15A NCAC 02H .0801 is proposed for readoption :

15A NCAC 02H .0801 PURPOSE

The purpose of these Rules is to set out ~~certification~~Certification criteria for laboratory facilities performing any tests, analyses, measurements, or monitoring required under G.S. 143 Article 21 or any rules adopted thereunder, and to establish fees for ~~certification~~Certification program support.

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10);*
Eff. February 1, 1976;
Amended Eff. November 2, 1992; December 1, 1984; November 1, 1978;
Temporary Amendment Eff. October 1, 2001;
Amended Eff. August 1, 2002.

Commented [SD1]: Terms defined within this Rule were capitalized throughout. Editorial – no impact. I will not add Comment boxes for those from this point forward.

15A NCAC 02H .0802 is proposed readoption :

15A NCAC 02H .0802 SCOPE

These Rules apply to laboratory facilities which perform and report ~~analyses~~tests, analyses, measurements or monitoring for persons subject to G.S. ~~143-215.1,~~ 143-215.1 and 143-215.63, et seq. ~~seq.~~; ~~the Environmental Management Commission Rules for Surface Water Monitoring and Reporting found in Subchapter 2B of this Chapter, Section .0500 (Only facilities classified in accordance with Classification of Water Pollution Control Systems Rules found in 15A NCAC 08G .0300 are subject to these Rules.); Groundwater Rules found in 15A NCAC 02L .0100, .0200, and .0300; Waste Not Discharged to Surface Waters Rules found in 15A NCAC 02H .0200; Point Source Discharges to the Surface Waters Rules found in 15A NCAC 02H .0100. These Rules also apply to all wastewater treatment plant laboratories for municipalities having Local Pretreatment Programs as regulated in 15A NCAC 02H .0900. Laboratory facilities performing and reporting analyses for field parameters only, shall be considered for certification as specified in Rule .0805(g) of this Section.~~ These Rules do not apply to facilities which are not classified in accordance with Classification of Water Pollution Control Systems Rules found in 15A NCAC 08G .0300 and biological toxicity testing in accordance with 15A NCAC 2H .1100.

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10);*
Eff. February 1, 1976;
Amended Eff. November 2, 1992; July 1, 1988; December 1, 1984;
Temporary Amendment Eff. October 1, 2001;
Amended Eff. August 1, 2002.

Commented [SD2]: Added language to include terms that better characterize all parameters that fall under the scope of these Rules – they are not all considered "analyses".
Clarity – no impact.

Commented [SD3]: Rather than trying to list all Rules under the G.S. that are subject, we just listed the G.S. and included the exceptions per recommendation from DWR legal counsel. Ensures no pertinent rule is overlooked and alleviates the need to update when new rules are adopted.
Simplification and clarity – no impact.

15A NCAC 02H .0803 is proposed for readoption :

15A NCAC 02H .0803 DEFINITIONS

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

~~(1) "Analytical chemistry experience" means experience analyzing samples in a chemistry laboratory or supervising a chemistry laboratory that analyzes samples.~~

~~(2) "Certification" means a declaration by the state that the personnel, equipment, records, quality control procedures, and methodology cited by the applicant are accurate and that the applicant's proficiency has been considered and found to be acceptable pursuant to these Rules.~~

~~(3) "Certified Data" shall be defined as any analytical result, including the supporting documentation, obtained through the use of a method or procedure which has been deemed acceptable by the State of North Carolina for Laboratory Certification purposes pursuant to these Rules.~~

~~(4) "Commercial Laboratory" means any laboratory, including its agents or employees, which is seeking to analyze or is analyzing samples, including Field Parameters, for others for a fee.~~

~~(5) "Decertification" means loss of certification.~~

~~(6) "Falsified data or information" means data or information which has been made untrue by alteration, fabrication, omission, substitution, or mischaracterization. The agency need not prove intent to defraud to prove data is falsified.~~

~~(7) "Field Parameters", for the purpose of these Rules shall include Total Residual Chlorine, Conductivity, Dissolved Oxygen, pH, Settleable Residue, and Temperature.~~

~~(8) "Inaccurate data or other information" means data or information that is in any way incorrect, or mistaken.~~

~~(9) "Industrial Laboratory" means a laboratory, including its agents or employees, operated by an industry to analyze samples, including Field Parameters, from its wastewater or wastewater from its water treatment plant(s).~~

~~(10) "Municipal Laboratory" means a laboratory, including its agents or employees, operated by a municipality or other local government to analyze samples, including Field Parameters, from its wastewater or wastewater from its water treatment plant(s).~~

~~(11) "Other" laboratory means a facility that does not require laboratory certification as part of its routine operation and does not analyze samples for a fee, or is doing business as a non-profit facility.~~

~~(12) "Pretreatment Program" means a program of waste pretreatment requirements set up in accordance with 15A NCAC 02H .0900 and approved by the Division of Water Quality.~~

~~(13) "State" means the North Carolina Department of Environment and Natural Resources, or its successor.~~

~~(14) "State Laboratory" means the Laboratory Section of the North Carolina Division of Water Quality, or its successor.~~

Commented [SD4]: Removed this language to allow for the broader range of sample types in Industrial facility permits. Technical correction – no effect

Commented [SD5]: Removed this language to allow for the broader range of sample types in Municipal facility permits. Technical correction – no effect

~~(15) "Unacceptable results" means those results on performance evaluation samples that exceed the specified acceptable range as indicated by a US EPA accredited vendor.~~

~~(16) "Uncertified data" shall be defined as any analytical result, including the supporting documentation, obtained using a method or procedure which is not acceptable to the State Laboratory pursuant to these Rules.~~

(1) Acceptable Proficiency Testing results means those results on Proficiency Testing samples that are within the Vendor-specified acceptable range as indicated by a State Laboratory approved Vendor or Split samples that are within the specified acceptance range as indicated by the State Laboratory.

(2) Analytical chemistry experience means experience analyzing samples in a chemistry laboratory or supervising a chemistry laboratory that analyzes samples.

(3) Approved Procedure means an analytical procedure developed by the State Laboratory, based upon relevant reference methods, and approved for use for monitoring subject to G.S. 143-215.1 and 143-215.63, et seq.

(4) Certification means a declaration by the State Laboratory that the personnel, equipment, records, quality control procedures, and methodology cited by the applicant comply with these Rules and that the applicant's proficiency has been considered and found to be acceptable pursuant to these Rules.

(5) Certified Data means any analytical result, including the Supporting Records, obtained through the use of a method or procedure which has been deemed acceptable by the State Laboratory for laboratory Certification purposes pursuant to these Rules.

