# ENVIRONMENTAL LABORATORY APPROVAL PROGRAM CERTIFICATION MANUAL

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#### Denial

Denial means the Department's refusal to approve, in total or in part, an environmental laboratory's application for approval, including initial approval and renewal of approval. Reasons to deny approval include the following:

- 1. Failure to submit a completed application (as detailed in Certification Manual <u>ltem 130</u>)
- 2. Failure to pay, in the specified time-frame, the required fee for initial application for approval or renewal of application for approval
- 3. Failure of laboratory staff to submit documentation showing they meet the requisite qualifications of education, training and experience as required in Certification Manual <u>Item 140</u>
- 4. Owner(s) and/or technical director(s) lack character to ensure compliance by having prior sustained administrative charges and/or criminal offense(s) (10 NYCRR Part 55, Subpart 55-2.6 (a). 7. ii and iii)
- 5. Failure to successfully analyze and report proficiency test samples as required in Certification Manual <u>Item 300</u>
- 6. Pattern of repetitive unsatisfactory performance in required proficiency testing in one or more proficiency testing categories (10 NYCRR Part 55, Subpart 55-2.6 (a). 7. iv)
- 7. Failure to provide a Quality Manual demonstrating compliance with the ELAP quality standards
- 8. Failure to provide a corrective action plan within 30 calendar days of ELAP's issuance of a deficiency report
- 9. Failure to implement the corrective actions detailed in the corrective action report within the specified time frame as required by ELAP
- 10. Failure to implement and maintain an effective quality system in compliance with the ELAP quality standards
- 11. Failure to pass an on-site assessment
- 12. Misrepresentation of any material fact pertinent to receiving or maintaining approval
- 13. Denial of entry during normal business hours for conduction of an on-site assessment

Information related to the denial process can be found in <u>10 NYCRR Part 55, Subpart</u> <u>55-2</u>.6 (a). and (b).

### Suspension

Suspension means the Department's temporary removal, in total or in part, of an environmental laboratory's approval for a period of time not exceeding six (6) months. A suspended laboratory is required, on notice of suspension, to discontinue the analysis of samples for the suspended field(s) of accreditation and to return its

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certificate(s) of approval to the ELAP office. The laboratory will normally be reinstated, without the need to reapply for approval, when the area of non-compliance has been corrected. Reasons to suspend approval include the following:

- 1. Failure to notify ELAP, within 30 calendar days, of any change in key accreditation criteria including ownership, technical director(s), location, or major equipment.
- 2. Failure to pay the required fee for continuing approval in the specified timeframe.
- 3. Failure of an on-site assessment through (a) inadequacy of the laboratory's quality system; (b) deficiencies that are repeat of deficiencies previously cited by ELAP or another NELAP Accrediting Body; or (c) a determination by the Department that the public health, safety or welfare imperatively requires emergency action.

NOTE: The finding of repeat deficiencies is taken very seriously by the Department and can result in immediate suspension. Failure to correct the repeat deficiencies will result in the total revocation of approval (see below).

- 4. Failure to maintain a passing score on proficiency testing studies, as defined in Certification Manual <u>Item 300</u>
- 5. Failure to employ staff that meet the educational, training and experience requirements listed in Certification Manual <u>Item 140</u>

A laboratory subject to suspension through failing an on-site assessment receives a notice of proposed suspension, and is then allowed ten (10) days to provide a rebuttal. Failure by the laboratory to demonstrate within this time-frame that the proposed suspension was **based on a mistake of fact** will lead to immediate suspension.

Information related to the suspension process can be found in <u>10 NYCRR Part 55</u>, <u>Subpart 55-2</u>.6 (c).

### Revocation

Revocation means the Department's withdrawal, in total or in part, of a laboratory's approval. A revoked laboratory is required, on notice of revocation, to discontinue the analysis of samples for the revoked field(s) of accreditation and to return its certificate(s) of approval to the ELAP office. Reasons to revoke approval include the following:

1. Denial of entry during normal business hours for conduction of an on-site assessment

2. Failure to pass an on-site assessment

NOTE: A pattern of deficiencies is discovered during the on-site assessment that suggests that the laboratory lacks an effective quality system.

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- 3. Failure to provide a corrective action plan within 30 calendar days of ELAP's issuance of a deficiency report
- 4. Failure to implement the corrective actions detailed in the corrective action report within the specified time frame as required by ELAP

NOTE: This includes a finding of any deficiency that is a repeat of a deficiency previously cited by ELAP or another NELAP Accreditation Body.

5. Failure to successfully analyze and report proficiency test samples as required in Certification Manual <u>Item 300</u>

NOTE: For a suspended lab, unsatisfactory performance in the next PT event results in three (3) consecutive failed PT events.

- 6. Submitting to ELAP proficiency test results that were generated by a laboratory other than the laboratory to which the samples were sent by ELAP or a proficiency test provider approved by ELAP.
- 7. Misrepresentation of any material fact pertinent to obtaining or maintaining approval
- 8. Falsification any report related to laboratory analysis
- 9. Issuance of a report on laboratory work actually performed in another laboratory without clearly identifying the examining laboratory on the report.
- 10. Failure to correct any of the above causes of suspension within six (6) months of the effective date of the suspension
- 11. Conviction of any crime, including but not limited to, any offense relating to the furnishing of, or billing for, environmental laboratory services, which is considered an offense involving theft or fraud
- 12. Failure to pay the required fee for continuing approval in the specified timeframe
- 13. Sustained administrative charges
- 14. Aiding and/or abetting in the violation of any of the provisions of Subpart 55-2
- 15. Violation of local (municipal) ordinance related to sample collection, analysis, and/or reporting

Information related to the revocation process can be found in <u>10 NYCRR Part 55</u>, <u>Subpart 55-2</u>.6 (d).