

567—83.6(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(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 (PT) sample annually within acceptance limits;
- (2) Failure to notify the department within the time period specified in 83.5(3) of changes in essential personnel, equipment, laboratory facilities, or other major changes that 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 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.

83.6(3) *Provisional certification procedure.*

a. Laboratory notification. If a laboratory is subject to a downgrade to provisional status on the basis of 83.6(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.

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) 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 for that analyte, related analytical series, environmental program area, or the entire laboratory.

1. Unacceptable 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. Equipment deficiency within three months of notification.

(2) The laboratory shall submit a corrective action report(s), including documentation that demonstrates the laboratory has complied with the required corrective actions.

e. Reinstatement. Certification will be reinstated when the laboratory can demonstrate that all conditions for laboratory certification have been met to the department's satisfaction and that the deficiencies that caused provisional certification status have been corrected. The SHL may conduct an on-site audit to verify that corrective actions have been implemented.

83.6(4) *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:

- (1) Failure to analyze a PT sample annually within acceptance limits;
- (2) Failure to correct previously identified deficiencies, which resulted in provisional certification status, within the prescribed time frames of 83.6(3) "d"(1);
- (3) Failure to satisfy the department that the laboratory is producing accurate data;
- (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.

83.6(5) *Suspended certification procedure.*

a. Laboratory notification. If a laboratory is subject to downgrading to suspended status on the basis of 83.6(4), the department will notify the laboratory or owner in writing of its intent to suspend certification in accordance with 561—Chapter 7. 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 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, be supported with a statement of the reason(s) for the challenge, and be signed by a responsible official from the 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) 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 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. Equipment deficiency within three months of notification.

(2) The laboratory shall review the problems cited and, within the time period designated by the department, 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 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 is required 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 is also required if an additional on-site audit is required.

(2) Certification will be reinstated when the laboratory can demonstrate that all conditions for laboratory certification have been met and that the deficiencies that caused the suspension have been corrected. This may include an on-site audit, successful analysis of unknown samples, or any other measure that the department deems appropriate.

83.6(6) *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) Failure to correct deficiencies according to the time period specified in 83.6(5) "d"(1);
- (2) Submission of a PT sample to another laboratory for analysis and reporting the data as its own;
- (3) Falsification of data or other deceptive practices;
- (4) Failure to use required analytical methodology for analyses submitted to the department;
- (5) Failure to satisfy the department that the laboratory is maintaining the required standard of quality based on the on-site audit;
- (6) 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;
- (7) 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
- (8) 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 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—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.

83.6(7) *Revoked certification procedure.*

a. *Laboratory notification.* Except for the instance when the laboratory voluntarily requests revocation in 83.6(6) "d," if a laboratory is subject to revocation on the basis of 83.6(6), the department will notify the party in writing of its intent to revoke certification in accordance with 561—Chapter 7. 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.* When a laboratory requests revocation pursuant to 83.6(6) "d," the revocation will be issued promptly and will be effective immediately with no appeal process.

(1) 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, be supported with a statement of the reason(s) for the challenge, and be signed by a responsible official.

(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.

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

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