(6) CFR means the Code of Federal Regulations.

(7) Commercial Laboratory means any laboratory, including its agents or employees, which is seeking to analyze or is analyzing samples, including Field Parameters, for others for a fee.

(8) Decertification means loss of Certification.

(9) Director means Director of the Division of Water Resources or its successor.

(10) Division means the Division of Water Resources or its successor.

(11) Falsified Data or Information means data or information that, whether by intent or reckless disregard for accuracy, has been altered, fabricated, or otherwise falsely mischaracterized by omission or substitution, such that the value or information reported is incorrect, incomplete, and/or inaccurate. The agency need not prove intent to defraud to prove data is falsified.

(12) Field Laboratory means a laboratory, including its agents or employees, which is seeking Certification to analyze or is analyzing samples for Field Parameters only.

(13) Field Parameter(s) for the purpose of these Rules shall include Total Residual Chlorine, Free Available Chlorine, Conductivity, Dissolved Oxygen, pH, Settleable Residue, Salinity, Sulfite, Turbidity, Temperature, Vector Attraction Reduction Option 5, Vector Attraction Reduction Option 6, and Vector Attraction Reduction Option 12.

Commented [SD6]: Added definition for clarity – no impact

Commented [SD7]: Added definition for clarity – this potentially saves money for laboratories by eliminating the need to purchase methods/compendiums for some parameters.

Commented [SD8]: Revised definition to provide clarity – no impact

Commented [SD9]: Added definition for clarity – no impact

Commented [SD10]: Added definition for clarity – no impact

Commented [SD11]: Added definition for clarity – no impact

Commented [SD12]: Revised definition for clarity and improved legal defensibility based on DWR legal counsel's recommendation and stakeholder input – no effect.

Commented [SD13]: Added definition for clarity – no impact

Commented [SD14]: Added additional parameters to the definition – this will potentially have a negative impact for some laboratories – by expanding the list of short-hold, field amenable tests, some labs may be able to change status from a Municipal/Industrial/Other lab to a Field Lab, where annual fees are less.

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

(15) Industrial Laboratory means a laboratory, including its agents or employees, operated by an industry to analyze samples under the scope of these Rules.

(16) In-situ means in the original or natural place or site; or an aliquot taken and analyzed immediately (as soon as possible after collection) at the site.

Commented [SD15]: Added definition for clarity – no impact

(17) Matrix Spike means an additional aliquot of an environmental sample to which a known concentration of the analyte(s) of interest is added before sample preparation, cleanup and determinative procedures have been implemented. It is used to assess the performance of the method by measuring the effects of interferences caused by the sample matrix and reflects the bias of the method for the particular matrix in question.

Commented [SD16]: Added definition for clarity – no impact

(18) Mobile Laboratory means a collection of analytical equipment and instruments contained in an environmentally controlled, covered, vehicle that can be deployed to a project site, for other than Field Laboratory Certification purposes. All Mobile laboratories will be considered separate laboratories and will require separate Certification.

Commented [SD17]: Added definition for clarity – currently undefined - There are only 2 mobile laboratories certified currently. This may potentially impact those laboratories since they have more than one mobile unit certified under one certificate. This will depend upon how they deploy those mobile units for NC projects and how many units they determine they will need for NC to obtain certification.

(19) Municipal Laboratory means a laboratory, including its agents or employees, operated by a municipality or other local government to analyze samples under the scope of these Rules. Municipal Laboratories may cost-share among Municipal Laboratories or charge a cost recovery fee or surcharge to operate their Pretreatment Program.

Commented [SD18]: Revised definition for clarity – no impact

(20) NPDES means National Pollutant Discharge Elimination System.

Commented [SD19]: Added definition for clarity – no impact

(21) Other Laboratory means a facility that does not require State Laboratory Certification as part of its routine operation and does not analyze samples for a fee, or is doing business as a non-profit facility.

(22) Parameter means the analyte, element, compound, or property being measured.

Commented [SD20]: Added definition for clarity – no impact

(23) Parameter Method means a type of analytical technique, including materials and tools, used to measure a parameter which is different from other analytical methods used to measure the same parameter.

Commented [SD21]: Added definition for clarity – gives laboratories more flexibility and may potentially negatively impact labs if a lab is decertified for a Parameter by multiple methods, the laboratory could maintain certification for the unaffected methods for that Parameter. Currently, the lab would be decertified for all methods for that Parameter and would have to contract or subcontract to a certified laboratory until the decertification period is over and all requirements for recertification are met.

(24) Pretreatment Program means a program of waste pretreatment requirements set up in accordance with 15A NCAC 02H .0900, et seq. and approved by the Division.

(25) Proficiency Testing (PT) sample means a performance evaluation sample whose true value is unknown to the laboratory and provided by a State Laboratory approved Vendor to test whether the laboratory can produce analytical results within the specified acceptance criteria.

Commented [SD22]: Added definition for clarity – no impact

(26) Recertification means re-instating Certification at the end of the Decertification period imposed by the Division pursuant to 15A NCAC 02H .0807 by showing to the satisfaction of the State Laboratory that is has corrected the deficiency(ies).

Commented [SD23]: Added definition for clarity – no impact

(27) Second Source means from a different manufacturer or from the same manufacturer and identified by a different lot number.

Commented [SD24]: Added definition for clarity – no impact

(28) Split sample means two or more representative portions taken from a sample or subsample and analyzed by at least two laboratories approved by the State Laboratory.

(29) Standard Operating Procedure (SOP) means a prescriptive reference document that describes a laboratory's analytical or operational procedures with adequate detail to allow someone similarly qualified to reproduce the procedures used to generate the test or desired result.

(30) State means the North Carolina Department of Environmental Quality, or its successor.

(31) State Laboratory means the Water Sciences Section, or its successor, including the Laboratory Certification Branch of the North Carolina Division of Water Resources, or its successor.

(32) Supporting Record means any document or other source of information compiled, recorded or stored in written form or by electronic process, or in any other manner that provides any information necessary to historically reconstruct and/or characterize a reported value.

(33) Unacceptable Proficiency Testing results means those results on Proficiency Testing samples that do not fall within the Vendor-specified acceptable range as indicated by a State Laboratory approved Vendor; or Split samples that do not fall within the specified acceptable range as indicated by the State Laboratory; or a failure to meet a reporting deadline imposed by the Vendor or State Laboratory.

(34) Uncertified Data means any analytical result, including the Supporting Records, obtained using a method or procedure which is not acceptable to the State Laboratory pursuant to these Rules; or analytical results produced by a laboratory for an analysis not falling under the Scope of these Rules; or analytical results produced by a laboratory without proper Certification.

