15A NCAC 02H .0805 CERTIFICATION AND RENEWAL OF CERTIFICATION

(a) Prerequisites and requirements for Certification. The following requirements shall be met by all laboratories, excluding Field Laboratories, prior to Certification. Once certified, failure to comply with any of the following items shall be a violation of Certification requirements.

(1) Laboratory Procedures. Analytical methods, sample preservation, sample containers, and sample holding times shall conform to the requirements found in:

(A) 40 CFR Part 136 and 40 CFR Part 503;

(B) Standard Methods for the Examination of Water and Wastewater;

(C) Test Methods for Evaluating Solid Waste, SW-846, Third Edition;

(D) Control of Pathogens and Vector Attraction in Sewage Sludge; EPA/625/R-92/013;

(E) Massachusetts Department of Environmental Protection, Method for the Determination of Volatile Petroleum Hydrocarbons (VPH), February 2018, Revision 2.1, and Method for the Determination of Extractable Petroleum Hydrocarbons (EPH), May 2004, Revision 1.1, and

(F) The State Laboratory may develop Approved Procedures for Field Parameters based upon the methods in any of the sources referenced in Parts(a)(1)(A) through (E) of this Rule.

(G) The procedures and methods listed in this Subparagraph are incorporated by reference, including subsequent amendments and editions.

(H) The materials in this Subparagraph are available for inspection at the State Laboratory, 4405 Reedy Creek Road, Raleigh, North Carolina, 27607 or may be obtained from:

(i) The Code of Federal Regulations, 40 CFR Part 136 and 40 CFR Part 503, may be obtained from the Superintendent of Documents, U.S. Government Printing Office (GPO), Superintendent of Public Documents, Washington, D.C., 20402 and free of charge at http://www.ecfr.gov.

(ii) Standard Methods for the Examination of Water and Wastewater, is available for purchase from American Water Works Association (AWWA), 6666 West Quincy Avenue, Denver, CO 80235; American Public Health Association (APHA), 8001 Street, NW, Washington, D.C. 20001; or Water Environment Federation (WEF), 601 Wythe Street, Alexandria, VA 22314; and http://www.standardmethods.org/.

(iii) Test Methods for Evaluating Solid Waste, SW-846, Third Edition may be obtained from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, D.C. 20402 and free of charge at http://www.epa.gov/osw/hazard/testmethods/sw846/online/.

(iv) Control of Pathogens and Vector Attraction in Sewage Sludge; EPA/625/R-92/013 is available from US EPA; Office of Research and Development, Washington, D.C. 20460 and free of charge at http://www.water.epa.gov/scitech/wastetech/biosolids/.

(v) Massachusetts Department of Environmental Protection, Method for the Determination of Volatile Petroleum Hydrocarbons (VPH), February 2018, Revision 2.1, et seq. and Method for the Determination of Extractable Petroleum Hydrocarbons (EPH), May 2004, Revision 1.1, et seq may be obtained from the Massachusetts Department of Environmental Protection, Senator William X. Wall Experiment Station, 37 Shattuck Street, Lawrence, MA, 01843-1398 and free of charge at https://www.mass.gov/files/documents/2018/02/23/VPH%20GC%20PIDFID_Revision%202_1_February%202018.pdf and http://www.mass.gov/eea/docs/dep/cleanup/laws/eph0504.pdf, respectively.

(vi) State Laboratory Approved Procedures for Field Parameters may be obtained by request from the State Laboratory or on the State Laboratory website at https://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch.

(J) The Commission or assigned delegate may approve other analytical procedures, parameters, or Parameter Methods that produce verifiable and repeatable results.

