SECTION .1100 - BIOLOGICAL LABORATORY CERTIFICATION

15A NCAC 02H .1101 PURPOSE

These Rules set forth the requirements for certification of commercial, industrial, and public laboratories to perform biological toxicity testing and population surveys of water and wastewater as required for National Pollutant Discharge Elimination System (NPDES) permits by G.S. 143-215.3(a)(10) and Environmental Management Commission Rules for Classifications and Water Quality Standards Applicable to the Surface Waters of North Carolina, found in Subchapter 2B of this Chapter, Section .0200, and Rules for Surface Water Monitoring, Reporting, found in Subchapter 2B of this Chapter, Section .0500.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66;
Eff. October 1, 1988;
Amended Eff. March 1, 1993.

15A NCAC 02H .1102 SCOPE

These Rules apply to commercial, industrial, or public laboratories which perform toxicity testing of water or wastewater for persons subject to any requirements for monitoring of toxicity through direct measurement of the effects of a specific water or wastewater or aquatic organisms in laboratory tests or through field surveys.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66;
Eff. October 1, 1988.

15A NCAC 02H .1103 DEFINITIONS

The following terms as used in this Section shall have the assigned meaning:

(1) Categories are groups of parameters which differ by measured test exposure regimes (chronic and acute) and, in the case of toxicological assay, through the presence or absence of vertebrae in the species of test organisms used or being a member of the plant kingdom. All field population survey techniques are contained within one category.

(2) Certification is a declaration by the Division that personnel, equipment, records, quality control procedures, and methodology cited by the applicant are accurate and that the applicants' proficiency has been considered and found acceptable.

(3) Commercial Laboratory means any laboratory, including its employees and agents, which analyzes, for others, wastewater samples for toxicity measurements or for their resultant impacts on the receiving waters.

(4) Decertification is the loss of certification.

(5) Director means the Director of the North Carolina Division of Environmental Management, or his successor.

(6) Division means the North Carolina Division of Environmental Management, or its successor.

(7) Evaluation samples are samples submitted by the State Laboratory to the commercial, municipal, industrial, or public laboratory as an unknown toxicant for measurement of toxicity or as an unknown set of preserved organisms for identification to specified levels of taxonomic classification.

(8) Falsified data or information means data or information that has been made untrue by alteration, fabrication, intentional omission, substitution, or mischaracterization. The agency need not prove intent to defraud to prove data is falsified.

(9) Inaccurate data or other information means data or information that is in any way incorrect or mistaken.

(10) Industrial Laboratory means a laboratory, including its employees and agents, operated by an industry to analyze samples from its wastewater treatment plants for toxicity measurements or resultant impacts to receiving waters.

(11) Parameters are subgroups of categories. Parameters are unique and separate if they are in separate categories or are performed using different species of test organisms. For the

category, Aquatic Population Survey, separate parameters are to be considered fish, macroinvertebrates, algae, aquatic macrophytes, and zooplankton.

(12) Public Laboratory means a laboratory, including its employees and agents, operated by a municipality, county, water and sewer authority, sanitary district, metropolitan sewerage district, or state or federal installation or any other governmental unit to analyze samples from its wastewater treatment plant(s) for toxicity measurements or resultant impacts to receiving waters.

(13) Recertification is reaffirmation of certification.

(14) Split samples are samples from either a surface water effluent discharge, surface water, or aquatic biological population survey which are segregated at the point of sampling or in the case of field survey, collected independently and then analyzed separately by both the State Laboratory and the commercial, public or industrial laboratory.

(15) State laboratory means the Environmental Sciences Branch of the Water Quality Section of the North Carolina Division of Environmental Management or its successor.

(16) Toxicant - Any specific chemical or compound or mixture of chemicals or compounds regulated within an NPDES permit and/or defined as a toxic substance in Rule .0202 of Subchapter 2B.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66;
Eff. October 1, 1988;
Amended Eff. April 1, 1993.

15A NCAC 02H .1104 FEES ASSOCIATED WITH CERTIFICATION PROGRAM

(a) Certification Fees:

(1) Certification Fees shall be a minimum of five hundred dollars per year ($500.00). The first category will be certified at a cost of five hundred dollars ($500.00). Additional categories will be certified at a cost of four hundred dollars ($400.00) per category. The addition of parameters not included in the original certification will be certified at a cost of one hundred dollars ($100.00) per parameter.

