

Regulation 61-81

State Environmental Laboratory Certification Program

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Statutory Authority:

S.C. Code Sections 44-1-10 et seq. and 44-55-10 et seq.

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A. Authority

This Regulation implements Code Section 44-55-10 et seq., known as the South Carolina Safe Drinking Water Act; Code Section 48-1-10 et seq., known as the South Carolina Pollution Control Act; and Act #436 of 1978, known as the South Carolina Hazardous Waste Management Act.

B. Purpose

This Regulation provides the mechanism to assure the validity and quality of the data being generated for compliance with State regulations.

C. Scope

This Regulation applies to any laboratory performing analyses to determine the quality of air, drinking water, hazardous waste, solid waste, or wastewater; performing bioassays; or performing any other analyses related to environmental quality evaluations required by the Department or which will be officially submitted to the Department.

D. Definitions

(1) "Acceptable results" means a variance of less than plus or minus two (2) standard deviations from the true value of a performance audit sample, as utilized by the EPA for its evaluation of state laboratories, unless another variance for a specific parameter is announced prior to the analysis.

(2) "Board" means the governing body of the South Carolina Department of Health and Environmental Control.

(3) "Certificate" means that document issued by the State Environmental Laboratory Certification Officer showing those parameters for which a laboratory has received certification. The certificate remains the property of the Department and must be surrendered at the direction of the Department.

(4) "Certification" means a declaration by the Department that a laboratory has been evaluated under the State Environmental Laboratory Certification Program and found acceptable to analyze specified parameters.

(5) "CFR" means the Code of Federal Regulations.

(6) "Commissioner" means the duly constituted Commissioner of the Department or his authorized agent.

(7) "Department" means the South Carolina Department of Health and Environmental Control, including personnel thereof authorized and empowered by the Board to act on behalf of the Department or Board.

(8) "EPA" means the United States Environmental Protection Agency.

(9) "Evaluation" means a complete review of the quality control procedures, records keeping, reporting procedures, methodology, and analytical technique of a laboratory for specific parameters.

(10) "Interim approval" means a declaration by the Department that a laboratory has been evaluated under the State Environmental Laboratory Certification Program prior to the date of required certification and has been determined to be in substantial compliance with its requirements.

(11) "Laboratory" means any facility that performs analyses to determine the quality of air, drinking water, solid waste, hazardous waste, wastewater, performs bioassays; or any other analyses related to environmental quality evaluations required by the Department or which will be officially submitted to the Department.

(12) "Laboratory Director" means that person who has been given the responsibility by the laboratory's governing body (owners, directors, commissioners, councilmen, mayor, board members or who so ever occupies the status of proprietor) of supervising the operations of the laboratory and insuring the quality of data reported.

(13) "Performance audit sample" means a sample in which the concentrations of the constituents required for certification are known only to the State Environmental Laboratory Certification Officer and is used to determine analysts' proficiency.

(14) "State Environmental Laboratory Certification Officer" means that person designated by the Department who is responsible for the management of the State Environmental Laboratory Certification Program or his authorized delegate.

E. Parameters Requiring Certification

Certification of the laboratory is required before the Department will accept analytical data for any parameter required by the following:

- (1) State Safe Drinking Water Act and Regulation
- (2) State Pollution Control Act and Regulations
- (3) State Solid Waste Management Regulation
- (4) State Hazardous Waste Act and Regulations

F. Certification Criteria

It is the responsibility of the Department to inform laboratories certified under this regulation and those who have applied for certification of requirements in acceptable procedures, methodology, techniques, facilities, quality control, records keeping, and equipment, including any changes in those requirements. At no time shall requirements be imposed on a laboratory as a condition of certification that are not also imposed on the environmental laboratories of the Department.

G. Certification

It is the responsibility of the laboratory to initiate the application for certification under this Regulation. A pre-evaluation form must be filed with the Department, if requested by the State Environmental Laboratory Certification Officer. Upon review of the information provided, an on-site evaluation will be scheduled.

Each laboratory requesting certification will be evaluated by the State Environmental Laboratory Certification Officer who may be assisted by members of the Department's environmental laboratory staff upon his request. A written report will be filed with the State Environmental Laboratory Certification Officer within thirty (30) days following the evaluation. A copy of this report will be mailed to the Laboratory Director and the governing body.

(1) Issuance of Certification

Within seven (7) days of the receipt of the written report of the evaluation, the State Environmental Laboratory Certification Officer will notify the laboratory of his determination. If the adequacy of the laboratory capability and its proficiency have been established and in the absence of substantial deficiencies, certification will be issued to the laboratory for the evaluated parameters. The certificate will remain the property of the Department.

If there is an equipment deficiency, certification may be granted upon the receipt of a copy of a purchase order; or a repeat visit may be made to substantiate proper use of the item.

(2) Certification Continuance Between Evaluations

(a) In order to maintain certification for each parameter, the laboratory will analyze a minimum of one performance audit sample annually where technically feasible.

(b) In order to maintain certification, the laboratory will participate in split sampling with the Department Laboratory when required by the State Environmental Laboratory Certification Officer.

(3) Frequency of Certification

The laboratory will be evaluated for renewal of certification every three (3) years.

At any time during the certification period, at the discretion of the State Environmental Laboratory Certification Officer, an on site evaluation will be performed. For the convenience of the laboratory personnel and the evaluators, advanced notice of the inspection will be given.

(4) Laboratory Name

Any facility certified under this program will maintain only one name for the facility. This name will be used in all official correspondence with the Department.

H. Loss of Certification

(1) Total Laboratory Certification

Once certified, a laboratory's certificate will be withdrawn for knowingly and willfully falsifying data.

(2) Parameter Certification

Once certified, a laboratory will have its certification for a parameter withdrawn by failure to:

(a) Obtain acceptable results on a performance audit sample and a repeat audit sample.

(b) Comply with any part of Section F of this Regulation.

(c) Report results of performance audit samples within thirty (30) calendar days of receipt of samples.

I. Recertification

(1) A laboratory having lost certification for falsifying reports or misrepresenting data will not be eligible for recertification for a period of one (1) year, unless the responsible individual(s) is/are no longer associated with the laboratory.

(2) A laboratory having lost parameter certification as described in Section H(2) will have its certification reinstated after obtaining acceptable results on a performance audit sample.

J. Contract Laboratories

Any laboratory which sub-contracts analytical work to another must establish that the contracted laboratory has been certified by the Department for the appropriate parameters. Laboratory records must indicate who performs the analyses and the name of the contract laboratory must be included in these records.

K. Appeals

In the event a Laboratory Director disagrees with a decision affecting certification, an appeal, in accordance with Department Regulation #72, December 28, 1976, entitled "Procedures for Contested Cases", can be made to the Board.

L. Reciprocity

Laboratories, located in other states, which have been certified under an equivalent program, as determined by the State Environmental Laboratory Certification Officer, are eligible for certification under this Regulation. A notarized copy of the laboratory's certificate and a copy of the program, if requested, must be received by the Department prior to consideration for State certification.

Laboratories in states without an equivalent program may be evaluated under this Regulation upon payment of a fee, set by the Board, and expenses incurred by the Department evaluator(s).

M. Effective Date

This Regulation shall become effective January 1, 1981. Prior to the effective date, the Department may evaluate laboratories and make recommendations to assure compliance with the requirements of this Regulation, and issue an interim approval should the requirements be met before the effective date.