ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT WATER DIVISION - WATER SUPPLY PROGRAM ADMINISTRATIVE CODE

CHAPTER 335-7-13 LABORATORY CERTIFICATION

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335-7-13-.01 Purpose.

This chapter provides the mechanism to assure the validity and quality of the data being generated to determine compliance with the requirements of this division.
Author: Aubrey H. White III, James M. Arnold
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335-7-13-.02 Applicability.

This chapter applies to any laboratory performing Department-required analyses to determine the quality of drinking water.
Author: Aubrey H. White III, James M. Arnold
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335-7-13-.03 Definitions.

The following words and phrases, unless a different meaning is plainly required by the context, shall have the following meaning:

(1) Analytical Method – "method" number assigned by EPA that describes the proper process for obtaining accurate and repeatable analyte concentration results.

(2) Certificate – the document issued by the Department showing those drinking water parameters and the EPA-approved Drinking Water method for which a laboratory has received certification, and the type of certification. The certificate remains the property of the Department and must be surrendered at its direction.

(3) Certification – a declaration by the Department that a laboratory has been evaluated under the State Drinking Water Laboratory Certification Program and found acceptable to analyze specified parameters.

(4) Certification Authority (CA) – the agency in a state, or EPA, which certifies drinking water laboratories. In the state of Alabama, the CA for Drinking Water laboratories is the Department.

(5) Certified Laboratory – a laboratory that meets the regulatory performance criteria and any other requirements for the drinking water parameters and methods listed on the certificate.

(6) Corrective Action Plan – report submitted by a laboratory detailing steps it must take to satisfactorily correct deficiencies either found during an audit or that caused an unsatisfactory result on a performance evaluation (PE) sample and prevents their reoccurrence.

(7) Department – the Alabama Department of Environmental Management.

(8) EPA – the United States Environmental Protection Agency.

(9) EPA Manual for the Certification of Laboratories Analyzing Drinking Water – the latest edition and any addendums, which describes criteria and procedures that EPA uses in evaluating laboratories for certification.

(10) Interim Certification – a laboratory that is granted certification when it is impossible or unnecessary to perform an on-site audit.

(11) Not Certified – a laboratory, which possesses deficiencies, and the Department has determined cannot consistently produce valid data.

(12) On-site Audit – an inspection of a drinking water laboratory that seeks to be certified or plans to continue certified status. This inspection will include an evaluation of their facility, instrumentation, sample analysis processes, quality assurance manual/system, and personnel training and capabilities.

(13) On-site Auditor – a person approved by the CA and/or EPA to conduct an on-site audit.

(14) Parameter – a drinking water analyte for which a laboratory is seeking certification.

(15) Performance Evaluation (PE) Sample – an annual (or more frequent if required by the method) sample received from an American National Standards Institute (ANSI)-certified PE vendor that is analyzed by the laboratory. The laboratory results are compared to the known value by the certified PE vendor, and determined to be either acceptable or unacceptable.

(16) Provisionally Certified – a laboratory that has deficiencies but demonstrates its ability to consistently produce valid data within the acceptance limits specified in the National Primary Drinking Water Regulations (NPDWR) and within the requirements of their certification authority.

(17) Reciprocity – a type of certification that is issued by the Department to out of state laboratories that hold equivalent certification issued by EPA or EPA-approved state programs.

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335-7-13-.04 Parameters Requiring Certification.

Certification of the laboratory is required before the Department will accept analytical data for any parameter required by this division or a Water Supply Permit issued pursuant to this division, unless specifically exempted.
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335-7-13-.05 Certification Manual.

Unless otherwise directed in writing by the Department, certified laboratories and laboratories seeking certification shall comply with the EPA Manual for the Certification of Laboratories Analyzing Drinking Water. If there is a conflict between the Certification Manual and the EPA method, the EPA method shall govern.
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335-7-13-.06 Certification Process.

A laboratory must hold a valid certification issued by the Department before analyzing parameters that require certification and submitting the results to the Department.

(1) The certification of a laboratory is effective for one year.

(2) In order for a laboratory located in Alabama to be certified, the laboratory must complete the following:

(a) Submit a completed ADEM-approved application form. This form must include the parameters for which the laboratory is seeking certification.

(b) Submit the appropriate application fee.

(c) Submit a satisfactory set of PE samples for the parameters, using the EPA-approved drinking water analytical method for which the laboratory is applying to be certified.

(d) Successfully pass an on-site audit, conducted by an on-site auditor, within the previous three years.

1. For a laboratory seeking certification for the first time, the audit will not be scheduled until after submittal of the application and fee.

2. As a result of the on-site audit, the Department may require a corrective action plan that includes the steps to be taken to satisfactorily address any deficiencies noted in the audit report. The corrective action plan must be submitted within 60 days of receipt of the audit report.

(3) In order for a laboratory located outside of Alabama to be granted certification reciprocity, the laboratory must complete the following:

(a) Submit a completed ADEM-approved application form. This form must include the parameters for which the laboratory is seeking certification.

(b) Submit the appropriate certification fee.

(c) A copy of the certification package (certificate and scope of analysis) for the appropriate parameters, from the CA which issued the laboratory's original certification. This certification shall come directly from the CA and may not be submitted by the applicant.

(4) A certified laboratory must notify the CA in writing within 30 days of major changes in personnel, equipment, or laboratory location.

(a) A major change in personnel is the loss or replacement of the laboratory supervisor or a situation in which a trained and experienced analyst is no longer available to analyze a particular parameter for which certification has been granted.

(b) Upon notification by the Department that the change has resulted in a deficiency, the laboratory shall correct the deficiency by the deadline established by the Department.