(35) US EPA means the United States Environmental Protection Agency.

(36) Vector Attraction Reduction Option refers to the 12 numbered options for demonstrating a reduction in vector attraction of sewage sludge in 40 CFR Part 503.33(b)(1) through (b)(12).

(37) Vendor means an accredited Proficiency Testing sample provider recognized by The NELAC Institute (TNI) or its successor.

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10);*
Eff. February 1, 1976;
Amended Eff. November 2, 1992; December 1, 1984; November 1, 1978;
Temporary Amendment Eff. October 1, 2001;
Amended Eff. August 1, 2002.

Commented [SD25]: Added definition for clarity – no impact

Commented [SD26]: Added definition for clarity – no impact

Commented [SD27]: Added definition for clarity – no impact

Commented [SD28]: Provides clarity by describing both PT results and Split sample results and removes an obsolete reference to EPA accredited vendor. EPA no longer accredits PT vendors. – no effect

Commented [SD29]: Expanded to provide clarity – no effect

Commented [SD30]: Added definition for clarity – no impact

Commented [SD31]: Added definition for clarity - no impact

Commented [SD32]: Added definition for clarity – no impact

15A NCAC 02H .0804 is proposed for readoption :

15A NCAC 02H .0804 PARAMETERS FOR WHICH CERTIFICATION MAY BE REQUESTED

(a) Commercial ~~laboratories~~Laboratories are required to obtain ~~certification~~Certification for ~~parameters~~Parameter Methods used to generate data which will be reported by the client to the State in accordance with Rule .0802 of this Section. ~~comply with State surface water monitoring, groundwater, and pretreatment Rules.~~ Municipal and Industrial Laboratories are required to obtain ~~certification~~Certification for ~~parameters~~Parameter Methods used to generate data which will be reported to the State in accordance with Rule .0802 of this Section. ~~to comply with State surface water monitoring, groundwater, and pretreatment Rules. Commercial, Municipal, and Industrial and Other~~ Commercial Laboratories~~facilities~~ are required to obtain ~~certification~~Certification for ~~field~~Field ~~parameters~~Parameter Methods used to generate data which will be reported by the client to the State in accordance with Rule .0802 of this Section. ~~comply with State surface water, groundwater, and pretreatment Rules.~~Municipal and Industrial laboratories are required to obtain Certification for Field Parameter Methods used to generate data which will be reported to the State in accordance with Rule .0802 of this Section.

(b) Inorganics: Each of the inorganic, physical characteristic and microbiological analytes listed in this paragraph will be considered a certifiable parameter. Analytical methods shall be determined from the sources listed in Rule .0805 (a) (1) of this Section. One or more analytical methods or Parameter Methods may be listed with a laboratory's certified parameters. A listing of certifiable inorganic, physical characteristic and microbiological parameters follows:

~~(1) Alkalinity~~
~~(2) Aquatic Humic Substances~~
~~(3) BOD~~
~~(4) COD~~
~~(5) Chloride~~
~~(6) Chlorine, Total Residual~~
~~(7) Chlorophyll~~
~~(8) Coliform, Fecal~~
~~(9) Coliform, Total~~
~~(10) Color~~
~~(11) Conductivity~~
~~(12) Cyanide~~
~~(13) Dissolved Oxygen~~
~~(14) Fluoride~~
~~(15) Hardness, Total~~
~~(16) MBAS~~
~~(17) Ammonia Nitrogen~~
~~(18) Total Kjeldahl Nitrogen (TKN)~~

Commented [SD33]: Editorial changes to capitalize defined terms and make wording consistent to provide clarity – no impact.

Commented [SD34]: Added language to better define Inorganics – provides clarity – no impact.

Commented [SD35]: Removed – not necessary – no impact

~~(19) Nitrate plus Nitrite Nitrogen~~

~~(20) Nitrate Nitrogen~~

~~(21) Nitrite Nitrogen~~

~~(22) Total Phosphorus~~

~~(23) Orthophosphate~~

~~(24) Oil and Grease~~

~~(25) pH~~

~~(26) Phenols~~

~~(27) Residue, Settleable~~

~~(28) Residue, Total~~

~~(29) Residue, Total Dissolved 180°C~~

~~(30) Residue, Total Suspended~~

~~(31) Salmonella~~

~~(32) Sulfate~~

~~(33) Sulfide~~

~~(34) Sulfite~~

~~(35) Temperature~~

~~(36) Total Organic Carbon (TOC)~~

~~(37) Turbidity~~

~~(38) Leachate Procedures~~

~~(39) Vector Attraction Reduction – All Options~~

(1) Acidity

(2) Alkalinity

(3) Biochemical Oxygen Demand

(4) Bromide

(5) Carbonaceous Biochemical Oxygen Demand

(6) Chemical Oxygen Demand

(7) Chloride

(8) Chlorine, Free Available

(9) Chlorine, Total Residual

(10) Chlorophyll

(11) Coliform, Fecal

(12) Coliform, Total

(13) Color

(14) Conductivity/Specific Conductance

(15) Cyanide

(16) Dissolved Organic Carbon

Commented [SD36]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water Quality/Chemistry Lab/Certification/Memos/new methods memo 2002.pdf

Commented [SD37]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/Bromide%20approval%20to%20certify%202012.pdf

Commented [SD38]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/FreeAvailableChlorineDirectorApproval2012.pdf

Commented [SD39]: Provided clarification that the parameter includes Conductivity measured at ambient and 25°C temperatures – no effect.

Commented [SD40]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/AdditionalParameterDirectorApprovalLetter-03022007-DWQ-LAB-CERT.pdf

(17) Dissolved Oxygen

(18) Enterococci

(19) Escherichia Coliform (*E. coli*)

(20) Flash Point

(21) Fluoride

(22) Hardness, Total

(23) Ignitability

(24) Surfactants as Methylene Blue Active Surfactants

(25) Nitrogen, Ammonia

(26) Nitrogen, Nitrite plus Nitrate

(27) Nitrogen, Nitrate

(28) Nitrogen, Nitrite

(29) Nitrogen, Total Kjeldahl

(30) Oil and Grease

(31) Orthophosphate

(32) Paint Filter Liquids

(33) pH

(34) Phenols

(35) Phosphorus, Total

(36) Residue, Settleable

(37) Residue, Total

(38) Residue, Total Dissolved

(39) Residue, Total Suspended

(40) Residue, Volatile

(41) Salinity

(42) Salmonella

(43) Silica

(44) Sulfate

(45) Sulfide

(46) Sulfite

(47) Temperature

(48) Total Organic Carbon

(48) Turbidity

(49) Vector Attraction Reduction: Option 1

(50) Vector Attraction Reduction: Option 2

(51) Vector Attraction Reduction: Option 3

(52) Vector Attraction Reduction: Option 4

Commented [SD41]: Editorial, changed format of parameter name for clarity – no effect

Commented [SD42]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/AdditionalParameterDirectorApprovalLetter-03022007-DWQ-LAB-CERT.pdf

Commented [SD43]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/AdditionalParameterDirectorApprovalLetter-03022007-DWQ-LAB-CERT.pdf

Commented [SD44]: Currently certified under the Ignitability Parameter, but separated in proposed revision since Flash Point is actually a different method-defined parameter – technical correction - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/new%20methods%20memo%202002.pdf – could impact some laboratories that elect to maintain certification for both Flash Point and Ignitability since they will be charged separately but only if they are above the minimum annual fee; however may save some labs money in the event they are decertified for one of the parameters, since they would lose certification for only that parameter and not both.