(2) Proficiency Testing. Annually, each certified laboratory shall achieve Acceptable Proficiency Testing Results on a minimum of one evaluation sample for each Parameter Method listed on their Certified Parameters Listing for which Proficiency Testing Samples are available from more than one Vendor, as required by these Rules. When two Proficiency Testing Samples for the same Parameter Method are analyzed and submitted at the same time, an unacceptable result on one or both samples shall be considered the first unacceptable result for Certification purposes. A laboratory that submits Unacceptable Proficiency Testing Results for two Proficiency Testing Samples for the same Parameter Method submitted at the same time shall analyze a remedial Proficiency Testing Sample to show a return to control and send a description of corrective actions to the State Laboratory that includes the Root Cause of the failure and the corrective actions taken to prevent recurrence. Proficiency Testing samples shall be analyzed in the same manner that routine samples are analyzed using the same staff, sample tracking, sample preparation procedures, analytical methods, standard operating procedures, calibration techniques, quality control procedures, and acceptance criteria.

(A) All laboratories shall participate annually in an evaluation study by analyzing Proficiency Testing Samples obtained from a State Laboratory-approved Vendor as unknowns, and arranging with the Vendor to send the graded results directly to the State Laboratory by the date due. A laboratory that submits Unacceptable Proficiency Testing Results shall analyze a remedial Proficiency Testing Sample using the same Parameter Method to show a return to control and send a description of corrective actions to the State Laboratory that includes the Root Cause of the failure and the corrective actions taken to prevent recurrence.

(B) Laboratories requesting initial Certification or additional Parameter Method Certification shall submit an acceptable Proficiency Testing sample result from the most recent attempt analyzed within the last six months for each Parameter Method for which Proficiency Testing samples are available. Laboratories shall analyze Proficiency Testing samples obtained from a State Laboratory-approved Vendor as unknowns and arrange with the Vendor to send the graded results directly to the State Laboratory. Laboratories that submit two consecutive Unacceptable Proficiency Testing Results for a particular Parameter Method shall then submit two consecutive Acceptable Proficiency Testing results from the most recent attempt analyzed within the six months prior to initial Certification for that Parameter Method.

(C) If Proficiency Testing Samples are not available, Certification for that Parameter shall be based on the on-site inspection, adherence to the approved procedures, and the other requirements in this Section. Analysis of Split Samples may also be required if Proficiency Testing Samples are not available or if analysis of Proficiency Testing Samples is not representative of the entire analytical process.

(3) Supervisory Requirements.

(A) The supervisor of a Commercial Laboratory shall have a Bachelor's degree in chemistry or other science curricula from a college or university recognized as accredited by the U.S. Department of Education, plus two years of laboratory experience in analytical chemistry, or a two-year associate degree in chemistry technology, environmental sciences, or other science curricula from a college, university, or technical institute, recognized as accredited by the U.S. Department of Education, plus four years of experience in analytical chemistry.

(B) The supervisor of a non-Commercial Municipal, Industrial, Mobile, or Other Laboratory shall have a Bachelor's degree in chemistry or other science curricula from a college or university recognized as accredited by the U.S. Department of Education, plus six months of laboratory experience in analytical chemistry or an equivalent combination of education and work experience, or a two-year associate degree in chemistry technology, environmental sciences, or other science curricula from a college or university recognized as accredited by the U.S. Department of Education, plus two years of experience in analytical chemistry or an equivalent combination of education and work experience. Non-degree supervisors shall have six years of laboratory experience in analytical chemistry or an equivalent combination of education and work experience.

(C) All laboratory supervisors shall be subject to review by the State Laboratory. One person may serve as supervisor of no more than two certified laboratories. The supervisor shall provide personal and direct supervision of the technical personnel and shall be responsible for adherence to all requirements in this Section. The supervisor shall work in the laboratory or contact the laboratory once each day tests, analyses, measurements, or monitoring required under G.S. 143 Article 21 are performed and Supporting Records shall be maintained as evidence of this supervision. If the supervisor will be absent, the supervisor shall arrange for a substitute capable of insuring adherence to all requirements in this Rule. The substitute supervisor shall not be in charge for more than 12 consecutive weeks. Previous laboratory-related performance shall be considered when reviewing the qualifications of a potential laboratory supervisor.

