

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 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 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 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.

a. Water supply (drinking water). The requirements of this chapter apply to all laboratories conducting drinking water analyses (with the exception of the University of Iowa Hygienic Laboratory) pursuant to 567—Chapters 40, 41, 42, 43, and 47. Routine, on-site monitoring for pH, turbidity, and chlorine residual and on-site operation and maintenance-related analytical monitoring are excluded from this requirement.

b. Underground storage tanks. The requirements of this chapter also apply to all laboratories conducting underground storage tank analyses (with the exception of the University of Iowa Hygienic Laboratory) for petroleum constituents pursuant to 567—Chapter 135. Routine on-site monitoring conducted by or for underground storage tank owners for leak detection or a nonregulatory purpose are excluded from this requirement.

c. Wastewater. The requirements of this chapter also apply to all laboratories conducting analyses of wastewater, groundwater or sewage sludge (with the exception of the University of Iowa Hygienic Laboratory) pursuant to 567—Chapters 63, 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.

567—83.2(455B) Definitions.

“*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.

“*Environmental program area*” means the water supply (drinking water) program, underground storage tank program, or wastewater program pursuant to 83.1(3).

“*Manual for the Certification of Laboratories Analyzing Environmental Samples for the Iowa Department of Natural Resources*” (1999) (Iowa Manual) is incorporated by reference in this chapter.

1. 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, 4th edition, March 1997, EPA document 815-B-97-001.

2. Chapter 2 of the Iowa Manual pertains to laboratories analyzing samples for the underground storage tank program.

3. Chapter 3 of the Iowa Manual pertains to laboratories analyzing samples for the wastewater and sewage sludge disposal programs.

“Performance evaluation sample (PE)” 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.

“Provisional certification” means a laboratory has deficiencies, which must be corrected within the specified time frames listed in 83.7(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.

“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 (455B.114).

“Suspended certification” means a temporary suspension of certification for a laboratory, conditional upon meeting the time frames in 83.7(4)“d” for the correction of the deficiency.

“Temporary certification” means short-term transitional certification granted in certain circumstances when the department implements certification in a new environmental program area.

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 forms provided by the department and shall be accompanied by the nonrefundable fee specified in 83.3(2). The application for 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 must be supplied to the department prior to the on-site visit. Failure to submit a complete application may result in denial of the renewal.

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 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 is not performed.

(2) Out-of-state laboratories will be responsible for paying the expenses of an on-site visit, 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 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) Any laboratory requiring additional on-site visits is responsible for paying the expenses of the additional on-site visits. The department or its agent will bill the laboratory directly for these expenses. The laboratory certification fees will be increased by \$300 per visit in those cases where multiple on-site visits are necessary.

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. The applicable fees shall be based on the type of analytical service provided as follows. The fee for certification of a single analyte, or for any analyses not covered in subparagraphs (1) to (4) below, shall be \$300.

(1) Water supply laboratory certification fees.

1. The fee for microbiological analyses including total coliform, fecal coliform, *E. coli*, heterotrophic bacteria, viruses, algae, diatoms, rotifers, and *Giardia* shall be \$600. Laboratories may also be certified for fluoride, nitrate and nitrite with no additional fee (when they are certified for microbiological analyses) providing they are not seeking certification for any other inorganic analyte.

2. The fee for inorganic analyses including nitrate, nitrite, fluoride, arsenic, sodium, and other inorganics shall be \$1,200. However, a laboratory certified to conduct inorganic analyses under the wastewater program may be certified to conduct inorganic analyses under the water supply program for an additional \$300 (\$1,500 total).

3. The fee for volatile organic chemical analyses such as benzene and trichloroethylene shall be \$1,200. However, a laboratory certified to conduct analyses for volatile organic chemicals under the wastewater program may be certified to conduct analyses for volatile organic compounds under the water supply program for an additional \$600 (\$1,800 total).

4. The fee for synthetic (nonvolatile) organic chemical analyses such as atrazine and pentachlorophenol shall be \$1,200. However, a laboratory certified to conduct analyses for synthetic organic chemicals under the wastewater program may be certified to conduct analyses for synthetic organic chemicals under the water supply program for an additional \$600 (\$1,800 total).

5. The fee for chemical analyses for dioxins shall be \$600.

6. The fee for asbestos fiber analyses shall be \$300.

7. The fee for analyses of radionuclides shall be \$300. However, a laboratory certified to conduct radionuclide analyses under the wastewater program may be certified to conduct the same analyses for the water supply program for an additional \$100 (\$400 total).