Commented [SD45]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/new%20methods%20memo%202002.pdf

Commented [SD46]: Changed to parameter name format in 40 CFR Part 136 and provides clarity – no effect

Commented [SD47]: Changed parameter name format to provide consistency – no effect

Commented [SD48]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/new%20methods%20memo%202002.pdf

Commented [SD49]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/AdditionalParameterDirectorApprovalLetter2-10052007-DWQ-LAB-CERT.jpg

Commented [SD50]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/AdditionalParameterDirectorApprovalLetter2-10052007-DWQ-LAB-CERT.jpg

Commented [SD51]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/AdditionalParameterDirectorApprovalLetter-03022007-DWQ-LAB-CERT.pdf

(53) Vector Attraction Reduction: Option 5

(54) Vector Attraction Reduction: Option 6

(55) Vector Attraction Reduction: Option 7

(56) Vector Attraction Reduction: Option 8

(57) Vector Attraction Reduction: Option 12

(c) Metals: Each of the metals and certified leaching procedures for metals listed in this Paragraph ~~following~~ will be considered a certifiable parameter. ~~Metals analyte:~~ One or more Parameter Methods may be listed with a laboratory's certified parameters. Analytical methods shall be determined from the sources listed in Rule .0805 (a) (1) of this Section. A listing of certifiable metals and leaching procedures follows:

(1) Aluminum

(2) Antimony

(3) Arsenic

(4) Barium

(5) Beryllium

~~(6) Cadmium~~

~~(7) Calcium~~

~~(8) Chromium, Total~~

~~(9) Chromium, Hexavalent~~

~~(10) Cobalt~~

~~(11) Copper~~

~~(12) Iron~~

~~(13) Lead~~

~~(14) Magnesium~~

~~(15) Manganese~~

~~(16) Mercury~~

~~(17) Molybdenum~~

~~(18) Nickel~~

~~(19) Selenium~~

~~(20) Silver~~

~~(21) Thallium~~

~~(22) Tin~~

~~(23) Vanadium~~

~~(24) Zinc~~

(6) Boron

(7) Cadmium

(8) Calcium

(9) Chromium, Hexavalent (Chromium VI)

Commented [SD52]: Currently listed as *Vector Attraction Reduction – All Options*. Split out for clarity since Options 9, 10 and 11 are not necessary and should be excluded from the scope of this certification. May potentially impact some laboratories if they elect to maintain certification for multiple options since they will be charged separately but only if they are above the annual fee minimum.

Commented [SD53]: Added language to better define Metals – provides clarity – no impact.

Commented [SD54]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/new%20methods%20memo%202002.pdf

Commented [SD55]: Provide clarity – no effect

(10) Chromium, Total
(11) Chromium, Trivalent (Chromium III)
(12) Cobalt
(13) Copper
(14) Hardness, Total (Calcium + Magnesium)
(15) Iron
(16) Lead
(17) Lithium
(18) Magnesium
(19) Manganese
(20) Mercury
(21) Molybdenum
(22) Nickel
(23) Potassium
(24) Phosphorus
(25) Selenium
(26) Silica
(27) Silver
(28) Sodium
(29) Strontium
(30) Thallium
(31) Tin
(32) Titanium
(33) Vanadium
(34) Zinc
(35) Synthetic Precipitation Leaching Procedure for Metals (SPLP)
(36) Toxicity Characteristic Leaching Procedure for Metals (TCLP)

(d) Organics: Each of the organic parameters ~~analytical categories~~ and certified leaching procedures for organics listed in this Paragraph shall be considered a certifiable parameter. One or more Parameter Methods may be listed with a laboratory's certified parameters. Analytical methods shall be determined from the sources listed in Rule .0805(a) (1) of this Section. A listing of certifiable organic parameters and leaching procedures follows:

~~(1) Purgeable Halocarbons~~
~~(2) Purgeable Aromatics~~
~~(3) Acrolein, Acrylonitrile, Acetonitrile~~
~~(4) Phenols~~
~~(5) Benzidines~~
~~(6) Phthalate Esters~~

Commented [SD56]: Added this parameter based on anticipated monitoring requirements. May impact labs if they elect to add this to their scope of certification and are over the minimum annual fee.

Commented [SD57]: Added this parameter under the metals subsection for clarity to indicate method of derivation – May impact labs if they elect to add this to their scope of certification in addition to inorganic Hardness methods and are over the minimum annual fee.

Commented [SD58]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/AdditionalParameterDirectorApprovalLetter-03022007-DWQ-LAB-CERT.pdf

Commented [SD59]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/new%20methods%20memo%202002.pdf

Commented [SD60]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/AdditionalParameterDirectorApprovalLetter-03022007-DWQ-LAB-CERT.pdf

Commented [SD61]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/new%20methods%20memo%202002.pdf

Commented [SD62]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/AdditionalParameterDirectorApprovalLetter-03022007-DWQ-LAB-CERT.pdf

Commented [SD63]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/AdditionalParameterDirectorApprovalLetter-03022007-DWQ-LAB-CERT.pdf

Commented [SD64]: Moved placement under Metals and split out TCLP from SPLP for clarity since they are different method-defined parameters. May potentially impact laboratories that elect to maintain certification for both parameters and are above the minimum annual fee since they will be charged separately.

Commented [SD65]: Added language to better define Organics – provides clarity – no impact.