(2) Certification fees are due upon application and no later than 45 days prior to the requested certification date.

(b) Renewal Fees:

(1) The certified laboratory will pay the state a four hundred dollar ($400.00) per year renewal fee for each category of certification or the minimum fee five hundred dollars ($500.00) if only one category is certified.

(2) Recertification fees shall be four hundred dollars ($400.00) per category recertified.

(3) Out-of-state laboratories shall reimburse the state for actual travel and subsistence costs incurred in certification, recertification and maintenance of certification.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66;
Eff. October 1, 1988.

15A NCAC 02H .1105 CERTIFICATION

(a) Certification is affirmation by the Director or his delegate that the requirements specified by these rules have been met for specific categories and parameters and that all fees associated with certification have been received.

(b) Commercial, public and industrial laboratories must obtain certification from the Division of Environmental Management only for biological parameters which will be reported to comply with the rules and requirements as stated in an administrative letter, permit condition, permit limit, special order by consent, judicial order, or the biological monitoring requirements established by the Division.

(c) For the purposes of certification and setting fees, parameters are grouped in the following five categories:

(1) Acute Toxicity Testing/Invertebrate;

(2) Acute Toxicity Testing/Vertebrate;

(3) Chronic Toxicity Testing/Invertebrate;
(4) Chronic Toxicity Testing/Vertebrate;
(5) Agal and Aquatic Plant Toxicity Testing;
(6) Aquatic Population Survey and Analysis.

(d) All certifications are designated for the period of one year after initial certification.

(e) Protocol Documents considered as standard methodology and facilities and equipment requirements considered as minimum acceptable resources will be listed in the Certification Criteria/Procedures Document.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(1)(10); 143-215.66; Eff. October 1, 1988.

15A NCAC 02H .1106 DECERTIFICATION

(a) A laboratory certification may be revoked for all categories for:
(1) Failing to maintain the facilities, records, personnel, equipment or quality assurance program as set forth in the application or these Rules; or
(2) Submitting inaccurate or falsified data reports or other information; or
(3) Failing to pay required fees by the date due.

(b) A laboratory certification may be revoked for a category for failure to:
(1) Obtain acceptable results on two consecutive evaluation sample submittals from the Division. Acceptable results on performance evaluation samples are those that vary by less than two standard deviations of the value established by the Division. The state laboratory may apply specific variance or statistical limits or performance criteria on performance evaluation samples or split samples for a particular testing procedure, including control population effects and taxonomic identification, as published in the Certification Criteria/Procedures Document; or
(2) Obtain acceptable results as set out in Paragraph (1) of this Rule on two consecutive split samples that have also been analyzed by the Division; or
(3) Submit a split sample to the Division as requested; or
(4) Use approved testing techniques; or
(5) Report to the state laboratory equipment changes that would affect its ability to perform a test category within 30 days of such change; or
(6) Report to the state laboratory analysis of performance evaluation samples submitted by the Division within required time of completion; or
(7) Maintain records and perform quality controls as set forth by these Rules and the Division for a particular category; or
(8) Maintain equipment required for any certified parameter; or
(9) Implement and maintain Quality Control Programs approved in conjunction with certification; or
(10) Maintain a qualified staff.

(c) Decertification Requirements:
(1) A laboratory is not to analyze samples for parameters in decertified categories for programs described in Rule .1102 of this Section.
(2) A decertified commercial laboratory must notify any clients affected by the decertification of such and supply the state laboratory with a list of those clients affected and written certification that those clients have been notified. Should the decertified laboratory arrange for a certified laboratory to perform analyses during the period of decertification, the decertified laboratory must supply the Division with the name of the replacement laboratory and the client(s) involved. The certified laboratory's name which performs analyses must appear on all data submitted to the Division.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66; Eff. October 1, 1988; Amended Eff. March 1, 1993.

15A NCAC 02H .1107 RECERTIFICATION

(a) A laboratory decertified for any reason, other than the submittal of falsified data reports or other information, may be recertified after 30 days, upon satisfactory demonstration to the state laboratory that all deficiencies have been corrected.

(b) In the case of a laboratory decertified for submitting falsified data reports or other information, recertification shall not occur until at least 12 months after the decertification and then only at such time as the laboratory has satisfactorily demonstrated to the Director that the standards for initial certification have been met.