(4) Laboratory Manager. Each laboratory shall designate a laboratory manager and include his or her name and title on the application for Certification. The laboratory manager shall be administratively above the laboratory supervisor and will be in responsible charge in the event the laboratory supervisor ceases to be employed by the laboratory and will be responsible for filling the laboratory supervisor position with a replacement qualified pursuant to these Rules. At Commercial Laboratories, where the owner is the laboratory supervisor, the laboratory manager and laboratory supervisor may be the same person if there is no one administratively above the laboratory supervisor.

(5) Application. Each laboratory requesting initial Certification shall submit an application to the State Laboratory that includes the laboratory name, contact information, EPA laboratory code number, applicable permit number(s), laboratory supervisor information, analytical methods, and equipment. The application may be obtained by request from the State Laboratory or on the State Laboratory website at https://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/application-forms. The application fee and the laboratory's quality assurance manual, including Standard Operating Procedures for all requested Parameter Methods, must also be submitted. Separate application and Certification shall be required for each Mobile Laboratory and the applicant shall supply the vehicle make, vehicle identification number, and license number. Separate application and Certification shall be required for all stationary laboratories maintained on properties that do not share a common boundary line, even though operated under the same management; however, separate Certification shall not be required for separate buildings on the same or adjoining grounds. Analysis of Field Parameters away from the physical location of the laboratory shall be permitted without separate Certification. After receiving a completed application and prior to issuing Certification, a representative of the State Laboratory may visit each laboratory to verify the information in the application and the adequacy of the laboratory.

(6) Facilities, Supplies, and Equipment. Each laboratory requesting Certification shall be maintained so as to ensure the security and integrity of samples. Samples shall be analyzed in such a manner that contamination or error will not be introduced. Each facility shall contain or be equipped with the following:

(A) A source of water that will meet the minimum criteria of the approved methodologies; and

(B) Glassware, chemicals, supplies, and equipment required to perform all tests, analyses, measurements, or monitoring included in its Certification.

(7) Analytical quality assurance and quality control program. Each laboratory shall have a documented analytical quality assurance and quality control program. Each laboratory shall have a copy of each approved test, analysis, measurement, or monitoring procedure being used in the laboratory. Each laboratory shall develop documentation outlining the analytical quality control practices used for the Parameter Methods included in its Certification, including Standard Operating Procedures for each certified Parameter Method. Quality assurance, quality control, and Standard Operating Procedure documentation shall indicate the effective date of the document and be reviewed every two years and updated if changes in procedures are made. Each laboratory shall have a formal process to track and document review dates and any revisions made in all quality assurance, quality control, and Standard Operating Procedure documents. Supporting Records shall be maintained as evidence that these practices are implemented. The quality assurance, quality control, and Standard Operating Procedure documents shall be available for inspection by

the State Laboratory. The following shall be included in each certified laboratory's quality assurance and quality control program. For analysis of Field Parameters, a certified laboratory shall follow the quality assurance and quality control requirements in Subparagraphs (g)(1) through (9) of this Rule.

(A) Unless specified by the method or this Rule, each laboratory shall establish performance acceptance criteria for all quality control analyses. Each laboratory shall calculate and document the precision and accuracy of all quality control analyses with each sample set. When the method of choice specifies performance acceptance criteria for precision and accuracy, and the laboratory chooses to develop laboratory-specific limits, the laboratory-specific limits shall not be less stringent than the criteria stated in the approved method.

(B) If quality control results fall outside established limits or show an analytical problem, the laboratory shall identify the Root Cause of the failure. The problem shall be resolved through corrective action, the corrective action process documented, and any samples involved shall be reanalyzed, if possible. If the sample cannot be reanalyzed, or if the quality control results continue to fall outside established limits or show an analytical problem, the results shall be qualified as such.

(C) Except where otherwise specified in an analytical method, laboratories shall analyze five percent of all samples in duplicate to document precision. Laboratories analyzing fewer than 20 samples per month shall analyze one duplicate during each month that samples are analyzed.

(D) Unless the referenced method states a greater frequency or the parameter is not amenable to spiking, laboratories shall spike five percent of samples monthly. Laboratories analyzing fewer than 20 samples per month shall analyze one Matrix Spike during each month that samples are analyzed.

