TRACKED CHANGES VERSION – Final Rule 5/14/2025

CHAPTER 83
LABORATORY CERTIFICATION
~~[Prior to 4/10/96, see 567—Chapter 42]~~

PART A
GENERAL

567—83.1(455B) Authority, purpose, and applicability.

83.1(1) *Authority.* Pursuant to Iowa Code section 455B.113, a laboratory certification program is required for laboratories performing analyses of samples that~~which~~ are required to be submitted to the department as a result of Iowa Code provisions, rules, operation permits, or administrative orders. Pursuant to Iowa Code section 455B.114, the department may suspend or revoke the certification of a laboratory upon its determination ~~of the department~~ that the laboratory no longer fulfills one or more of the requirements for certification.

83.1(2) *Purpose.* The purpose of these rules is to provide the procedures for laboratories to use to apply for and maintain certification, to establish laboratory certification fees, ~~to maintain certification,~~ and to provide the appropriate methods and references for evaluating laboratory competence including the requirements for laboratories to become certified.

83.1(3) *Applicability to environmental program areas.* This chapter applies to the following laboratories:

a. Water supply (drinking water). ~~The requirements of this chapter apply to~~ A~~a~~ll laboratories conducting drinking water analyses pursuant to 567—Chapters 40, 41, ~~42,~~ and 43. ~~Routine, on-site monitoring for alkalinity, calcium, conductivity, residual disinfectant, orthophosphate, pH, silica, temperature, turbidity and on-site operation and maintenance related analytical monitoring are excluded from this requirement, and may be performed by a Grade I, II, III, or IV certified operator meeting the requirements of 567—Chapter 81, any person under the supervision of a Grade I, II, III, or IV certified operator meeting the requirements of 567—Chapter 81, or a laboratory certified by the department to perform water supply analyses under this chapter.~~

b. Underground storage tanks. ~~The requirements of this chapter also apply to~~ A~~a~~ll laboratories conducting underground storage tank (UST) analyses for petroleum constituents pursuant to 567—Chapter 135. Routine on-site monitoring conducted by or for ~~underground storage tank~~ UST owners for leak detection or a nonregulatory purpose is excluded from this requirement.

c. Wastewater (nonpotable water). ~~The requirements of this chapter also apply to~~ A~~a~~ll laboratories conducting analyses of wastewater, groundwater or sewage sludge (municipal biosolids), or manure pursuant to 567—Chapters 63, 65, 67, and 69. ~~Routine on-site monitoring for pH, temperature, dissolved oxygen, total residual chlorine and other pollutants that must be analyzed immediately upon sample collection, settleable solids, physical measurements such as flow and cell depth, and operational monitoring tests specified in 567—subrule 63.3(4) are excluded from this requirement.~~

d. Solid waste and contaminated sites. ~~The requirements of this chapter also apply to~~ A~~a~~ll laboratories conducting analyses of solid waste parameters pursuant to 567—Chapters 100 through ~~129,130,~~ contaminated site parameters pursuant to 567—Chapters 133 and 137, and regulated substances other than petroleum parameters regulated under 567—Chapter 135. ~~Any parameter that must be analyzed immediately upon sample collection is excluded from the requirements of this chapter. Any samples collected or testing conducted that is not part of the specific monitoring required by the department for regulatory purposes are also excluded from the requirements of this chapter.~~

83.1(4) *Exclusions.* Any parameter that must be analyzed immediately upon sample collection is excluded from the requirements of this chapter. Any samples collected or testing conducted that is not part of the specific monitoring required by the department for regulatory purposes are also excluded from the requirements of this chapter.

~~[**ARC 9915B**, IAB 12/14/11, effective 1/18/12]~~

567—83.2(455B) Definitions.

"*Batch*" means environmental samples that are prepared, analyzed, or both together with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of 1 to 20 environmental

Commented [1]: Common definitions used during audits and the overall program were added for clarity.

samples of the same quality systems matrix (water supply, wastewater, etc.), meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) that are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed 20 samples. If there is a conflict between this definition and the requirements of an approved method, the more stringent requirements shall apply.

"Certified" means a laboratory demonstrates to the satisfaction of the department its ability to consistently produce valid data within the acceptance limits as specified within the department's requirements for certification and meets the minimum requirements of this chapter and all applicable regulatory requirements. A laboratory may be certified for an analyte, an analytical series, or an environmental program area, except in the UST program area, where certification for individual analytes is not allowed.

"Corrective action report" or *"CAR"* means documentation that demonstrates a laboratory has satisfied cited deficiencies or deviations.

"Critical staff" means an analyst who is the only person at a laboratory performing a particular function or analysis (no backup analyst).

"Demonstration of capability" or *"DOC"* means a procedure used to demonstrate the ability of an analyst to generate acceptable accuracy for each method the analyst performs.

"Discharge monitoring report-quality assurance" or *"DMRQA"* means an effluent performance test study regulated by the National Pollutant Discharge Elimination System (NPDES) program and administered by the EPA.

"Environmental program area" means the water supply (drinking water) program, underground storage tank program, wastewater program (nonpotable water), or solid waste and contaminated site program pursuant to 83.1(3).

"Essential staff" means an analyst who is primarily responsible for a particular analysis/program and handles the administrative or technical tasks associated with the analysis or program.

"Holding time" means the maximum time a sample may be held before beginning of an associated analysis.

"Level of quantitation" or *"LOQ"* means the analyte concentration that produces a signal sufficiently stronger than the blank, such that it can be detected with a specified level of uncertainty during routine operations.

"Manual for the Certification of Laboratories Analyzing Environmental Samples for the Iowa Department of Natural Resources" ~~(2017) (Iowa Manual)~~ is incorporated by reference in this chapter.

Chapter 1 ~~of the Iowa Manual~~ pertains to certification of laboratories analyzing samples of drinking water and incorporates by reference the Manual for the Certification of Laboratories Analyzing Drinking Water, 5th edition, January 2005, EPA document 815-R-05-004, ~~January 2005~~; Supplement 1, June 2008, EPA 815-F-08-006; and Supplement 2, November 2012, EPA 815-F-12-006.

Chapter 2 ~~of the Iowa Manual,~~ (~~2017~~2020), pertains to laboratories analyzing samples for the ~~underground storage tank~~ UST program.

Chapter 3 ~~of the Iowa Manual,~~ (2017), pertains to laboratories analyzing samples for wastewater and sewage sludge disposal programs.

Chapter 4 ~~of the Iowa Manual,~~ (2017), pertains to laboratories analyzing samples for the solid waste and contaminated site programs.