~~(7) Nitrosamines~~

~~(8) Organochlorine Pesticides~~

~~(9) Polychlorinated Biphenyls~~

~~(10) Nitroaromatics and Isophorone~~

~~(11) Polynuclear Aromatic Hydrocarbons~~

~~(12) Haloethers~~

~~(13) Chlorinated Hydrocarbons~~

~~(14) Purgeable Organics~~

~~(15) Base/Neutral and Acid Organics~~

~~(16) Chlorinated Acid Herbicides~~

~~(17) Organophosphorus Pesticides~~

~~(18) Total Petroleum Hydrocarbons - (TPH) California GC Method - Diesel Range Organics~~

~~(19) Total Petroleum Hydrocarbons - (TPH) California GC Method - Gasoline Range Organics~~

Commented [SD66]: Removed – Not necessary

~~(20) Nonhalogenated Volatile Organics~~

~~(21) N-Methylcarbamates~~

~~(22) 1,2, Dibromoethane (EDB)~~

~~(23) Extractable Petroleum Hydrocarbons~~

~~(24) Volatile Petroleum Hydrocarbons~~

~~(25) Chlorinated Phenolics~~

~~(26) Adsorbable Organic Halides~~

(1) 1,2-Dibromoethane (EDB); 1,2-Dibromo-3-chloro-propane (DBCP); 1,2,3-Trichloropropane (TCP)

Commented [SD67]: Added these additional analytes to the parameter to allow laboratories the opportunity to obtain certification for the additional constituents found in the EDB methods. – No effect

(2) Acetonitrile

(3) Acrolein, Acrylonitrile

Commented [SD68]: Split out Acetonitrile from the Acrolein, Acrylonitrile parameter to reflect current approved reference methods target analyte lists. May potentially impact some laboratories which may elect to maintain certification for both parameters and which are above the minimum annual fee since they will be charged separately.

(4) Adsorbable Organic Halides

(5) Base/Neutral and Acid Organics

(6) Benzidines

(7) Chlorinated Acid Herbicides

(8) Chlorinated Hydrocarbons

(9) Chlorinated Phenolics

(10) Explosives

Commented [SD69]: Added this parameter based on anticipated monitoring requirements. May impact labs if they elect to add this to their scope of certification and are over the minimum annual fee.

(11) Extractable Petroleum Hydrocarbons

(12) Haloethers

(13) N-Methylcarbamates

(14) Nitroaromatics and Isophorone

(15) Nitrosamines

(16) Nonhalogenated Volatile Organics

(17) Organochlorine Pesticides
(18) Organophosphorus Pesticides
(19) Phenols
(20) Phthalate Esters
(21) Polychlorinated Biphenyls
(22) Polynuclear Aromatic Hydrocarbons
(23) Purgeable Aromatics
(24) Purgeable Halocarbons
(25) Purgeable Organics
(26) Total Organic Halides
(27) Total Petroleum Hydrocarbons – Diesel Range Organics
(28) Total Petroleum Hydrocarbons – Gasoline Range Organics
(29) Volatile Petroleum Hydrocarbons
(30) Synthetic Precipitation Leaching Procedure for Organics (SPLP)
(31) Toxicity Characteristic Leaching Procedure for Organics (TCLP)

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10);*
Eff. February 1, 1976;
Amended Eff. November 2, 1992; December 1, 1984;
Temporary Amendment Eff. October 1, 2001;
Amended Eff. August 1, 2002.

Commented [SD70]: Added parameter currently approved by Director's letter – no effect - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Memos/new%20methods%20memo%202002.pdf

Commented [SD71]: Moved placement under Organics and split out TCLP from SPLP for clarity and since they are different method-defined parameters. May potentially impact laboratories that elect to maintain certification for both since they will be charged separately.

15A NCAC 02H .0805 is proposed for readoption :

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

(a) Prerequisites and requirements for Certification. The following requirements must be met by all laboratories, excluding Field Laboratories, prior to ~~certification~~Certification. Once certified, failure to comply with any of the following items will be a violation of ~~certification~~Certification requirements. All ~~"Field Parameter" only facility~~Field Laboratory requirements are located in Paragraph (g) of this Rule.

Commented [SD72]: Editorial – no effect

~~(1) Laboratory Procedures. Analytical methods, sample preservation, sample containers and sample holding times shall conform to those requirements found in 40 CFR 136.3; Standard Methods for the Examination of Water and Wastewater, 18th Edition; or Test Methods for Evaluating Solid Waste, SW 846, Third Edition. These and subsequent amendments and editions are incorporated by reference. This material is available for inspection at the State Laboratory, 4405 Reedy Creek Road, Raleigh, North Carolina, 27607. Copies of the Code of Federal Regulations, 40 CFR Part 136, may be obtained for a cost of forty-two dollars ($42.00), from the Superintendent of Documents, U.S. Government Printing Office (GPO), Superintendent of Public Documents, Washington, DC, 20402. The publication number is 869-042-00148-6. Standard Methods for the Examination of Water and Waste, is available for purchase from the American Water Works Association (AWWA), 6666 West Quincy Avenue, Denver, CO 80235. The costs are as follows: 18th Edition - one hundred sixty dollars ($160.00), 19th Edition - one hundred eighty dollars ($180.00), 20th Edition - two hundred dollars ($200.00). Copies of Test Methods for Evaluating Solid Waste, SW 846, Third Edition may be purchased for a cost of three hundred sixty seven dollars ($367.00) from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, DC 20402. Vector Attraction Reduction Options shall be Control of Pathogens and Vector Attraction in Sewage Sludge; EPA/625/R-92/013, Chapter 8. The document is available from US EPA; Office of Research and Development, Washington, NC 20460 at no cost. The method for Total Petroleum Hydrocarbons shall be the California Gas Chromatograph Method, Eisenberg, D.M., and others, 1985, Guidelines for Addressing Fuel Leaks: California Regional Quality Control Board San Francisco Bay Region. The method for Total Petroleum Hydrocarbons is available from the State Laboratory at no cost. The methods for Volatile Petroleum Hydrocarbons and Extractable Petroleum Hydrocarbons shall be Massachusetts Department of Environmental Protection, Method for the Determination of Volatile Petroleum Hydrocarbons (VPH) and Method for the Determination of Extractable Petroleum Hydrocarbons (EPH); January, 1998. The Director may approve other analytical procedures that have been demonstrated to produce verifiable and repeatable results and that have a widespread acceptance in the scientific community.~~

(1) Laboratory Procedures. Analytical methods, sample preservation, sample containers and sample holding times shall conform to those 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) 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 above.

(G) These and subsequent amendments, revisions and editions are incorporated by reference.

(H) This material is available for inspection at the State Laboratory, 4405 Reedy Creek Road, Raleigh, North Carolina, 27607 or may be obtained from:

(i) Copies of 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 on the internet 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) Copies of 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 on the internet at http://www.epa.gov/osw/hazard/testmethods/sw846/online/.