(5) If a complete renewal application with satisfactory PE results, audit report, and fee is not received by the certification expiration date:

(a) The laboratory may apply to renew its certificate up to 30 days after expiration.

(b) After 30 days, the laboratory may submit a complete application for initial certification if it wishes to resume analyzing drinking water samples.

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335-7-13-.07 Types Of Certification.

(1) Certified Laboratory. A Certified Laboratory may submit to the Department analytical results for compliance purposes for those analytes for which it is certified.

(2) Provisionally Certified Laboratory.

(a) A Provisionally Certified Laboratory may analyze drinking water samples for compliance purposes for those analytes for which it is certified.

(b) The public water system shall be given written notification of the certification status.

(c) The certification status shall be noted on all applicable analyte result reports.

(d) The certification will not be issued if the Department determines the laboratory cannot perform an analysis within the acceptance limits specified by the EPA Method, by EPA regulations, or by the EPA Manual for the Certification of Laboratories Analyzing Drinking Water.

(3) Interim Certification.

(a) A laboratory may be granted Interim Certification if the laboratory has the appropriate instrumentation, is using the approved methods, has adequately trained personnel to perform the analyses, and has satisfactorily analyzed PE samples for the analytes in question.

(b) The public water system shall be given written notification of the certification status.

(c) The certification status shall be noted on all analyte results reports for which it is relevant.

(4) Not Certified. A laboratory that is not certified shall not submit analytical results to the Department for compliance purposes for the relevant parameters.
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335-7-13-.08 Certification Downgrade Process.

(1) A laboratory may be downgraded to "provisionally certified" status for a parameter or group of parameters for any of the following reasons:

(a) Failure to satisfactorily analyze a PE sample at least annually, or as directed by the Department;

(b) Failure of a certified laboratory to notify the Department within 30 days of major changes (e.g., in personnel, equipment, or laboratory location);

(c) Failure to satisfy the Department that the laboratory is maintaining the required standard of quality, based upon an on-site audit; or

(d) Failure to report compliance data to the public water system or the Department in a timely manner.

(2) If a laboratory is subject to downgrading in accordance with paragraph (1) of this rule, it shall respond to an intent to downgrade notification from the Department within 30 days. The written response shall specify the corrective actions being taken, the time frame those actions will take to complete, and any proposed actions that need the concurrence of the Department.

(3) A laboratory that fails to satisfactorily analyze a PE sample may avoid a downgrade in certification if it identifies and corrects the problem to the Department’s satisfaction within 30 days of being notified of the failure.

(a) The laboratory shall submit a second PE sample within the Department-specified timeframe from the first unsatisfactory PE sample.

(b) If the second PE sample is unsatisfactory, the laboratory may be downgraded to “provisionally certified”.

(4) After the Department notifies a laboratory that it has been downgraded to "provisionally certified" status for procedural, administrative, equipment, or personnel deficiency, the laboratory must correct any noted issues within 90 days.

(5) If the laboratory was downgraded to "provisionally certified" status because of a failure to satisfactorily analyze a PE sample, the laboratory shall correct its deficiencies and satisfactorily

analyze another PE sample within 30 days of receipt of the certification downgrade.
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335-7-13-.09 Certification Revocation Process.

(1) A laboratory may be downgraded from certified, provisionally certified, or interim certified status to "not certified" for a particular parameter analysis for any of the following reasons:

(a) Reporting PE data from another laboratory as its own;

(b) Falsification of data or other deceptive practices;

(c) Failure to use the analytical methodology specified in the regulations;

(d) For provisionally certified laboratories, failure to successfully analyze a PE sample for a particular contaminant within the acceptance limits specified;

(e) For provisionally certified laboratories, failure to satisfy the Department that the laboratory has corrected deficiencies identified during on-site evaluations;

(f) For provisionally certified laboratories, persistent failure to report compliance data to the public water system or the Department in a timely manner;

(g) Refusal to participate in an on-site audit; or,

(h) Failure to submit complete application package.

(2) A laboratory may respond to a determination to revoke its certificate up to 30 days after notification by the Department. If the Department does not receive a response by that date or, if the response does not fully resolve the deficiencies noted by the Department, the certificate is immediately revoked.

(a) The response shall include an explanation of the reasons for the challenge and shall be signed by the laboratory's responsible authority (such as the director, owner, or president).

(b) Denial of the response by the Department results in the immediate revocation of the certificate.

(c) If the Department determines the response to be valid, the Department may suspend the revocation of certification or upgrade the certification status to "provisionally certified" or "certified".

(d) A laboratory with a revoked certificate shall not submit analyses to the Department for compliance purposes for any analyte covered by the revocation.

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335-7-13-.10 Certification Upgrade/Reinstatement Process.

(1) A laboratory shall submit a written request to the Department seeking an upgrade or reinstatement of certification.

(2) The laboratory shall demonstrate to the Department's satisfaction that any noted deficiencies which resulted in provisionally certified status or revocation have been corrected.

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335-7-13-.11 Recordkeeping.

(1) A laboratory shall maintain easily accessible records for five years from the creation of a record or until the next on-site audit is complete, whichever is longer.

(2) The laboratory shall make copies of analyses, raw data, calculations, and quality control data available to the relevant client water system upon request.

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335-7-13-.12 Special Requirements.

(1) A laboratory shall notify the Department and the water system of any exceedance of a lead/copper action level or total coliform/ E Coli positive result within 24 hours of completion of the analysis.

(a) The notification shall be made to the Drinking Water Branch staff by a method approved by the Department.

(b) If the analysis result is determined outside of normal business hours, the laboratory shall use a method approved by the Department to notify the Drinking Water Branch staff as soon as possible the next business day.

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