8. The fee for certification of Information Collection Rule (ICR) parameters shall be \$300.

(2) Underground storage tank laboratory certification fees. The fee for analyses for petroleum constituents using methods OA-1 and OA-2 shall be \$1,200. However, a laboratory certified to conduct analyses for petroleum constituents under the wastewater program may be certified to conduct the same analyses for the underground storage tank program for an additional \$300 (\$1,500 total).

(3) Wastewater program laboratory certification fees.

1. The fee for analyses of basic wastewater constituents which includes biochemical oxygen demand (BOD), carbonaceous biochemical oxygen demand (CBOD), total suspended solids (TSS), and ammonia nitrogen (NH₃) shall be \$300.

2. The fee for microbiological analyses shall be \$600.

3. The fee for effluent toxicity analyses shall be \$600.

4. The fee for inorganic analyses shall be \$300 per analyte to a maximum of \$1,200. However, a laboratory certified to conduct inorganic analyses under the water supply program may be certified to conduct inorganic analyses under the wastewater program for an additional \$300 (\$1,500 total).

5. The fee for synthetic (nonvolatile) organic chemical analyses shall be \$1,200. However, a laboratory certified to conduct analyses for synthetic organic chemicals under the water supply program may be certified to conduct analyses for synthetic organic chemicals under the wastewater program for an additional \$600 (\$1,800 total).

6. The fee for volatile organic chemical analyses shall be \$1,200. However, a laboratory certified to conduct analyses for volatile organic chemicals under the water supply program may be certified to conduct analyses for volatile organic compounds under the wastewater program for an additional \$600 (\$1,800 total).

7. The fee for analyses for petroleum products using methods OA-1 or OA-2 shall be \$1,200. However, a laboratory certified to conduct analyses for petroleum constituents under the underground storage tank program may be certified to conduct the same analyses for the wastewater program for an additional \$300 (\$1,500 total).

8. The fee for analyses of radionuclides shall be \$300. However, a laboratory certified to conduct radionuclide analyses under the water supply program may be certified to conduct the same analyses for the wastewater program for an additional \$100 (\$400 total).

(4) The fee for certification of a single analyte, or for any analyses not covered by subparagraphs (1) to (3), shall be \$300.

d. Payment of fees. Fees shall be paid by bank draft, check, money order, or other means acceptable to the department, made payable to the Iowa Department of Natural Resources. Purchase orders are not an acceptable form of payment.

83.3(3) Reciprocity. Reciprocal certification of out-of-state laboratories by Iowa, and of Iowa laboratories by other states or accreditation providers, is encouraged. A laboratory must meet all Iowa certification criteria and pay all applicable fees, pursuant to 567—Chapter 83. Any laboratory 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 14 days of notification.

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

b. Third-party accreditation. The department may accept third-party accreditation from national accreditation providers on an individual basis.

567—83.4(455B) Procedure for initial laboratory certification for wastewater laboratories. Rescinded IAB 8/11/99, effective 9/15/99.

567—83.5(455B) Procedures for 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 567—83.6(455B) for laboratory recertification. For changes in certification, the relevant fee must accompany the application where appropriate.

567—83.6(455B) Laboratory recertification. Laboratories shall be recertified every two years after initial certification. Applications for recertification must be on forms provided by the department and must be postmarked at least 60 days prior to the renewal date. Applications shall be accompanied by the fee specified in 83.3(2). To be recertified, laboratories must meet the following requirements.

83.6(1) Laboratories must use the approved methodology for all analyses the results of which are to be submitted to the department. A laboratory may not analyze and report data from samples collected for an environmental program area until certified in that area.

83.6(2) Certified laboratories must satisfactorily analyze PEs at least once every 12 months for each analyte by each method for which the laboratory wishes to retain certification unless a PE sample is not available for the particular analyte or method. Results must be submitted to Iowa department of natural resources or as otherwise directed, along with a statement of the method used within 30 days of receipt from the provider. The laboratory must maintain records of all PE samples for a minimum of 5 years.

83.6(3) Laboratories must notify the department, in writing, within 30 days of major changes in essential personnel, equipment, laboratory location, or other major change which might alter or impair analytical capability. Examples of a major change in essential personnel are 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.