(E) All analytical records, including original observations and information necessary to facilitate historical reconstruction of the calculated results, shall be maintained for five years. All analytical data and records pertinent to each certified analysis shall be available for inspection upon request. All analytical records shall be legible to all parties and safeguarded against unauthorized amendment, obliteration, erasures, overwriting, and corruption. Records that are stored only on electronic media shall be maintained throughout the five-year retention period and supported in the laboratory by all hardware and software necessary for data retrieval and review. All documentation errors shall be corrected by drawing a single line through the error so that the original entry remains legible. Entries shall not be obliterated by erasures or markings. Wite-Out®, correction tape, or similar products designed to obliterate documentation shall not to be used; instead, the correction shall be written adjacent to the error. The correction shall be initialed by the responsible individual and the date of change documented. All manual data and log entries shall be written in indelible ink.

(F) All laboratories shall use printable laboratory benchsheets. Certified Data shall be traceable to the associated sample analyses and shall consist of:

(i) the method or Standard Operating Procedure;
(ii) the laboratory identification;
(iii) the instrument identification;
(iv) the sample collector;
(v) the signature or initials of the analyst;
(vi) the date and time of sample collection;
(vii) the date of sample analyses;
(viii) the time of sample analyses (when required to document a required holding time or when time-critical steps are imposed by the method, a federal regulation, or this Rule);
(ix) sample identification;
(x) sample preparation, where applicable;
(xi) the volume of sample analyzed, where applicable;
(xii) the proper units of measure;
(xiii) the dilution factor, where applicable;
(xiv) all manual calculations;

(xv) all quality control assessments;
(xvi) the value from the measurement system;
(xvii) the final value to be reported; and
(xviii) any other data needed to reconstruct the final calculated result.

Each item shall be recorded each time that samples are analyzed. The date and time that samples are placed into and removed from ovens, water baths, incubators and other equipment shall be documented if a time limit is required by the method.

(G) If certified for total suspended residue, total dissolved residue, or total residue, laboratories shall analyze one standard monthly during each month samples are analyzed.

(H) For analytical procedures requiring analysis of a series of standards, the concentrations of these standards shall bracket the range of the sample concentrations measured. One of the standards shall have a concentration equal to or less than the laboratory's lowest reporting concentration for the parameter involved. All data sets shall reference the corresponding calibration. Laboratories shall analyze or back-calculate a standard at the same concentration as the lowest reporting concentration each day samples are analyzed. A calibration blank and calibration verification standard shall be analyzed prior to sample analysis, after every tenth sample, and at the end of each sample group, unless otherwise specified by the method, to check for carryover and calibration drift.

(i) The concentration of reagent, method, and calibration blanks shall not exceed 50 percent of the lowest reporting concentration or as otherwise specified by the reference method.

(ii) Laboratories shall analyze one known second source standard to verify the accuracy of standard preparation if an initial calibration is performed and in accordance with the referenced method requirements thereafter.

(iii) For electrode analyses, a series of two or more non-zero standards shall be used.

(iv) For metals analyses, a series of three or more non-zero standards or standards as set forth in the analytical procedure shall be analyzed with each sample set.

(v) For colorimetric analyses, a series of five or more non-zero standards for a curve prepared every 12 months or three or more non-zero standards for curves established each day, or standards as set forth in the analytical procedure, shall be analyzed to establish a calibration curve. A manufacturer's factory-set calibration (internal curve) shall be verified with the same number of standards and frequency as a prepared curve.

(vi) For ion chromatographic analyses, a series of five or more non-zero standards for a curve prepared every 12 months or three or more non-zero standards for curves established each day, or standards as set forth in the analytical procedure, shall be analyzed to establish a calibration curve.

(I) Each day samples are placed into or removed from an incubator, oven, water bath, refrigerator, or other temperature-controlled device, the temperature shall be checked, recorded, dated, and initialed. If a method requires more frequent monitoring, the method shall be followed. During each use of an autoclave, the temperature, pressure, cycle time, and items autoclaved shall be checked, recorded, dated, and initialed.