"Method detection limit" or *"MDL"* means the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte.

"National environmental laboratory accreditation program" or *"NELAP"* means the third-party accreditation program that is managed by the NELAC Institute (TNI), a 501(c)(3) nonprofit organization, and that is based on consensus standards representing the best professional practices for laboratories.

"Quality assurance plan" or *"QA plan"* means a document that describes the key elements of laboratory functions that provide quality testing results to the client. The key elements include but are not limited to a description of the laboratory organizational structure and lines of responsibility; sampling requirements,

procedures, and locations; sampling handling procedures; calibration procedures and frequencies; procedures for data reduction, validation, and reporting; quality control procedures including type, frequency and acceptance criteria; procedure(s) used to determine data precision and accuracy; corrective action contingencies; and preventative maintenance and schedules.

"~~Performance evaluation~~Proficiency Test ~~(PE)~~ sample" or *"PT sample"* means a reference sample provided to a laboratory for the purpose of demonstrating that a laboratory can successfully analyze the sample within limits of performance specified by the department. The true value of the concentration of the reference material is unknown to the laboratory at the time of analysis. ~~A PE sample may also be referred to as a proficiency testing sample or PT sample.~~

"Provisional certification" or *"provisional status"* means a laboratory has deficiencies, which must be corrected within the specified time frames listed in 83.6~~7~~(3~~2~~)*"d,"* but demonstrates to the satisfaction of the department its ability to consistently produce valid data within the acceptance limits as specified within the department's certification requirements.

"Reporting limit" means a value established by the laboratory that is at or above the LOQ consistent with the method and compliance reporting requirements.

"Revoked certification" means a laboratory no longer fulfills the requirements of this chapter, and certification is revoked by the director upon determination of the director that the laboratory no longer fulfills the requirements for certification (Iowa Code section 455B.114).

"Signature authority" means the person with the managerial, educational, and technical experience authorized to sign analytical reports on behalf of the laboratory.

"Standard operating procedure" or *"SOP"* is a set of written instructions that describe, in detail, how to perform a laboratory method or process safely, consistently, and effectively.

"SHL" means the State Hygienic Laboratory at the University of Iowa.

"Suspended certification" means a temporary suspension of certification for a laboratory, conditional upon meeting the time frames in 83.6~~7~~(5~~4~~)*"d"* for the correction of the deficiency.

"Temporary certification" or *"temporary status"* means short-term transitional certification granted to a new laboratory that has no history of generating compliance data. ~~in certain circumstances when the department implements certification in a new environmental program area.~~

"Traceability" means the unbroken chain of events in the process of a sample being collected, received at the laboratory, prepared for analysis, analyzed, data reviewed and reported, and final disposal of the sample.

~~[**ARC 3735C**, IAB 4/11/18, effective 5/16/18]~~

PART B
CERTIFICATION PROCESS

567—83.3(455B) Application for laboratory certification.

83.3(1) *Application forms.* Application for laboratory certification~~, other than for temporary certification,~~ shall be made on department form~~s~~ 542-0492 (July 2021) ~~provided by the department~~ and shall be accompanied by the nonrefundable fee specified in 83.3(2). The application for certification renewal ~~of certification~~ shall be made at least 60 days prior to the certification expiration date. The department may require submission of additional information necessary to evaluate the application. All ~~required~~ documentation and fees must be submitted~~supplied~~ to the department prior to the on-site ~~visit~~audit. Failure to submit a complete application may result in denial of the renewal or certificate update.

83.3(2) *Fees and expenses.*

a. A nonrefundable fee for the administration, completion of on-site laboratory surveys and assessments, and enforcement of laboratory certification requirements shall be paid with the certification application.

(1) The on-site ~~visit~~audit will not be conducted and certification will not be issued until the fees and expenses are paid and all other certification requirements are met. The fee for certification will not be refunded if an on-site ~~visit~~audit is not performed.

(2) Out-of-state laboratories will be responsible for paying the expenses of an on-site ~~visit~~audit, in addition to the standard certification fee if required, and the department or its agent will bill the out-of-state laboratory

directly for the expenses.

(3) When a laboratory's certification status is changed to "provisional" or "suspended" and the period for correcting deficiencies extends beyond the certification period, the laboratory must continue to pay the required fees in order to maintain its certification status.

(4) Additional fees. Additional fees will be assessed for the following, and the department or its agent will bill the laboratory directly.

1. The laboratory is responsible for paying for any additional on-site visitaudits, at a fee of $300 per visitaudit. An example of this is when an additional on-site visitaudit is required when a laboratory seeks certification for an entirely new set of parameters for which it had previously not been certified.

2. When an on-site visitaudit is required to inspect for deficiencies that the laboratory musthas been required to correct, the fee is $500 per visitaudit.

b. Certification in multiple environmental program areas. Where a laboratory is certified for the same analyte in more than one environmental program area, the laboratory must meet all the applicable certification requirements in addition to the payment of the fees.

c. In general, the department does not certify calculations. However, it is acceptable to report calculated results to clients and for regulatory reporting purposes.

cd. The Aapplicable fees shall be based on the type of analytical service provided as follows:

ANALYTICAL GROUP	REGULATORY PROGRAM & PARAMETERS[1]	FEE
Asbestos	SDWA	$400
Basic Drinking Water	SDWA (includes total coliform bacteria, *E. coli*, heterotrophic plate count, nitrate, nitrite, and & fluoride)	$800
Basic Wastewater	CWA (includes BOD_5, $CBOD_5$, total suspended solidsTSS, and & ammonia)	$400
Bacteria	CWA (includes total coliform, fecal coliform, and *E. coli*)	$800
	SDWA (includes total coliform, *E. coli*, and heterotrophic plate count)	$800
	SDWA (basic drinking water) & CWA combined	$1,300
Dioxin	SDWA	$800
Effluent Toxicity Testing	CWA	$800
Inorganics, including metals	CWA metals, inorganic compounds, and physical characteristics ($400 per analyte up to a maximum of $1,600)	$400 to 1,600
	SDWA (includes metals, nitrate, nitrite, ammonia, cyanide, fluoride, bromate, bromide, chlorite, and total organic carbon & other inorganic chemicals)	$1,600
	SW/CS	$1,600
	CWA & SDWA combined	$2,400
	CWA & SW/CS combined	$2,400
	SDWA & SW/CS combined	$2,400
	CWA, SDWA, and SW/CS combined	$2,800
Radionuclides	CWA	$400
	SDWA (includes gross alpha, gross beta, photon emitters, radium, strontium, tritium, and & uranium)	$400
	SDWA & CWA combined	$650
Synthetic Organic Chemicals (SOC)	CWA	$1,600
	SDWA	$1,600
	SW/CS	$1,600
	CWA & SDWA combined	$2,400
	CWA & SW/CS combined	$2,400
	SDWA & SW/CS combined	$2,400
	CWA, SDWA, and SW/CS combined	$2,800
Volatile Organic Chemicals (VOC)	CWA	$1,600
	SDWA	$1,600