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

(v) The methods for Volatile Petroleum Hydrocarbons and Extractable Petroleum Hydrocarbons shall be Massachusetts Department of Environmental Protection, Method for the Determination of Volatile Petroleum Hydrocarbons (VPH) and Method for the Determination of Extractable Petroleum Hydrocarbons (EPH); May, 2004, Revision 1.1. These methods may be obtained from the Massachusetts Department of Environmental Protection, Senator William X.

Commented [SD73]: No new requirement added - http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/technical-assistance-policies - may potentially have a negative impact on some laboratories since they would not have to purchase some approved reference methods.

Wall Experiment Station, 37 Shattuck Street, Lawrence, MA, 01843-1398 and free of charge on the internet at http://www.mass.gov/eea/docs/dep/cleanup/laws/vph0504.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 Certification website at http://portal.ncdenr.org/web/wq/lab/cert.

(J) The Director or assigned delegate may approve other analytical procedures, parameters or Parameter Methods that have been demonstrated to produce verifiable and repeatable results and that have a widespread acceptance in the scientific community.

~~(2) Performance Evaluations. Annually, each certified laboratory must demonstrate acceptable performance on evaluation samples as required by these Rules.~~

(2) Proficiency Testing. Annually, each certified laboratory must demonstrate acceptable performance on a minimum of one evaluation sample, for all Parameter Methods listed on their Certified Parameters Listing for which Proficiency Testing samples are readily available, 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 will 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 must analyze a remedial Proficiency Testing sample to demonstrate a return to control and send a corrective action report to the State Laboratory that details the root cause of the failure and the corrective action(s) taken to prevent recurrence. Proficiency Testing samples must be analyzed in the same manner that routine samples are analyzed using the same staff, sample tracking, sample preparation and analysis methods, standard operating procedures, calibration techniques, quality control procedures and acceptance criteria.

~~(A) Municipal and Industrial laboratories must participate in the annual Environmental Protection Agency Discharge Monitoring Report Quality Assurance (EPA/DMR/QA) Study by analyzing performance evaluation samples obtained from an accredited vendor as unknowns, and reporting data produced to the State. The laboratory is responsible for submitting acceptable results for all parameters listed on their certificate.~~

(A) All laboratories must participate annually in an evaluation study(ies) 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 must analyze a remedial Proficiency Testing sample using the same Parameter Method to demonstrate a return to control and send a corrective action report to the State

Commented [SD74]: No new requirement added - http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/technical-assistance-policies - may potentially have a negative impact on some laboratories since they would not have to purchase some approved reference methods.

Commented [SD75]: Updated contact information, added URLs and reformatted the Rule for easier readability – no effect

Commented [SD76]: No new requirement added – updated to current industry nomenclature - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Technical%20Assistance%20Documents/PTRequirementsDocument20120120Revision%201.2F.pdf

Laboratory that details the root cause of the failure and the corrective action(s) taken to prevent recurrence.

~~(B) Commercial laboratories must participate annually in water pollution studies by analyzing performance evaluation samples obtained from an accredited vendor as unknowns, and reporting data produced to the State. The laboratory is responsible for submitting acceptable results for all parameters listed on their certificate. When two samples for the same parameter are submitted and analyzed at the same time, an unacceptable result on one or both samples will be considered the first unacceptable result for certification purposes and a rerun sample must be submitted.~~

~~(C)~~(B) Laboratories requesting initial ~~certification~~Certification or additional Parameter Method Certification must submit an acceptable ~~performance~~ Proficiency Testing sample result from the most recent attempt analyzed within the last six months, for each ~~parameter~~Parameter Method for which ~~performance~~ Proficiency Testing samples are readily available. Laboratories must 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~~Unacceptable Proficiency Testing results for a particular ~~parameter~~ Parameter Method must then submit two consecutive ~~acceptable~~Acceptable Proficiency Testing results from the most recent attempt analyzed within the six months prior to initial Certification for that ~~parameter~~ Parameter Method.~~prior to initial certification.~~

~~(D)~~(C) If Proficiency Testing ~~performance~~ samples are not readily available, ~~available for a parameter,~~ Certification~~certification~~ for that parameter will be based on the proper use of the approved procedure, the on-site inspection, ~~and~~and/or adherence to the other requirements in this Section. Analysis of ~~split~~Split samples may also be required.

(3) Supervisory Requirements.

(A) The supervisor of a ~~commercial laboratory~~Commercial Laboratory must have a minimum of a ~~B.S. or A.B.~~ four-year degree in chemistry or closely related science curriculum from an accredited college or university plus a minimum of two years laboratory experience in analytical chemistry, or a ~~two year~~ two-year associate degree from an accredited college, university, or technical institute in chemistry technology, environmental sciences, or closely related science curriculum plus a minimum of four years experience in analytical chemistry.

(B) The supervisor of a ~~municipal or industrial waste water treatment plant~~ non-Commercial Municipal, Industrial, Mobile or Other Laboratory~~laboratory~~ must have a minimum of a ~~B.S. or A.B.~~ four-year degree in chemistry or closely related science curriculum from an accredited college or university plus a minimum of six months laboratory experience in analytical chemistry or an equivalent combination of education and work experience, or a

Commented [SD77]: No new requirement added – updated to current industry nomenclature - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Technical%20Assistance%20Documents/PTRequirementsDocument20120120Revision%201.2F.pdf

Commented [SD78]: No new requirement added – updated to current industry nomenclature - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Technical%20Assistance%20Documents/PTRequirementsDocument20120120Revision%201.2F.pdf

Commented [SD79]: Editorial – no effect

Commented [SD80]: Editorial – no effect

Commented [SD81]: Editorial – no effect

~~two-year~~ two-year associate degree from an accredited college, university, or technical institute in chemistry technology, environmental sciences, or closely related science curriculum plus a minimum of two years experience in analytical chemistry or an equivalent combination of education and work experience. Non-degree supervisors must have at least six years laboratory experience in analytical chemistry or an equivalent combination of education and work experience.

(C) All laboratory supervisors are 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 be held responsible for the proper performance and reporting of all analyses made for these Rules. The supervisor must work in the laboratory or ~~visit~~ contact the laboratory once each day of normal operations and Supporting Records shall be maintained as evidence. If the supervisor is to be absent, the supervisor shall arrange for a substitute capable of insuring the proper performance of all laboratory procedures, however, the substitute supervisor cannot be in charge for more than ~~six~~ twelve consecutive weeks. ~~Existing laboratory supervisors that do not meet the requirements of this Rule may be accepted after review by the State Laboratory and meeting all other certification requirements.~~ Previous laboratory-related performance will be considered when reviewing the qualifications of a potential laboratory supervisor.