(J) The analytical balance shall be checked with one ASTM Type 1, Class 1 or 2, or equivalent standard weight each day used. These weights shall be verified every five years. The analytical balance shall be verified monthly with three ASTM Type 1, Class 1 or 2, or equivalent standard weights across the range of use. The values obtained shall be recorded, dated, and initialed. Laboratory analytical balances shall be serviced by a metrology vendor or technician every 12 months to verify that the balance is functioning within manufacturer's specifications.

(K) Chemical containers shall be dated when received and when opened. Reagent containers shall be dated, identified, and initialed when prepared. Chemicals and reagents exceeding the expiration date shall not be used. The laboratory shall have a documented system of traceability for the purchase, preparation, and use of all chemicals, reagents, standards, and consumables.

(L) A record of sample collection date, sample collection time, sample collector, and the use of proper preservatives and preservation techniques shall be maintained. Each North Carolina sample shall indicate the collection site on all record transcriptions.

(M) Sample preservation shall be verified and documented. If a laboratory receives a sample subject to G.S. 143-215.1 and 143-215.63 that does not meet sample collection, holding time, or preservation requirements, the laboratory shall document the incident, notify the sample collector or client, and secure another sample that meets the regulatory requirements, if possible. If another viable sample cannot be secured, the original sample may be analyzed but the results reported shall be qualified with the nature of the sample collection, holding time, or preservation infractions and the laboratory shall notify the State Laboratory of the infractions. The notification shall include a statement indicating corrective action taken to prevent future infractions.

(N) All temperature-measuring devices shall have accuracy that meets or exceeds one-half the tolerance required for its intended use. All temperature-measuring devices shall be used, stored, and maintained according to the manufacturer's instructions.

(i) Reference Temperature-Measuring Devices shall meet National Institute of Standards and Technology (NIST) specifications for accuracy and shall be recalibrated in accordance with the manufacturer's recalibration date not to exceed five years. If no recalibration date is given, the Reference Temperature-Measuring Device shall be recalibrated every five years.

(ii) Excluding digital, incubator, and infrared temperature-measuring devices, all non-Reference Temperature-Measuring Devices shall be verified at the temperature of use every 12 months against a Reference Temperature-Measuring Device and their accuracy shall be corrected.

(iii) Digital temperature-measuring devices and temperature-measuring devices used in incubators shall be verified at the temperature of use every three months against a Reference Temperature-Measuring Device and their accuracy shall be corrected.

(iv) Infrared temperature-measuring devices shall be verified every three months at three different temperatures over the temperature range of use against a Reference Temperature-Measuring Device and their accuracy shall be corrected. Each day of use, infrared temperature-measuring devices shall be verified against a non-Reference Temperature-Measuring Device that meets NIST specifications for accuracy. If the infrared temperature-measuring device does not agree within 0.5 degrees Celsius during the daily verification, the laboratory shall take corrective action.

(O) Mechanical volumetric liquid-dispensing devices (e.g., fixed and adjustable auto-pipettors and bottle-top dispensers) used for critical volume measurements shall be calibrated once every six months.

(P) Each laboratory shall develop and implement a documented training program that includes documentation that:

(i) staff have the education, training, experience, or demonstrated skills needed to generate quality control results within method-specified limits and meet the requirements of these Rules;

(ii) staff have read the laboratory quality assurance manual and applicable Standard Operating Procedures; and

(iii) staff have obtained acceptable results on Proficiency Testing Samples pursuant to Rule .0803(1) of this Section or other demonstrations of proficiency (e.g., side-by-side comparison with a trained analyst, acceptable results on a single-blind performance evaluation sample, an initial demonstration of capability study prescribed by the reference method).

(b) Issuance of Certification.

(1) Upon compliance with these Rules, Certification shall be issued by the Director or assigned delegate, for each of the applicable Parameter Methods requested within 30 calendar days of payment of the initial invoice.