83.6(4) Site visits.

(1) Certification of the University of Iowa Hygienic Laboratory (UHL), as the designee of the department for appraisal authority, is the responsibility of the UHL quality assurance officer. The quality assurance officer reports directly to the office of the 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 UHL and review results for acceptable performance. Inadequacies or unacceptable performance shall be reported by the quality assurance officer to the UHL and the department for correction. The department shall be notified if corrective action is not taken.

(2) Laboratories must consent to a periodic site visit by the department or its designee, at least every two years. However, an on-site visit may be conducted more frequently if the laboratory undergoes a major change which may alter or impair analytical capability, fails a PE sample analysis, or if the department questions an aspect of data submitted which is not satisfactorily resolved.

83.6(5) Period of validity. 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 provided a laboratory has submitted a timely and complete application, until certification is either renewed or revoked.

83.6(6) Reporting requirements. Laboratories may not analyze or report sample results for any analyte, analytical series, or environmental program area until 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. Water supply program.

(1) Certified laboratories must report to the department, or its designee such as the University Hygienic Laboratory, all analytical test results for all public water supplies, using forms provided or approved by the department or by electronic means acceptable to the department. If a 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. It is the responsibility of the laboratory to correctly assign and track the sample identification number as well as 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 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 which must be collected after a positive result from a routine or previous repeat total coliform sample, per 567—41.2(455B);
- Confirmation: a sample which verifies a routine sample, normally used in determination of compliance with a health-based standard, such as nitrate;
- Special: a nonroutine sample, such as raw, plant, and troubleshooting samples;
- Maximum residence time: a sample which is collected at the maximum residence time location in the distribution system, usually for total trihalomethane measurement; and
- Replacement: a sample 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 which has been specifically required by the department to demonstrate compliance with public health standards;

- 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 laboratory to the department:

- Routine MOR data;
- Distribution samples for the Total Coliform Rule 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 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 public water supply for which the analyses were performed.

(3) Analytical results must be reported to and received by the department's designee 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 to the department by facsimile transmission (fax) or other method acceptable to the department, and to the public water supply for which the analyses were conducted:

1. Results of positive coliform bacteria samples and their associated repeat and follow-up samples.

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

b. Underground storage tank program. Certified laboratories must report to the person requesting the analysis and include the information required in 567—subrule 135.10(2) in their laboratory report.

c. Wastewater program. Certified laboratories must report to the person requesting the analysis and include the information required in 567—paragraphs 63.2(2)“b” to “e” in their laboratory report.

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. In addition to the analytes specifically listed in 83.6(7)“a,” PE samples are required for certification of the unregulated and discretionary compounds listed in 567—Chapter 41, using statistical acceptance limits determined by the PE sample provider.

(1) Volatile organic chemical (VOC) PE laboratory certification. Analysis for VOCs shall only be conducted by laboratories certified 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 its designee, at least once a year.
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) To receive approval for vinyl chloride, the laboratory must:
 1. Analyze PE samples which include vinyl chloride provided by EPA, the department, or its authorized designee, at least once a year.
 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 chemicals (SOCs) PEs—laboratory certification. Analysis under this paragraph shall only be conducted 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 its authorized designee, at least once a year.

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

<u>Contaminant</u>	<u>Acceptance Limit, in percent</u>
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
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 PE—laboratory certification. Analysis under this paragraph shall be conducted only by laboratories certified by EPA or the department or its authorized designee. To receive approval to conduct analyses for antimony, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite, selenium and thallium, the laboratory must:

1. Analyze PE samples which include those substances provided by EPA, the department, or its designee, at least once a year.

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

<u>Contaminant</u>	<u>Acceptance Limit</u>
Antimony	(+ or -) 30% at greater than or equal to 0.006 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
Nickel	(+ or -) 15% at greater than or equal to 0.01 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 PE—laboratory certification. To obtain certification to conduct analyses for lead and copper, laboratories must:

1. Analyze PE samples which include lead and copper provided by EPA, the department, or its designee, at least once a year; and

2. Achieve quantitative acceptance limits as follows:

- 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;

3. Achieve method detection limits as follows:

- Lead: 0.001 mg/L (only if source water compositing is done); and
- Copper: 0.001 mg/L or 0.020 mg/L when atomic absorption direct aspiration is used (only if source water compositing is done);

4. Be currently certified by EPA or the department to perform analyses to the specifications described in 567—paragraph 41.4(1)“g.”

b. Underground storage tank program. A laboratory must achieve quantitative 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).

c. Wastewater program. Achieve acceptable quantitative results on PE samples every 12 months 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.