ANALYTICAL GROUP	REGULATORY PROGRAM & PARAMETERS[1]	FEE
	SW/CS	$1,600
	CWA & SDWA combined	$2,400
	CWA & SW/CS combined	$2,400
	SDWA & SW/CS combined	$2,400
	CWA, SDWA, ~~and~~ & SW/CS combined	$2,800
Underground Storage Tank Program Methods (UST)	OA1 &~~and~~ OA2 for UST, CWA, & SW/CS programs	$1,600
	OA1, OA2, ~~PAH, and~~ & Air Gas for UST, CWA, & SW/CS programs	$2,000
Other analyte~~s~~ not included in the above categories~~2~~	SDWA, CWA, UST, or SW/CS	$400 per analyte

[1]CWA: Analysis of wastewater samples for the federal Clean Water Act.
SDWA: Analysis of drinking water samples for the federal Safe Drinking Water Act.
SW/CS: Analysis of water, soil, or solid samples for the solid waste or contaminated sites programs.
UST: Analysis of water and soil samples for the underground storage tank program.

~~2The fee for an additional analyte may be charged at the discretion of the appraisal authority.~~

e~~d~~. ~~Payment of fees.~~ Fees shall be paid by ~~bank draft~~ cashier's check, check, money order, credit card, electronic payment, or other means acceptable to the department, made payable to the Iowa department of natural resources laboratory certification program. Credit card or electronic payment may incur an additional fee. Purchase orders are not an acceptable form of payment. The fee shall be paid at least 60 days prior to the expiration date of any certification held by a laboratory. If a laboratory does not submit the application and fee by the expiration date, the laboratory is prohibited from conducting certified analytical tests until the application and fee are received by the department.

83.3(3) *Reciprocity.* Reciprocal certification of out-of-state laboratories by Iowa, and of Iowa laboratories by other states, ~~or accreditation providers,~~ is allowed. If the reciprocal state has a certification program for the area the lab is applying for in Iowa, the laboratory is required to obtain certification from their reciprocal state prior to receiving certification from Iowa. A laboratory must meet all Iowa certification criteria and pay all applicable fees as listed in this chapter. Any laboratory that~~which~~ is granted reciprocal certification in Iowa using primary certification from another state or provider is required to report any change in certification status from the accrediting state or provider to the department within 15 days of notification. A copy of the assessment report including the laboratory's approved corrective actions must be submitted to the department within 15 days after it is approved by the resident state or third-party accreditation provider. A laboratory that loses primary certification, either in its resident state program or third-party accreditation program, will also immediately lose certification for the same program area and parameters in Iowa, pursuant to 83.6~~7~~(6~~5~~)*"a"*(8~~9~~).

a. Out-of-state laboratories. Where an out-of-state laboratory has received an on-site ~~visit~~audit within its own state, the fee for certification shall not be reduced if an on-site ~~visit~~audit is not performed by Iowa.

b. Third-party accreditation. The department ~~may~~ will accept third-party accreditation from ~~national accreditation providers on an individual basis.~~ a state NELAP accreditation authority. The laboratory must provide the most recent on-site assessment and approved corrective action report.

~~[**ARC 3735C**, IAB 4/11/18, effective 5/16/18]~~

~~**567—83.4(455B) Procedure for initial certification for laboratories analyzing solid waste and contaminated site program parameters.** Rescinded **ARC 3735C**, IAB 4/11/18, effective 5/16/18.~~

567—83.4~~5~~(455B) Procedures for new laboratory certification ~~of new laboratories~~ or changes in certification. Laboratories that wish to become certified to conduct testing for an analyte or a method after the deadline for initial certification has passed, and any laboratory seeking initial certification, shall follow the procedures specified in rule 567—83.6~~5~~(455B) for laboratory recertification. For changes in certification, the relevant fee must accompany the application where appropriate. New laboratories with no history of generating compliance data in any program area will be issued a temporary certification for a period of up to six months after the initial on-site audit. The laboratory may be re-audited in person or a document review may be conducted at the discretion of the SHL auditor(s).

Commented [2]: Labs that do not have a complete application submitted and have not paid a fee will not be able to analyze samples if the certificate is expired.

Commented [3]: The intention is to give new labs a second review to make sure SOPs are being followed, etc.

567—83.56(455B) Laboratory recertification. Laboratories shall be recertified every two years after initial certification. Applications for recertification must be on department ~~forms~~ form 542-0492 (June 2021) ~~provided by the department~~ and must be ~~postmarked~~ 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~~.~~

83.56(1) *Approved methodology ~~required~~.* Laboratories must use ~~the approved methodology for all analyses the results of which are to be submitted to the department.~~ 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.

83.56(2) *~~Performance evaluation (p~~Proficiency testing~~)~~ samples ~~required~~.* Certified laboratories must satisfactorily analyze ~~PE~~PTs at least once every 12 months for each analyte by each method in each program area for which the laboratory ~~wishes~~ intends to retain certification unless a ~~PE~~PT sample is not available for the particular analyte, ~~or~~ method, or program area. Results must be submitted electronically by the PT provider to the ~~Iowa~~ department ~~of natural resources~~ at labcert@dnr.iowa.gov ~~and the state of Iowa hygienic laboratory, or as otherwise directed,~~ along with a statement of the method used once the study is published. ~~within 30 days of receipt from the provider.~~ The laboratory must maintain records of all ~~PE~~PT samples ~~for a minimum of 5 years.~~ 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

Commented [4]: This section was added to clarify that only one analyst is to analyze the PT sample following the SOP for the method used.

federal rules, the rules shall prevail. Approved PT vendors and fields of proficiency tables may be found at nelac-institute.org.

83.56(3) *Notification of major changes.* Laboratories must notify the department, in writing, ~~within 15 days~~ of major changes in critical or essential personnel, equipment, laboratory location, or other major change that~~which~~ might alter or impair analytical capability. ~~An example of a major change in essential personnel includes the loss or replacement of the laboratory supervisor, or a trained and experienced analyst is no longer available to analyze a particular parameter for which certification has been granted.~~ 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 systemic 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

Commented [5]: Notification of major changes was updated to reflect current conditions and added a section about data quality issues.