(2) Initial Certifications shall be valid for the remainder of the applicable Certification cycle that begins on January 1 and ends December 31 of the same year.

(c) Maintenance of Certification.

(1) To maintain Certification for each Parameter Method, a certified laboratory shall analyze one Proficiency Testing Sample per Parameter Method per year. A laboratory may be asked to analyze additional Proficiency Testing Samples for a Parameter Method if a question about the accuracy of data produced arises, if there are changes in equipment or personnel, if inaccurate information is reported with Proficiency Testing results, or if Unacceptable Proficiency Testing Results are submitted.

(2) In addition, if a Proficiency Testing Sample is not available, the State Laboratory may request the analysis of Split Samples. Acceptable Split Sample results shall be determined by the State Laboratory using scientifically valid statistical methodology.

(3) The State Laboratory may require certified laboratories to analyze blind Proficiency Testing Samples or Split Samples under direction of State Laboratory personnel if there is a question about the accuracy of data produced, if Proficiency Testing Samples are not available, or if analysis of Proficiency Testing Samples does not represent the entire analytical process.

(4) A certified laboratory shall be subject to periodic announced or unannounced inspections during the Certification period and shall make time and all records pursuant to Part (a)(7)(E) of this Rule available for inspection.

(5) A certified laboratory shall supply copies of all records pursuant to Part (a)(7)(E) of this Rule for any investigation upon written request by the State Laboratory.

(6) A certified laboratory shall provide the State Laboratory with written notice of laboratory supervisor or laboratory manager changes within 30 calendar days of such changes.

(7) A certified laboratory shall submit written notice of any changes of location, ownership, address, name, or telephone number within 30 calendar days of such changes.

(d) Certification Renewals. Certification renewals shall be issued for one year.

(e) Data Reporting.

(1) Certified Commercial Laboratories shall provide data reports to their clients that are signed by the laboratory supervisor. This signatory authority may be delegated in writing.

(2) If a certified laboratory refers or subcontracts analysis of samples to another laboratory certified for the Parameter, the referring laboratory shall supply the date and time that samples were collected to insure holding times are met. All record transcriptions of subcontracted samples shall state that the collection site is in North Carolina. Laboratories may subcontract sample fractions, extracts, leachates, and other sample preparation products provided that adherence to 15A NCAC 02H .0800 is documented. The initial client requesting the analyses shall receive the original or a copy of the report made by the laboratory that performs the analyses. Each reported result shall be traceable to the laboratory that performed the analysis on the final report.

(3) All Uncertified Data shall be documented as such on the benchsheet and on the final report.

(4) Sample results reported below the lowest reporting concentration, if required by the data receiver, shall be qualified as an estimated value.

(5) Reported data associated with quality control failures, improper sample collection, holding time exceedances, or improper preservation shall be qualified as such.

(f) Voluntary Discontinuation of Certification.

(1) A laboratory may discontinue Certification for any or all Parameter Methods by making a written request to the State Laboratory.

(2) After discontinuation of Certification, a laboratory shall only be recertified by meeting the requirements for initial Certification; however, laboratories that discontinue Certification during any investigation shall be subject to Rule .0808 of this Section.

(g) Prerequisites and Requirements for Field Laboratory Certification. Laboratories that meet the requirements of this Paragraph shall be certified as Field Laboratories. Once certified, failure to comply with any of the following items shall be a violation of Certification requirements.

(1) All analytical records, including original observations and information necessary to facilitate historical reconstruction of the calculated results, shall be maintained for five years. All analytical data and records pertinent to each certified analysis shall be available for inspection upon request. All analytical records shall be legible to all parties and safeguarded against unauthorized amendment, obliteration, erasures, overwriting and corruption. Records that are stored only on

electronic media shall be maintained throughout the five-year retention period and supported in the laboratory by all hardware and software necessary for data retrieval and review. All documentation errors shall be corrected by drawing a single line through the error so that the original entry remains legible. Entries shall not be obliterated by erasures or markings. Wite-Out®, correction tape, or similar products designed to obliterate documentation are not to be used; instead the correction shall be written adjacent to the error. The correction shall be initialed by the responsible individual and the date of change documented. All manual data and log entries shall be written in indelible ink.