(c) Should decertification occur due to either failure of performance samples or split samples, a written request must be made to the state laboratory requesting evaluations similar to the parameters for which the laboratory was decertified. Two consecutive samples must be successfully evaluated to achieve recertification. The first of these samples for recertification will be submitted or arranged by the Division no later than 30 days after receipt of the written request. The second will be submitted or arranged no later than 30 days after the first.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66;
Eff. October 1, 1988;
Amended Eff. March 1, 1993.

15A NCAC 02H .1108 RECIPROCITY

(a) Laboratories certified by other states or federal programs may be given reciprocal certification where such programs meet the requirements of these Rules. In requesting certification through reciprocity, laboratories shall include with the application a copy of their certification and the rules of the original certifying agency.

(b) Laboratories certified on the basis of program equivalency shall pay all fees specified by these Rules.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66;
Eff. October 1, 1988;
Amended Eff. March 1, 1993.

15A NCAC 02H .1109 ADMINISTRATION

The Director of the Division of Environmental Management, Department of Environment, Health, and Natural Resources, or his delegate, is delegated authority to issue certification, to reject applications for certification, to renew certification, to issue recertification, to issue decertification, and to issue reciprocity certification.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66;
Eff. October 1, 1988;
Amended Eff. March 1, 1993.

15A NCAC 02H .1110 IMPLEMENTATION

(a) Each laboratory requesting state certification or certification renewal or recertification shall submit an application in duplicate to the Division. Each application will be reviewed to determine the adequacy of personnel, equipment, records, quality control procedures and methodology. After receiving a completed application and prior to issuing certification, a representative of the Division may visit each laboratory to verify the information in the application and the adequacy of the laboratory.

(b) Analytical methods, sample preservation, sample containers and sample holding times shall conform to the methodologies specified in the Certification/Criteria Procedures Document. Deviations from these methods are acceptable only upon prior written approval from the state laboratory.

(c) In order to maintain certification, each laboratory will demonstrate satisfactory performance on evaluation samples submitted by the Division. These will be required no more than three times annually of certified laboratories for each parameter certified.

(d) In order to receive and maintain certification the following minimum criteria must be met:

(1) The supervisor of an aquatic toxicology or biological survey laboratory must have a minimum of a B.S. degree from an accredited college or university in a biological science or closely related science curriculum and at least three years of cumulative laboratory experience in aquatic toxicity testing or aquatic biological survey, as appropriate, or a M.S. degree in a biological or closely related science and at least one year of cumulative laboratory experience in aquatic toxicity testing or aquatic biological survey, as appropriate.

(2) All laboratory supervisors are subject to review by the Division. One person may serve as supervisor of no more than two laboratories. The supervisor is to provide direct supervision and evaluation of all technical personnel and is responsible for the proper performance and reporting of all analyses. Upon absence, the supervisor shall arrange for a suitable substitute capable of insuring the proper performance of all laboratory procedures. Existing laboratory supervisors who do not meet the minimum requirements may be accepted after review by the Division if they meet all other certification requirements and previous performance is deemed adequate.

(3) All applications and fees are due 45 days prior to the requested certification date. Problems identified with the applying laboratory and resolution of these problems may extend the requested 45 day period from application to certification.

(4) Each laboratory shall develop and maintain a document outlining quality control procedures for all parameters in their certification and dissolved oxygen, temperature, and pH. All aquatic toxicology laboratories must also develop and maintain a document outlining quality control procedures for total hardness and total residual chlorine. These documents are to be included with submittal of the application.

(5) Each laboratory certified for the category of Aquatic Population Survey and Analysis shall develop and maintain a document outlining quality control procedures for taxonomic identifications and life-stage determinations.

(6) Supporting records shall be maintained as evidence that these practices are being effectively carried out and shall be available to the state laboratory upon request.

(7) The quality control program is to be approved in conjunction with certification by the Director.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66;
Eff. October 1, 1988;
Amended Eff. October 1, 1993.

15A NCAC 02H .1111 BIOLOGICAL LABORATORY CERT/CRITERIA PROCEDURES DOCUMENT

The Biological Laboratory Certification/Criteria Procedures Document describes specific scientific reporting units, forms, test methods and procedures pertaining to certification.
The manual, and any addition thereto, shall be approved by the director before it is released to the public.
The manual shall be mailed to all certified biological laboratories and to any persons on the mailing list.
To be placed on the mailing list, a letter must be sent to the director.
If the manual is revised at any time, all changes shall be sent to the certified biological laboratories and those persons on the mailing list.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66;
Eff. October 1, 1988.