Commented [6]: This section was added because these are frequently cited deviations that require corrective actions.

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.

83.56(45) *Site ~~visit~~audits.*

a. SHL c~~C~~*ertification ~~of, the State of Iowa Hygienic Laboratory~~*. The department has designated ~~the State of Iowa Hygienic Laboratory (SHL~~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 ~~U.S. Environmental Protection Agency (~~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 quality assurance officer is responsible for the certification of SHL for those programs with no available EPA certification program, including wastewater, underground storage tank, solid waste, and contaminated site programs. The SHL quality assurance officer reports directly to the office of the SHL director and operates independently of all areas of the laboratory generating data to ensure complete objectivity in the evaluation of laboratory operations. The quality assurance officer will schedule a biennial on-site inspection of the SHL and review results for acceptable performance. Inadequacies or unacceptable performance shall be reported by the quality assurance officer to the SHL and the department for correction. The department shall be notified if corrective action is not taken.~~ 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 ~~visit~~audits. Laboratories must consent to a periodic site ~~visit~~audit by the department or its designee, at least every two years. However, ~~an~~ on-site ~~visit~~audits may be conducted more frequently if the laboratory undergoes a major change that~~which~~ may alter or impair analytical capability, fails a PE sample analysis, or if the department questions an aspect of data submitted that~~which~~ 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.

83.56(56) *Period of validity.*

a. Certification shall be valid for a period not to exceed two years from the date of issuance. ~~, except in the case of reciprocal certification of an out-of-state laboratory. Reciprocal certification shall be valid for a period equal to that of the resident state in which the laboratory is certified, but shall not exceed two years.~~ 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. ~~until certification is either renewed or revoked.~~

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.

83.56(67) *Reporting requirements.* Laboratories may not analyze or report sample results for any analyte, analytical series, or environmental program area until an~~the~~ 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,

Commented [7]: This section was added so all labs that report results to outside clients are on the same page.

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).

~~a~~c. *Water supply program.*

(1) Certified laboratories must report ~~to the department, or its designee,~~ all analytical test results for all public water supply systems (PWS)~~ies in a manner acceptable to the department, using forms, including electronic forms, provided or approved by the department or by electronic means acceptable to the department.~~ 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~~public water supply~~ 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 ~~of the laboratory~~ to correctly assign and track the sample identification number, ~~as well as~~ 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~~which~~ includes samples collected for compliance purposes ~~from such locations as the source/entry point and in the distribution system,~~ at various sampling frequencies;
- Repeat: a sample that~~which~~ 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 ~~at~~ by the same laboratory ~~from which~~ that analyzed the associated original routine sample ~~was analyzed~~;
- Confirmation: a sample that~~which~~ verifies a routine sample, normally used ~~in~~ to determin~~ation of~~ compliance with a health-based standard~~, such as nitrate~~;
- 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 ~~which is~~ collected at the maximum residence time location in the distribution system, usually for disinfection byproduct measurement; and
- Replacement: a sample that~~which~~ 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:

- ~~Monthly Operation Report (~~MOR~~)~~ data that~~which has been~~ is ~~specifically~~ required by the department to

demonstrate compliance with public health standards; and

- ~~Chemical results not required to be analyzed but which are detected during analysis, such as detection of a synthetic organic chemical during a routine analysis of that related analytical series for compliance reporting; 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 ~~the~~ 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.~~; or~~
- ~~Results for contaminants that are not required by the department to be analyzed, which are below detection level~~.

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

(2) Certified laboratories must report all analytical results to the PWS~~public water supply~~ 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 ~~the~~ 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 method acceptable to the department, and to the PWS~~public water supply~~ for which the analyses were conducted:

1. Results of positive routine coliform bacteria samples, and all repeat and follow-up samples; and~~,reported within 24 hours of the completion of each sample's analysis.~~
2. Results of any contaminant that~~which~~ exceeds public drinking water standards (maximum contaminant level, treatment technique, action level, or health advisory), and any subsequent confirmation samples.

~~For~~ R~~r~~esults available outside of routine business hours~~, the results~~ must ~~also~~ be reported to the department's Environmental Emergency Reporting Hotline ~~number~~ at ~~(~~515~~.)~~725.~~-~~8694.

(5) If requested by the department, certified laboratories shall report their ~~method detection levels~~ MDLs, ~~levels of quantitation~~LOQs, and any other pertinent information when reporting results for PWSs~~public water supplies~~.

~~*b*~~*d. Underground storage tank UST program.* No additional information. ~~Certified laboratories must report to the client requesting the analysis and include the information required in 567—subrule 135.10~~16(2) ~~in their laboratory report.~~

~~*c*~~*e. Wastewater program.* No additional information. ~~Certified laboratories must report to the client requesting the analysis and include the information required in 567—paragraphs 63.2(2)"b" to "e" in their laboratory report.~~

~~*f*~~*d. Solid waste and contaminated site programs.* No additional information. ~~Certified laboratories must report to the client requesting the analysis and include the information required in paragraph 83.6(7)"d" and 567—subrule 103.2(8).~~

~~83.6(7) Performance evaluation (PE) and acceptance limits. All PE samples must be obtained from EPA; a provider accredited by EPA, the National Environmental Laboratory Accreditation Program (NELAP) or National Institute of Standards and Technology (NIST); or other provider acceptable to the department. All PE samples must have statistical acceptance limits. Certain environmental program areas may have specific PE requirements, as follows:~~

~~*a. Water supply program.* Laboratories must be able to achieve at least the method detection limit for each specific analyte as listed in 567—Chapter 41, in addition to any method detection limit requirement listed in this paragraph.~~

~~(1) Volatile organic chemical (VOC). Analysis for VOCs shall only be conducted by laboratories certified~~

Commented [8]: The labcert program does not have the authority to require labs to report data not regulated in permits or otherwise specified such as water quality parameters. Monitoring must be assigned for specific compounds.

Commented [9]: These tables are being removed because The NELAC Institute has adopted the drinking water criteria by reference. The tables were identical to those in the federal regulations.