(2) All laboratories shall use printable laboratory benchsheets. Certified Data shall be traceable to the associated sample analyses and shall consist of:

(A) the method or Standard Operating Procedure;
(B) the laboratory identification;
(C) the instrument identification;
(D) the sample collector;
(E) the signature or initials of the analyst;
(F) the date and time of sample collection;
(G) the date of sample analyses;
(H) the time of sample analyses (when required to document a required holding time or when time-critical steps are imposed by the method, a federal regulation, or this Rule);
(I) sample identification;
(J) sample preparation, where applicable;
(K) the volume of sample analyzed, where applicable;
(L) the proper units of measure;
(M) the dilution factor, where applicable;
(N) all manual calculations;
(O) the quality control assessments;
(P) the value from the measurement system;
(Q) the final value to be reported; and
(R) any other data needed to reconstruct the final calculated result.

Each item shall be recorded each time samples are analyzed. Analyses shall conform to methodologies found in Subparagraph (a)(1) of this Rule.

(3) A record of instrument calibration or calibration verification shall be documented and available for inspection upon request.

(4) Laboratory Procedures. Laboratory procedures shall comply with Subparagraph (a)(1) of this Rule. A copy of each analytical method or Approved Procedure and Standard Operating Procedure shall be available to each analyst and available for review upon request by the State Laboratory. Standard Operating Procedure documentation shall state the effective date of the document and shall be reviewed every two years and updated if changes in procedures are made. Each laboratory shall have a formal process to track and document review dates and any revisions made in all Standard Operating Procedure documents. Supporting Records shall be maintained as evidence that these practices are implemented.

(5) Each laboratory shall develop and implement a documented training program that includes the following:

(A) that staff have the education, training, experience, or demonstrated skills needed to generate quality control results within method-specified limits and that meet the requirements of these Rules;
(B) that staff have read the laboratory quality assurance manual or applicable Standard Operating Procedures;
(C) that staff have obtained acceptable results on Proficiency Testing samples pursuant to Rule .0803(1) of this Section or other demonstrations of proficiency (e.g., side-by-side comparison with a trained analyst, acceptable results on a single-blind performance evaluation sample, an initial demonstration of capability study prescribed by the reference method).

(6) Each facility shall have glassware, chemicals, supplies, equipment, and a source of water that meets the criteria of the approved methodologies. Samples shall be analyzed in such a manner that contamination or error will not be introduced.

(7) Chemical containers shall be dated when received and when opened. Reagent containers shall be dated, identified, and initialed when prepared. Chemicals and reagents exceeding the expiration date shall not be used. Chemicals and reagents shall be assigned expiration dates by the laboratory if not given by the manufacturer. If the laboratory is unable to determine an expiration date for a chemical or reagent, a one-year time period from the date of receipt shall be the expiration date unless degradation is observed prior to this date. The laboratory shall have a documented system of traceability for all chemicals, reagents, standards, and consumables.

(8) If quality control results fall outside established limits or indicate an analytical problem, the laboratory shall identify the Root Cause of the failure. The problem shall be resolved through corrective action, the corrective action process documented, and any samples involved shall be reanalyzed, if possible. If the sample cannot be reanalyzed, or if the quality control results continue to fall outside established limits or indicate an analytical problem, the results shall be qualified as such.

(9) All temperature-measuring devices shall have accuracy that meets or exceeds one-half the tolerance required for its intended use. All temperature-measuring devices shall be used, stored, and maintained in accordance with the manufacturer's instructions.

(A) Reference Temperature-Measuring Devices shall meet National Institute of Standards and Technology (NIST) specifications for accuracy and shall be recalibrated in accordance with the manufacturer's recalibration date. If no recalibration date is given, the Reference Temperature-Measuring Device shall be recalibrated every five years.