567—83.7(455B) Criteria and procedure for provisional, suspended, and revoked laboratory certification.**83.7(1) 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) sample annually within Iowa acceptance limits;
- (2) Failure to notify the department within 30 days of changes in essential personnel, equipment, laboratory facilities or other major change 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;
- (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 contaminants which pose an acute risk to human health, including nitrate, nitrite, fecal coliform bacteria, and *Escherichia coli* bacteria.

83.7(2) Provisional certification procedure.

a. *Notification to the laboratory.* If a laboratory is subject to downgrading to “provisional” status on the basis of 83.7(1), 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 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 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) 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 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 equipment deficiency within three months of notification. Examples of a minor equipment deficiency are inadequate analytical balances or incubators.

(3) 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. 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 and that the deficiencies which resulted in provisional certification status have been corrected. This may include an on-site visit, successful analysis of unknown samples, or any other measure that the department deems appropriate.

83.7(3) 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 sample annually for contaminants which pose an acute risk to human health, including nitrate, nitrite, fecal coliform bacteria, 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 contaminants which pose an acute risk to human health, including nitrate, nitrite, fecal coliform bacteria, and *Escherichia coli* bacteria, or which pose an imminent risk to the environment;

(3) Failure to correct previously identified deficiencies, which resulted in “provisional” certification status, within the prescribed time frames of 83.7(2) “d”;

(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) Failure to satisfy the department that the laboratory is producing accurate data.

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 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—subrule 7.16(6).

83.7(4) Suspended certification procedure.

a. Notification to the laboratory. If a laboratory is subject to downgrading to “suspended” status on the basis of 83.7(3), the department will notify the laboratory or owner in writing of its intent to suspend certification in accordance with 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 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. 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.

(2) 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 PE 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 equipment 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.

(3) 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. 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 required if 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 also be required if an additional on-site visit 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 which produced the suspension have been corrected. This may include an on-site visit, successful analysis of unknown samples, or any other measure that the department deems appropriate.

83.7(5) Revoked certification criteria.

a. A laboratory may have its certification revoked for cause including, but not limited to, any of the following reasons.

- (1) For laboratories of any status, failure to analyze a PE sample within Iowa acceptance limits;
- (2) Failure to satisfy the department that the laboratory has corrected deficiencies identified during the on-site visit within three months for a procedural or administrative deficiency or within six months for an equipment deficiency;
- (3) Submission of a PE sample to another laboratory for analysis and reporting the data as its own;
- (4) Falsification of data or other deceptive practices;
- (5) Failure to use required analytical methodology for analyses submitted to the department;

(6) Failure to satisfy the department that the laboratory is maintaining the required standard of quality based on the on-site visit.

(7) 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.

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

b. The department may either downgrade or revoke certification based on cause.

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).

83.7(6) *Revoked certification procedure.*

a. Notification to the laboratory. If a laboratory is subject to revocation on the basis of 83.7(5), the department will notify the party in writing of its intent to revoke certification in accordance with 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. A laboratory must notify the laboratory's IDNR-regulated clientele and other state certifying agencies, to which the notice of revocation is pertinent, of the department's intent to revoke certification, within 30 days of receipt of the notice.

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.

(1) For an environmental program area or for the entire laboratory, 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) 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 intent.

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

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

[Filed emergency 8/22/86—published 9/10/86, effective 8/22/86]
[Filed emergency 11/14/86—published 12/3/86, effective 12/3/86]
[Filed emergency 9/30/88—published 10/19/88, effective 9/30/88]
[Filed 9/25/92, Notice 6/10/92—published 10/14/92, effective 11/18/92]*
[Filed 3/26/93, Notice 1/20/93—published 4/14/93, effective 5/19/93]
[Filed 7/30/93, Notice 5/12/93—published 8/18/93, effective 9/22/93]
[Filed 1/27/95, Notice 11/9/94—published 2/15/95, effective 3/22/95]
[Filed 3/22/96, Notice 11/8/95—published 4/10/96, effective 5/15/96**]
[Filed 7/23/99, Notice 4/7/99—published 8/11/99, effective 9/15/99]

CHAPTERS 84 to 89
Reserved

*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.

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