

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 15 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 water supply contaminants which pose an acute risk to human health, including nitrate, nitrite, 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 PE 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 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) 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 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—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. 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;
- (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 its submission to the laboratory, allowing compliance samples to be changed to other noncompliance sample types, or selective reporting of split sample results; or

(9) 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.

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).

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

83.7(6) *Revoked certification procedure.*

a. Notification to the laboratory. Except for the instance when the laboratory voluntarily requests revocation in 83.7(5)“d,” 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. 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 the laboratory requests revocation pursuant to 83.7(5)“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 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 567—83.3(455B) once the deficiencies have been corrected.

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