~~by EPA or the department or its authorized designee according to the following conditions. To receive approval to conduct analyses for the VOC contaminants in 567—subparagraph 41.5(1)*"b"*(1), except for vinyl chloride, the laboratory must:~~

~~1. Analyze PE samples provided by EPA, the department, or a third party provider acceptable to the department, at least once a year by each method for which the laboratory desires certification.~~

~~2. Achieve the quantitative acceptance limits for at least 80 percent of the regulated organic chemicals included in the PE sample, except for vinyl chloride.~~

~~3. Achieve quantitative results on the PE samples within plus or minus 20 percent of the actual amount of the substances when the actual amount is greater than or equal to 0.010 mg/L.~~

~~4. Achieve quantitative results on the PE samples within plus or minus 40 percent of the actual amount of the substances when the actual amount is less than 0.010 mg/L.~~

~~5. Achieve a VOC method detection limit of 0.0005 mg/L.~~

~~(2) Vinyl chloride. To receive approval for vinyl chloride, the laboratory must:~~

~~1. Analyze PE samples which include vinyl chloride provided by EPA, the department, or a third party provider acceptable to the department, at least once a year by each method for which the laboratory desires certification.~~

~~2. Achieve quantitative results on the PE samples within plus or minus 40 percent of the actual amount of vinyl chloride.~~

~~3. Achieve a method detection limit of 0.0005 mg/L.~~

~~(3) Synthetic organic chemical (SOC). Analysis for SOCs shall be conducted only by laboratories certified by EPA or the department or its authorized designee. To receive approval to conduct analyses for the SOC contaminants in 567—subparagraph 41.5(1)*"b"*(2), the laboratory must:~~

~~1. Analyze PE samples which include those substances provided by EPA, the department, or a third party provider acceptable to the department, at least once a year by each method for which the laboratory desires certification.~~

~~2. For each contaminant that has been included in the PE sample, achieve quantitative results on the analyses that are within the following acceptance limits:~~

~~ACCEPTANCE LIMITS~~

~~Contaminant~~	~~Acceptance Limit, in percent~~
~~Alachlor~~	~~(+ or -) 45~~
~~Aldicarb~~	~~2 standard deviations~~
~~Aldicarb sulfoxide~~	~~2 standard deviations~~
~~Aldicarb sulfone~~	~~2 standard deviations~~
~~Atrazine~~	~~(+ or -) 45~~
~~Benzo(a)pyrene~~	~~2 standard deviations~~
~~Carbofuran~~	~~(+ or -) 45~~
~~Chlordane~~	~~(+ or -) 45~~
~~2,4-D~~	~~(+ or -) 50~~
~~Dalapon~~	~~2 standard deviations~~
~~Dibromochloropropane (DBCP)~~	~~(+ or -) 40~~
~~Di(2-ethylhexyl)adipate~~	~~2 standard deviations~~
~~Di(2-ethylhexyl)phthalate~~	~~2 standard deviations~~
~~Dinoseb~~	~~2 standard deviations~~
~~Diquat~~	~~2 standard deviations~~
~~Endothall~~	~~2 standard deviations~~
~~Endrin~~	~~(+ or -) 30~~
~~Ethylene dibromide (EDB)~~	~~(+ or -) 40~~
~~Glyphosate~~	~~2 standard deviations~~
~~Heptachlor~~	~~(+ or -) 45~~
~~Heptachlor epoxide~~	~~(+ or -) 45~~
~~Hexachlorobenzene~~	~~2 standard deviations~~
~~Hexachlorocyclopentadiene~~	~~2 standard deviations~~
~~Lindane~~	~~(+ or -) 45~~
~~Methoxychlor~~	~~(+ or -) 45~~
~~Oxamyl~~	~~2 standard deviations~~
~~Pentachlorophenol~~	~~(+ or -) 50~~

Contaminant	Acceptance Limit, in percent
Picloram	2 standard deviations
Polychlorinated biphenyls (PCBs as decachlorobiphenyl)	0 – 200
Simazine	2 standard deviations
2,3,7,8-TCDD (Dioxin)	2 standard deviations
2,4,5-TP (Silvex)	2 standard deviations
Toxaphene	(+ or –) 45

(4) Inorganic chemical (IOC). Analysis for IOCs shall be conducted only by laboratories certified by EPA or the department or its authorized designee. To receive approval to conduct analyses for ammonia, antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nitrate, nitrite, selenium and thallium, the laboratory must:

1. Analyze PE samples provided by EPA, the department, or a third party provider acceptable to the department, at least once a year.

2. For each contaminant that has been included in the PE sample and for each method for which the laboratory desires certification, achieve quantitative results on the analyses that are within the following acceptance limits:

ACCEPTANCE LIMITS

Contaminant	Acceptance Limit
Ammonia	(+ or –) 20% at greater than or equal to 0.3 mg/L
Antimony	(+ or –) 30% at greater than or equal to 0.006 mg/L
Arsenic	(+ or –) 30% at greater than or equal to 0.003 mg/L
Asbestos	2 standard deviations based on study statistics
Barium	(+ or –) 15% at greater than or equal to 0.15 mg/L
Beryllium	(+ or –) 15% at greater than or equal to 0.001 mg/L
Cadmium	(+ or –) 20% at greater than or equal to 0.002 mg/L
Chromium	(+ or –) 15% at greater than or equal to 0.01 mg/L
Cyanide	(+ or –) 25% at greater than or equal to 0.1 mg/L
Fluoride	(+ or –) 10% at greater than or equal to 1 to 10 mg/L
Mercury	(+ or –) 30% at greater than or equal to 0.0005 mg/L
Nitrate	(+ or –) 10% at greater than or equal to 0.4 mg/L
Nitrite	(+ or –) 15% at greater than or equal to 0.4 mg/L
Selenium	(+ or –) 20% at greater than or equal to 0.01 mg/L
Thallium	(+ or –) 30% at greater than or equal to 0.002 mg/L

(5) Lead and copper. To obtain certification to conduct analyses for lead and copper, laboratories must:

1. Analyze PE samples that include lead and copper provided by EPA, the department, or a third party provider acceptable to the department, at least once a year by each method for which the laboratory desires certification; and

2. Achieve quantitative results on the analyses that are within the following acceptance limits:

- Lead: plus or minus 30 percent of the actual amount in the PE sample when the actual amount is greater than or equal to 0.005 mg/L. The practical quantitation level or PQL for lead is 0.005 mg/L; and
- Copper: plus or minus 10 percent of the actual amount in the PE sample when the actual amount is greater than or equal to 0.050 mg/L. The practical quantitation level or PQL for copper is 0.050 mg/L; and

3. Be currently certified by EPA or the department to perform analyses to the specifications described in 567—paragraph 41.4(1)*"g."*

(6) Disinfection byproducts. To obtain certification to conduct analyses for disinfection byproducts listed in 567—paragraph 41.6(1)*"b,"* laboratories must:

1. Analyze PE samples approved by EPA, the department, or a third party provider acceptable to the department at least once during each period of 12 consecutive months by each method for which the laboratory desires certification;

2. Achieve quantitative results on the PE sample analyses that are within the following acceptance limits:

Disinfection Byproduct	Acceptance limits (plus or minus this percent of true value)	Comments
TTHM	-	Laboratory must meet all four individual THM acceptance limits in order to successfully pass a PE sample for TTHM.
— Bromoform	20	-
— Bromodichloromethane	20	-

Disinfection Byproduct	Acceptance limits (plus or minus this percent of true value)	Comments
— Chloroform	20	-
— Dibromomethane	20	-
HAA5	40	Laboratory must meet the acceptance limits for 4 of the 5 HAA5 compounds in order to successfully pass a PE sample for HAA5.
— Monobromoacetic Acid	40	-
— Dibromoacetic Acid	40	-
— Monochloroacetic Acid	40	-
— Dichloroacetic Acid	40	-
— Trichloroacetic Acid	40	-
Chlorite	30	-
Bromate	30	-

3. Report quantitative data for concentrations at least as low as the levels listed in the following table for all disinfection byproduct samples analyzed for compliance with 567—41.6(455B).

Disinfection Byproduct	Minimum reporting level, mg/L1	Comments
TTHM2	-	-
— Bromoform	0.0010	-
— Bromodichloromethane	0.0010	-
— Chloroform	0.0010	-
— Dibromomethane	0.0010	-
HAA52	-	-
— Monobromoacetic Acid	0.0010	-
— Dibromoacetic Acid	0.0010	-
— Monochloroacetic Acid	0.0020	-
— Dichloroacetic Acid	0.0010	-
— Trichloroacetic Acid	0.0010	-
Chlorite	0.020	Applicable to chlorite monitoring conducted by a certified laboratory required under 567—paragraphs 41.6(1)*"c"*(3)"2" and 41.6(1)*"c"*(3)"3"
Bromate	0.0050 or 0.0010	Laboratories that use EPA Method 317.0 Revision 2, 321.8, or 326.0 must meet a 0.0010 mg/L MRL for bromate.

1The calibration curve must encompass the regulatory minimum reporting level (MRL) concentration. Data may be reported for concentrations lower than the regulatory MRL as long as the precision and accuracy criteria are met by analyzing an MRL check standard at the lowest reporting limit chosen by the laboratory. The laboratory must verify the accuracy of the calibration curve at the MRL concentration by analyzing an MRL check standard with a concentration less than or equal to 100 percent of the MRL with each batch of samples. The measured concentration for the MRL check standard must be plus or minus 50 percent of the expected value, if any field sample in the batch has a concentration less than five times the regulatory MRL. Method requirements to analyze higher concentration check standards and meet tighter acceptance criteria for them must be met in addition to the MRL check standard requirement.

2When adding the individual trihalomethanes or haloacetic acid concentrations to calculate the TTHM or HAA5 concentrations, respectively, a zero is used for any analytical result that is less than the MRL concentration for that disinfection byproduct, unless otherwise specified by the department.

b. Underground storage tank program. A laboratory must achieve acceptable results on PE samples every 12 months within plus or minus 20 percent of the true value for individual compounds (i.e., benzene, ethylbenzene, toluene, xylene by OA-1) and plus or minus 40 percent of the true value for multicomponent materials (i.e., gasoline, diesel fuel, motor oil by either OA-1 or OA-2). The PE samples must be provided by EPA, the department, or a third-party provider acceptable to the department.

c. Wastewater program. Achieve acceptable quantitative results every 12 months on PE samples equivalent to those used in the Water Pollution (WP) proficiency program, or the Discharge Monitoring Report Quality Assurance (DMRQA) program, both of which are administered by EPA or its designee.

d. Solid waste and contaminated site programs. Achieve acceptable quantitative results every 12 months on PE samples provided by EPA, the department, or a third-party provider acceptable to the department.`

83.56(8) *Record-keeping.*

a. Appraisal authority. The laboratory certification program appraisal authority must retain the records for on-site laboratory assessments audits and certification program reviews. The records must be maintained in an easily accessible manner for a period of at least six years, to 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, performance

~~evaluation/proficiency testing~~ 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.

~~[**ARC 9915B**, IAB 12/14/11, effective 1/18/12; **ARC 3735C**, IAB 4/11/18, effective 5/16/18]~~

Commented [10]: This section was added because laboratories routinely ask about record retention requirements.

567—83.6~~7~~(455B) Criteria and procedure for provisional, suspended, and revoked laboratory certification.

83.6(1) *Voluntary withdrawal of certification.* A laboratory may voluntarily withdraw certification for an analyte, a related analytical series, an environmental program area, or the entire laboratory at any time in lieu of receiving a downgraded certificate with a provisional, suspended, or revoked status.

83.6~~7~~(~~1~~2) *Provisional certification criteria.*

a. The department may downgrade certification to ~~"~~provisional~~"~~ status based on cause. The reasons for which a laboratory may be downgraded to ~~"~~provisionally certified~~"~~ status include, but are not limited to, the following list.

(1) Failure to analyze a performance evaluation (~~PE~~PT) sample annually within ~~Iowa~~ acceptance limits;

(2) Failure to notify the department within ~~15 days~~the time period specified in 83.5(3) of changes in essential personnel, equipment, laboratory facilities, or other major changes that~~which~~ might impair analytical capability;

(3) Failure to satisfy the department that the laboratory is maintaining the required standard of quality based on an on-site ~~visit~~audit;

(4) Failure to report compliance data in a timely manner to the department or the client, thereby preventing timely compliance with environmental program regulations.

b. The department may assess an administrative penalty for a laboratory's failure to comply with the laboratory certification or reporting requirements.

~~*c.* A laboratory will not be granted provisional certification by the department for water supply contaminants which pose an acute risk to human health, including nitrate, nitrite, and *Escherichia coli* bacteria.~~

83.6~~7~~(~~2~~3) *Provisional certification procedure.*

a. Laboratory n~~N~~otification. ~~to the laboratory.~~ If a laboratory is subject to a downgrad~~e~~ing to ~~"~~provisional~~"~~ status on the basis of 83.6~~7~~(~~1~~2), the department will notify the laboratory or owner in writing of the downgraded status. Certification may be downgraded to provisional for an analyte, a related analytical series, an environmental program area, or the entire laboratory.

b. Reporting. A provisionally certified laboratory may continue to analyze samples for compliance purposes. ~~, but must notify the laboratory's IDNR-regulated clientele and other state certifying agencies of the change in laboratory certification status. If there is cause to question the quality of the data generated by the laboratory, the department may suspend the laboratory's ability to submit data to the department for any or all analytes, pursuant to 83.7(3), which includes suspension of the ability of the laboratory's client to report the data of questionable quality to the department~~.

c. Right to appeal. There is no appeal for this process, as it does not affect a laboratory's ability to analyze compliance samples and report to the department.

d. Correction of deficiencies.