(4) Laboratory Manager. Each laboratory must designate a laboratory manager and include ~~his~~ their name and title on the application for ~~certification~~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,~~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 ~~state certification~~Certification shall submit an application ~~in duplicate,~~ accompanied by the application fee and the laboratory's Quality Assurance ~~Manual~~ Manual, including Standard Operating Procedures for all requested Parameter Methods, to the State Laboratory. Separate application and Certification shall be required for Mobile Laboratories and the applicant must supply the vehicle make, vehicle identification number and license number where applicable. Separate application and ~~certification~~Certification shall be required for all stationary laboratories maintained on separate premises even though operated under the same management; however, separate ~~certification~~Certification is not required for separate buildings on the same or adjoining grounds. Analysis of Field Parameters away from the physical location of the laboratory is permitted without separate Certification. After receiving a

Commented [SD82]: Provides clarity – no effect

Commented [SD83]: Allows the laboratories more flexibility in meeting supervisory obligations – less stringent

Commented [SD84]: Extended length of time to be in concert with current FRMLA policies – less stringent

Commented [SD85]: Removed – not necessary – this language was in the original Rule to grandfather existing supervisors into the program.

Commented [SD86]: Removed the requirement to reduce paper waste – negative impact

Commented [SD87]: Provides clarity that SOPs must be submitted when they are not a part of a laboratory's Quality Assurance Manual – no effect

Commented [SD88]: There are only 2 mobile laboratories certified currently. This may potentially impact those laboratories since they have more than one mobile unit certified under one certificate. This will depend upon how they deploy those mobile units for NC projects and how many units they determine they will need for NC to obtain certification.

Commented [SD89]: Provides clarity – no new requirement

completed application and prior to issuing ~~certification,~~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) Properly Maintained Facilities, Supplies, and Equipment. ~~Facilities and equipment.~~ Each laboratory requesting ~~certification~~Certification must be properly maintained so as to ensure the security and integrity of samples. A best effort must be made to perform analyses in a manner where possible sources of contamination or error will not be introduced. Each facility must contain or be equipped with the following:

~~(A) A minimum of 150 sq. ft. of laboratory space;~~

~~(B) A minimum of 12 linear feet of laboratory bench space;~~

~~(C) A sink with hot and cold water;~~

~~(D) An analytical balance capable of weighing 0.1 mg, mounted on a shock proof table;~~

~~(E) A refrigerator of adequate size to store all samples and maintain temperature of four degrees Celsius;~~

~~(F) A copy of each approved analytical procedure being used in the laboratory;~~

~~(G) A source of distilled or deionized water that will meet the minimum criteria of the approved methodologies;~~

~~(H) Glassware, chemicals, supplies, and equipment required to perform all analytical procedures included in their certification.~~

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

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

~~(7) Analytical Quality Control Program. Each laboratory shall develop and maintain a document outlining the analytical quality control practices used for the parameters included in their certification. Supporting records shall be maintained as evidence that these practices are being effectively carried out. The quality control document shall be available for inspection by the State Laboratory. The following are requirements for certification and must be included in each certified laboratory's quality control program:~~

~~(A) All analytical data pertinent to each certified analysis must be filed in an orderly manner so as to be readily available for inspection upon request.~~

~~(B) Excluding Oil and Grease, all residue parameters, leachate extractions, residual chlorine, and coliform, analyze one known standard in addition to calibration standards each day samples are analyzed to document accuracy. Analyze one suspended residue, one dissolved residue, one residual chlorine and one oil and grease standard quarterly. For residual chlorine, all calibration standards required by the approved procedure in use and by EPA must be analyzed.~~

Commented [SD90]: No new requirement - http://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/quality_assurance_policies_for_field_laboratories_10_01_2013.pdf - provides clarification to ensure data integrity and defensibility.

Commented [DS91]: Moved to Section .0805 (a) (7) (A) – no effect

Commented [SD92]: Changed from "a source of distilled or deionized water" to allow labs greater flexibility and to cater to just the analyses under the scope of their accreditation.

Commented [SD93]: Removed the more prescriptive minimum requirements to allow greater flexibility for labs that do not need all of these items to effectively analyze and report the parameters in the scope of their accreditation – potential negative impact.

(C) Except for Oil and Grease (EPA Method 413.1), settleable solids or where otherwise specified in an analytical method, analyze five percent of all samples in duplicate to document precision. Laboratories analyzing less than 20 samples per month must analyze at least one duplicate each month samples are analyzed.

(D) Any quality control procedures required by a particular approved method shall be considered as required for certification for that analysis.

(E) All quality control requirements in these Rules as set forth by the State Laboratory.

(F) Any time quality control results indicate an analytical problem, the problem must be resolved and any samples involved must be rerun if the holding time has not expired.

(G) All analytical records must be available for a period of five years. Records, which are stored only on electronic media, must be maintained and supported in the laboratory by all hardware and software necessary for immediate data retrieval and review.

(H) All laboratories must use printed laboratory bench worksheets that include a space to enter the signature or initials of the analyst, date of analyses, sample identification, volume of sample analyzed, value from the measurement system, factor and final value to be reported and each item must be recorded each time samples are analyzed. The date and time BOD and coliform samples are removed from the incubator must be included on the laboratory worksheet.

(I) For analytical procedures requiring analysis of a series of standards, the concentrations of these standards must bracket the concentration of the samples analyzed. One of the standards must have a concentration equal to the laboratory's lower reporting concentration for the parameter involved. For metals by AA or ICP, a series of at least three standards must be analyzed along with each group of samples. For colorimetric analyses, a series of five standards for a curve prepared annually or three standards for curves established each day or standards as set forth in the analytical procedure must be analyzed to establish a standard curve. The curve must be updated as set forth in the standard procedures, each time the slope changes by more than 10 percent at mid-range, each time a new stock standard is prepared, or at least every twelve months. Each analyst performing the analytical procedure must produce a standard curve.

(J) Each day an incubator, oven, waterbath or refrigerator is used, the temperature must be checked, recorded, and initialed. During each use, the autoclave maximum temperature and pressure must be checked, recorded, and initialed.

(K) The analytical balance must be checked with one class S, or equivalent, standard weight each day used and at least three standard weights quarterly. The values obtained must be recorded in a log and initialed by the analyst.

(L) Chemicals must be dated when received and when opened. Reagents must be dated and initialed when prepared.

Commented [DS94]: Removed since this is outdated and some methods require duplicates for these parameters now.

