(10) Analyst name;
(11) Matrix;
(12) Analyte;
(13) Analytical method used;
(14) The reporting limit;
(15) Analysis result;
(16) Units of measure;
(17) Subcontracting laboratory or laboratories, if used;
(18) Signature of signatory authorized to sign analytical reports; and
(19) Chain of custody records.

b. Additional reporting for all program areas.

(1) The use of whiteout to correct errors is strictly prohibited.
(2) Laboratory records and final reports shall be recorded in ink or electronically signed.
(3) A laboratory shall not express an analytical result as either:

1. Lower than the LOQ, such as using the MDL; or
2. As zero, unless specifically required by rule.

(4) Laboratories reporting data for the purpose of a monthly operation report (MOR) or discharge monitoring report (DMR) must follow the instructions and use the templates specified by the program area(s).

c. Water supply program.

(1) Certified laboratories must report all analytical test results for all public water supply systems (PWS) using the electronic reporting system provided by the department. New laboratories shall be fully compliant with electronic data reporting requirements no later than 45 days after the laboratory begins analysis of compliance samples. If a PWS is required by the department to collect and analyze a sample for an analyte not normally required by 567—Chapters 41 and 43, the laboratory testing for that analyte must also be certified and report the results of that analyte to the department. A PWS may request that a laboratory add additional analytes for analysis after samples are received by the laboratory, but may not remove an analyte originally requested after the laboratory has initiated analysis of those analytes without written department approval. It is the laboratory's responsibility to correctly assign and track the sample identification number, the facility ID, and source/entry point data for all reported samples.

1. The following are examples of sample types for which data results must be reported:

- Routine: a regular sample that includes samples collected for compliance purposes at various sampling frequencies;
- Repeat: a sample that must be collected after a positive result from a routine or previous repeat total coliform sample, per 567—paragraph 41.2(1)*"j."* Repeat samples must be analyzed by the same laboratory that analyzed the associated original routine sample;
- Confirmation: a sample that verifies a routine sample, normally used to determine compliance with a health-based standard;
- Special: a nonroutine sample, such as raw, plant, and troubleshooting samples, which cannot be used to comply with monitoring requirements assigned by the department;
- Maximum residence time: a sample collected at the maximum residence time location in the distribution system, usually for disinfection byproduct measurement; and
- Replacement: a sample that replaces a missed sample from a prior monitoring period resulting in a monitoring violation.

2. The following additional types of data must be reported to the department:

- MOR data that is required by the department to demonstrate compliance with public health standards; and
- Raw water sampling results specifically covered by 567—Chapters 40 to 43 for new surface water or groundwater sources, or reconstruction of groundwater sources.

3. The following are examples of data results that are not required to be reported by a laboratory to the department:

- Routine MOR data; or
- Distribution samples for the Total Coliform Rule 567—subrule 41.2(1) for water main repair or installation.

4. The sample type cannot be changed after submittal to the laboratory, without written department approval. The prescreening, splitting, or selective reporting of compliance samples is not allowed.

(2) Certified laboratories must report all analytical results to the PWS for which the analyses were performed.

(3) Analytical results must be reported to and received by the department by the seventh day of the month following the month in which the samples were analyzed.

(4) In addition to the monthly reporting of analytical results, the following results must be reported within 24 hours of the completion of the analysis, including data reduction, to the department by email or other acceptable method acceptable to the department, and to the PWS for which the analyses were conducted:

1. Results of positive routine coliform bacteria samples, and all repeat and follow-up samples; and

2. Results of any contaminant that exceeds public drinking water standards (maximum contaminant level, treatment technique, action level, or health advisory), and any subsequent confirmation samples.

Results available outside of routine business hours must be reported to the department's Environmental Emergency Reporting Hotline at 515.725.8694.

(5) If requested by the department, certified laboratories shall report their MDLs, LOQs, and any other pertinent information when reporting results for PWSs.

d. UST program. No additional information.

e. Wastewater program. No additional information.

f. Solid waste and contaminated site programs. No additional information.

83.5(8) *Recordkeeping.*

a. Appraisal authority. The laboratory certification program appraisal authority must retain the records for on-site laboratory audits and certification program reviews. The records must be maintained in an easily accessible manner for a period of six years, including the last two on-site audits. The records include correspondence used to determine compliance with the laboratory certification program requirements, and may include checklists, corrective action reports, final reports, certificates, PT study results, and any other related documents.

b. Laboratories. Laboratories shall retain laboratory records in paper or electronic form or a combination of both. Laboratory records include, but are not limited to, calibration curves; raw data; calculations and supporting data such as chromatographs; analytical results; lists of chemicals and equipment used; QA plans; SOPs; and PT results. Laboratory records shall be retained according to the following schedule:

(1) Drinking water: microbiology and turbidity, five years; chemical, ten years; lead and copper rule, twelve years.

(2) Wastewater: all analytes, three years. Federal DMRQA reports, three years.

(3) Sewage sludge (municipal biosolids): all analytes, five years.

(4) Solid waste and contaminated sites: all analytes, five years.

(5) Underground storage tanks: all analytes, five years.

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