~~(1) If a laboratory failed to analyze a PE sample within acceptance limits, the laboratory has 60 days from receipt of the notification of the failure to identify and correct the problem to the department's satisfaction, and analyze a second PE sample.If the laboratory fails to analyze this second sample within acceptance limits and~~

Commented [11]: This section was reworked to conform with state regulations regarding contested cases. Overall, the new language favors laboratories versus the old language.

~~has had acceptable PE sample results within the last year, the department will downgrade the laboratory to "provisionally certified" status and notify the laboratory in writing.~~

(~~2~~1) Once the department notifies a laboratory in writing that it has been downgraded to "provisionally certified" status, the laboratory must correct the problem within the following time frames, unless a written extension is obtained from the department. If the problem is not corrected, the laboratory is subject to suspension ~~or revocation~~ for that analyte, related analytical series, environmental program area, or the entire laboratory.

1. Unacceptable ~~PE~~PT sample result within two months of notification.
2. Procedural deficiency within three months of notification.
3. Administrative deficiency within three months of notification.
4. ~~Minor~~E~~e~~quipment deficiency within three months of notification. ~~Examples of a minor equipment deficiency are inadequate analytical balances or incubators.~~

(~~3~~2) The laboratory shall~~review the problems cited and, within the time period designated by the department, specify in writing to the department the corrective actions being taken, including an appropriate implementation schedule~~ submit a corrective action report(s) including documentation that demonstrates the laboratory has complied with the required corrective actions. ~~The department shall consider the adequacy of the response and notify the laboratory of its certification status in a timely basis by mail, and may follow up to ensure corrective actions have been taken.~~

e. Reinstatement. Certification will be reinstated when the laboratory can demonstrate that all conditions for laboratory certification have been met to ~~the satisfaction of the department~~ the department's satisfaction and that the deficiencies that~~which~~ caused~~resulted in~~ provisional certification status have been corrected. ~~This may include an on-site visit, successful analysis of PE samples, or any other measure that the department deems appropriate.~~ The SHL may conduct an on-site audit to verify that corrective actions have been implemented.

83.6~~7~~(~~34~~) *Suspended certification criteria.*

a. The department may downgrade certification to "suspended" status based on cause. The reasons for which a laboratory may be downgraded to "suspended" status include, but are not limited to, the following: ~~list.~~

(1) Failure to analyze a ~~PE~~PT sample annually within acceptance limits; ~~for water supply contaminants which pose an acute risk to human health, including nitrate, nitrite, and *Escherichia coli* bacteria, or which pose an imminent risk to the environment;~~

~~(2) Failure to analyze a PE sample annually within Iowa acceptance limits for water supply contaminants which pose an acute risk to human health, including nitrate, nitrite, and *Escherichia coli* bacteria, or which pose an imminent risk to the environment;~~

(~~3~~2) Failure to correct previously identified deficiencies, which resulted in "provisional" certification status, within the prescribed time frames of 83.6~~7~~(~~23~~)*"d"*(1);

~~(4) Failure to analyze a PE sample within Iowa acceptance limits when there is not a reliable history of successful PE sample analysis within the past 12 months~~;

(~~5~~3) Failure to satisfy the department that the laboratory is producing accurate data; ~~or~~

(4) Failure to use required analytical methodology for analyses submitted to the department; or

(5) Repeated failure to report compliance data in a timely manner.

b. Administrative penalty. The department may assess an administrative penalty for a laboratory's failure to comply with the laboratory certification or reporting requirements.

c. Emergency certification suspension. The department may suspend certification without providing notice and opportunity to the laboratory to be heard if the department finds that the public health, safety, or welfare imperatively requires emergency action, and incorporates a finding to that effect in its administrative order, pursuant to 561—Chapter 7~~subrule 7.16(6)~~.

83.6~~7~~(~~45~~) *Suspended certification procedure.*

a. Laboratory notification.~~Notification to the laboratory~~. If a laboratory is subject to downgrading to "suspended" status on the basis of 83.6~~7~~(~~43~~), the department will notify the laboratory or owner in writing of its intent to suspend certification in accordance with 561—Chapter 7~~561—7.16(17A,455A)~~. Certification may be suspended for an analyte, a related analytical series, an environmental program area, or the entire laboratory.

b. Reporting. Once the suspension is effective, a laboratory must immediately discontinue analysis and

Commented [12]: This section will be revised to conform with 567 IAC Chapter 7 – Rules of Practice in Contested Cases. Chapter 7 is being revised as part of EO10.

reporting of compliance samples, may not analyze or report samples for compliance with departmental standards, and must notify the laboratory's Iowa regulated clientele and other state certifying agencies of the change of the laboratory certification status within three days. Any results generated during the period of suspension may not be used for compliance purposes by the department.

c. Right to appeal.

(1) The laboratory may appeal this decision by filing a written notice of appeal and request an administrative hearing with the department director within 30 days of receipt of the notice of suspension of certification. Contested case procedures under 561—Chapter 7 shall govern administration of the appeal. The appeal must identify the specific portion(s) of the department action being appealed, and be supported with a statement of the reason(s) for the challenge, and must be signed by a responsible official from the laboratory. such as the president or owner for a commercial laboratory, or the laboratory supervisor in the case of a municipal laboratory, or the laboratory director for a state laboratory.

(2) If no timely notice of appeal is filed, suspension is effective 30 days after receipt of the notice of suspension unless an emergency suspension order is in effect.

d. Correction of deficiencies.

(1) If a laboratory failed to analyze a PE sample within acceptance limits, the laboratory has 30 days from receipt of the notification of the failure to identify and correct the problem to the department's satisfaction. If the laboratory fails to analyze this second sample within acceptance limits, the department will downgrade the laboratory to "suspended" status and notify the laboratory in writing.

(21) Once the department notifies a laboratory in writing that it has been downgraded to suspended status, the laboratory must correct the problem within the following timetable, unless a written extension is obtained from the department. If the problem is not corrected, the laboratory is subject to revocation for that analyte, related analytical series, environmental program area, or the entire laboratory.