(B) Excluding digital, incubator, and infrared temperature-measuring devices, all non-Reference Temperature-Measuring Devices shall be verified every twelve months against a Reference Temperature-Measuring Device and their accuracy shall be corrected.

(C) Digital temperature-measuring devices and temperature-measuring devices used in incubators shall be verified every three months against a Reference Temperature-Measuring Device and their accuracy shall be corrected.

(D) Infrared temperature-measuring devices shall be verified every three months at three different temperatures over the temperature range of use against a Reference Temperature-Measuring Device and their accuracy shall be corrected. Each day of use, infrared temperature-measuring devices shall be verified against a non-Reference Temperature-Measuring Device that meets NIST specifications for accuracy. If the infrared temperature-measuring device does not agree within 0.5 degrees Celsius during the daily verification, corrective action must be taken.

(10) Mechanical volumetric liquid-dispensing devices (e.g., fixed and adjustable auto-pipettors and bottle-top dispensers) shall be calibrated at least once every twelve months.

(11) Supervisors of laboratories certified only for Field Parameters shall:

(A) meet the requirements of Part (a)(3)(A) or (a)(3)(B) of this Rule;

(B) possess a chemistry or related degree with two years of related environmental experience or an equivalent combination of education and work experience; or

(C) hold any Water Pollution Control System Operator's Certification as defined by 15A NCAC 08G.

Supervisors shall provide personal and direct supervision of the technical personnel and shall be responsible for adherence to all requirements in this Rule. If the supervisor will be absent, the supervisor shall arrange for a substitute capable of insuring adherence to all requirements in this Rule. The substitute supervisor shall not be in charge for more than 12 consecutive weeks.

(12) A certified Field Laboratory shall be subject to inspections during the Certification period and shall make all records pursuant to this Section available for inspection.

(13) A certified Field Laboratory shall supply copies of all records pursuant to this Section for any investigation upon written request by the State Laboratory.

(14) A certified Field Laboratory shall pay all applicable fees in accordance with Rule .0806 of this Section.

(15) Application. Each Field Laboratory requesting initial Certification shall submit an application to the State Laboratory that includes the laboratory name, contact information, EPA laboratory code number, permit number(s), laboratory supervisor information, analytical methods, and equipment. The application may be obtained by request from the State Laboratory or on the State Laboratory

website at https://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/application-forms-0.

(16) Proficiency Testing. Each certified Field Laboratory shall be in accordance with Subparagraph (a)(2) of this Rule.

(17) Data Reporting. Each certified Field Laboratory shall be in accordance with Paragraph (e) of this Rule.

(18) Issuance of Certification. A Field Laboratory shall be issued Certification in accordance with Paragraph (b) of this Rule.

(19) Maintenance of Certification. A certified Field Laboratory shall submit written notice of any changes in the laboratory supervisor, location, ownership, address, name, and telephone number within 30 days of such changes.

(20) Certification Renewals. Certification renewals of certified Field Laboratories shall be issued in accordance with Paragraph (d) of this Rule.

(21) Discontinuation of Certification. A certified Field Laboratory may discontinue Certification in accordance with Paragraph (f) of this Rule.

(22) Decertification. A certified Field Laboratory may be decertified and must meet all Decertification requirements for infractions in accordance with Rule .0807 of this Section.

(23) Civil Penalties. Civil Penalties may be assessed against a certified Field Laboratory that violates or fails to act in accordance with any of the terms, conditions, or requirements of the Rule .0807 of this Section.

(24) Recertification. A decertified Field Laboratory may be recertified in accordance with Rule .0808 of this Section.

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.6A;*
Eff. February 1, 1976;
Amended Eff. July 1, 1988; July 1, 1985; December 1, 1984; November 1, 1978;
RRC Objection Eff. October 15, 1992 due to lack of statutory authority;
Amended Eff. December 21, 1992;
RRC Objection Removed Eff. December 16, 1993;
Temporary Amendment Eff. October 1, 2001;
Amended Eff. August 1, 2002;
Readopted Eff. July 1, 2019.