1. Unacceptable PEPT sample result within two months of notification.
2. Procedural deficiency within three months of notification.
3. Administrative deficiency within three months of notification.
4. Minor Eequipment deficiency within three months of notification. Examples of a minor equipment deficiency are inadequate analytical balances or incubators.
5. Major equipment deficiency within six months of notification. An example of a major equipment deficiency would be the inability of existing complex analytical equipment to produce acceptable results, such as a chromatograph or spectrophotometer.

(32) The laboratory shall review the problems cited and, within the time period designated by the department, specify in writing to the department the corrective actions being taken including an appropriate implementation schedulesubmit a corrective action report(s) including documentation that demonstrates the laboratory has complied with the required corrective actions. The department shall consider the adequacy of the response and notify the laboratory of its certification status in a timely basis by mail, and may follow up to ensure that corrective actions have been taken.

e. Reinstatement.

(1) Fee.

1. The laboratory will not be required to pay an additional fee if recertification affects an analyte or related analytical series, provided that:

- The laboratory is currently certified for other analytes, or
- A fee was paid within the two-year certification period for that related analytical series and the laboratory is certified for other parameters within that related analytical series.

2. A fee will be is required if when suspension affects a related analytical series, effectively deleting that fee group from certification (such as all microbiological parameters in SDWA-MICRO), an environmental program area, or the entire laboratory. A fee will is also be required if an additional on-site visitaudit is required.

(2) Certification will be reinstated when the laboratory can demonstrate that all conditions for laboratory certification have been met to the department's satisfaction and , in particular, that the deficiencies thatwhich produced caused the suspension have been corrected. This may include an on-site visitaudit, successful analysis

of unknown samples, or any other measure that the department deems appropriate.

83.67(56) *Revoked certification criteria.*

a. The department may revoke certification for cause. The reasons for which a laboratory's certification may be revoked include, but are not limited to, the following:

~~(1) For laboratories of any status, failure to analyze a PE sample within Iowa acceptance limits;~~

(21) Failure ~~to satisfy the department that the laboratory has correct~~to corrected deficiencies according to the time period specified in 83.6(5)*"d"*(1); ~~identified during the on-site visit within three months for a procedural or administrative deficiency or within six months for an equipment deficiency~~;

(32) Submission of a ~~PE~~PT sample to another laboratory for analysis and reporting the data as its own;

(43) Falsification of data or other deceptive practices;

(54) Failure to use required analytical methodology for analyses submitted to the department;

(65) Failure to satisfy the department that the laboratory is maintaining the required standard of quality based on the on-site ~~visit~~audit;

(76) Persistent failure to report compliance data to the regulated client or the department in a timely manner, thereby preventing compliance with state regulations and endangering public health;

(87) Subverting compliance with state regulations by actions such as changing the sample type for a noncompliance sample to a compliance sample after its submission to the laboratory, allowing compliance samples to be changed to other noncompliance sample types, or selective reporting of split sample results; or

(98) For laboratories certified through a reciprocal agreement with another state or third-party accreditation program, loss of certification in either the resident state or third-party accreditation program is cause for immediate revocation of certification in Iowa for the same parameters or program areas for which certification was lost.

b. ~~The department may either downgrade or revoke certification based on cause.~~ The department may assess an administrative penalty for a laboratory's failure to comply with the laboratory certification or reporting requirements.

c. Emergency revocation. The department may revoke certification without providing notice and opportunity to the laboratory to be heard if the department finds that the public health, safety, or welfare imperatively requires emergency action, and incorporates a finding to that effect in its administrative order, pursuant to 561—~~subrule 7.16(6)~~Chapter 7.

d. Laboratory-requested revocation (withdrawal of certification). The department may revoke certification upon receipt of a written request by the certified laboratory for removal from the certification program.

83.67(67) *Revoked certification procedure.*

a. *Laboratory notification.* ~~*Notification to the laboratory.*~~ Except for the instance when the laboratory voluntarily requests revocation in 83.67(56)*"d,"* if a laboratory is subject to revocation on the basis of 83.67(56), the department will notify the party in writing of its intent to revoke certification in accordance with 561—Chapter 7~~561—7.16(17A,455A)~~. Certification may be revoked for an analyte, a related analytical series, an environmental program area, or the entire laboratory.

b. *Reporting.* Once revocation is effective, a laboratory must immediately discontinue analysis and reporting of compliance samples, shall not analyze or report samples for compliance with departmental standards, and must notify the laboratory's Iowa-regulated clientele and other state certifying agencies of the change of the laboratory certification status within three business days of receipt of the final notice. Any results generated after revocation may not be used for compliance purposes by the department.

c. *Right to appeal.* ~~There is no appeal process for revocation of an analyte or a related analytical series unless the analyte(s) represents an entire environmental program area, such as underground storage tank parameters, or the entire laboratory.~~When a~~the~~ laboratory requests revocation pursuant to 83.67(56)*"d,"* the revocation will be issued promptly and will be effective immediately with no appeal process.

(1) ~~For an environmental program area or for the entire laboratory, the~~ The laboratory may appeal this decision by filing a written notice of appeal and request for an administrative hearing with the department director within 30 days of receipt of the notice of revocation of certification. Contested case procedures under 561—Chapter 7 shall govern further administration of the appeal. The appeal must identify the specific portion(s)

Commented [13]: This section will be revised to conform with 567 IAC Chapter 7 – Rules of Practice in Contested Cases. Chapter 7 is being revised as part of EO10.

of the department action being appealed, ~~and~~ be supported with a statement of the reason(s) for the challenge, and ~~must~~ be signed by a responsible official, ~~from the laboratory such as the president or owner for a commercial laboratory, or the laboratory supervisor in the case of a municipal laboratory, or the laboratory director for a state laboratory.~~

(2) If no timely notice of appeal is filed within the 30-day time period, revocation is effective 30 days after receipt of the notice of revocation~~intent~~.

d. Reinstatement. A laboratory that~~which~~ has had its certification revoked may apply for certification in accordance with rule 567—83.3(455B) once the deficiencies have been corrected.

~~[**ARC 3735C**, IAB 4/11/18, effective 5/16/18]~~

These rules are intended to implement Iowa Code sections 455B.113 through 455B.115.

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~~[1] Effective date of 42.2(1)"*b*"(9) and (10) delayed 70 days by the Administrative Rules Review Committee at its meeting held November 10, 1992.~~

~~[2] Effective date of Ch 83 delayed 70 days by the Administrative Rules Review Committee at its meeting held May 14, 1996.~~