~~(M) A record of date collected, time collected, sample collector, and use of proper preservatives must be maintained. Each sample must clearly indicate the State of North Carolina collection site on all record transcriptions.~~

~~(N) At any time a laboratory receives samples which do not meet sample collection, holding time, or preservation requirements, the laboratory must notify the sample collector or client and secure another sample if possible. If another sample cannot be secured, the original sample may be analyzed but the results reported must be qualified with the nature of the infraction(s) and the laboratory must notify the State Laboratory about the infraction(s). The notification must include a statement indicating corrective actions taken to prevent the problem for future samples.~~

~~(O) All thermometers must meet National Institute of Standards and Technology (NIST) specifications for accuracy or be checked, at a minimum annually, against a NIST traceable thermometer and proper corrections made.~~

(7) Analytical Quality Assurance and Quality Control Program. Each laboratory must have a documented analytical quality assurance and quality control program. Each laboratory must have a copy of each approved test, analysis, measurement or monitoring procedure being used in the laboratory. Each laboratory shall develop and maintain documentation outlining the analytical quality control practices used for the Parameter Methods included in their Certification. This must include Standard Operating Procedures for each certified Parameter Method. Quality Assurance, Quality Control and Standard Operating Procedure documentation must clearly indicate the effective date of the document and be reviewed at least every two years and updated as needed. Each laboratory must have a formal process to track and document review dates and any revisions made in all of their Quality Assurance, Quality Control and Standard Operating Procedure documents. Supporting Records shall be maintained as evidence that these practices are being effectively carried out. The Quality Assurance, Quality Control and Standard Operating Procedure documents shall be available for inspection by the State Laboratory. The following are requirements for Certification and must be included in each certified laboratory's Quality Assurance and Quality Control program. For analysis of Field Parameters, a certified laboratory may follow the quality assurance and quality control requirements in Paragraphs (g) (1) through (9) of this Rule.

(A) Unless specified by the method or this Rule, each laboratory must establish acceptance criteria for all Quality Control analyses. Each laboratory must calculate and document the precision and accuracy of all Quality Control analyses with each sample set, where applicable. 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 cannot be less stringent than the criteria stated in the approved method.

Commented [SD95]: Editorial – added to better characterize the content of this section of the Rule – no effect

Commented [SD96]: Added language to include terms that better characterize all parameters that fall under the scope of these Rules. Clarity – no impact.

Commented [DS97]: Provides clarification for laboratories whose SOPs are not a part of the Quality Assurance Manual – no effect

Commented [DS98]: Provided clarification of the elements of document control for QA/QC documents for data defensibility purposes and set a timeline for periodic review to ensure these documents are up to date. May have minimal impact in terms of personnel time to review.

Commented [DS99]: Provides clarity – no effect

Commented [DS100]: Added to ensure that laboratories develop quality control practices where none are prescribed by method or Rule. 40 CFR Part 136 requires this, but not all of the programs under the scope of our Rule fall under Clean Water Act requirements. Also, provides consistency across all regulatory programs. May potentially have some impact on some laboratories; however, most methods have quality control requirements already prescribed.

Commented [DS101]: Added for clarity - No new requirement – Has always been enforced using .0805 (a) (7) - Supporting Records shall be maintained as evidence that these practices are being effectively carried out.

Commented [DS102]: Provides clarity – Has always been enforced using the method requirement.

(B) Any time quality control results fall outside established limits or indicate an analytical problem, the laboratory must take steps to identify the root cause of the failure. The problem must be resolved through corrective action, the process documented and any samples involved must 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 must be appropriately characterized by qualification.

(C) Except where otherwise specified in an analytical method, analyze five percent of all samples in duplicate to document precision. Laboratories analyzing less than 20 samples per month must analyze at least one duplicate each month samples are analyzed.

(D) Unless the referenced method states a greater frequency or the parameter is not amenable to spiking, spike 5% of samples on a monthly basis. Laboratories analyzing less than 20 samples per month must analyze at least one Matrix Spike each month samples are analyzed.

(E) All analytical records, including original observations and information necessary to facilitate historical reconstruction of the calculated results, must be maintained so as to ensure their security and integrity for five years. All analytical data and records pertinent to each certified analysis must be accurate and filed in an orderly manner so as to be readily available for inspection upon request. All analytical records must be legible and safeguarded against unauthorized amendment, obliteration, erasures, overwriting and corruption. Records which are stored only on electronic media must be securely maintained throughout the five year retention period and supported in the laboratory by all hardware and software necessary for immediate data retrieval and review. All documentation errors must 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. Write the correction adjacent to the error. The correction must be initialed by the responsible individual and the date of change documented. All manual data and log entries must be written in indelible ink. Pencil entries are not acceptable.

(F) All laboratories must use printable laboratory benchsheets. Certified Data must be traceable to the associated sample analyses and must consist of the method or Standard Operating Procedure, laboratory identification, instrument identification, sample collector, signature or initials of the analyst, date of collection, time of collection, date of analyses, time of 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), sample identification, sample preparation where applicable, volume of sample analyzed where applicable, proper units of measure, dilution factor where applicable, all manual

Commented [DS103]: Provides clarity – no effect

Commented [DS104]: Provides clarity – no effect

Commented [DS105]: Provides clarity – no effect

Commented [DS106]: Added for clarity - No new requirement – Has always been enforced using .0805 (a) (7) - Supporting Records shall be maintained as evidence that these practices are being effectively carried out.

Commented [DS107]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/QualifyingDataPolicy20110406.pdf

Commented [DS108]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/Matrix%20Spike%20Policy20120511.pdf

Commented [DS109]: Added for clarity - No new requirement – Has always been enforced using .0805 (a) (7) - Supporting Records shall be maintained as evidence that these practices are being effectively carried out.

Commented [DS110]: Added for clarity – no effect

Commented [DS111]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/ElectronicDataSstorageAndSignature-20100409-DWQ-LAB-CERT.pdf and provides clarity to current Rule which reads: *All analytical records must be available for a period of five years.*

Commented [DS112]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/Error%20Correction%20Policy.pdf

Commented [DS113]: Changed from "printed" to reduce paper waste and allow laboratories the flexibility of electronic reporting. May potentially save some labs money.

calculations, quality control assessments, value from the measurement system, final value to be reported and any other data needed to reconstruct the final calculated result. Each item must be recorded each time samples are analyzed. The date and time samples are placed into and removed from ovens, water baths, incubators and other equipment must be documented where a time limit is imposed by the method.

(G) When certified for total suspended residue, total dissolved residue and/or total residue, laboratories must 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 must bracket the range of the sample concentrations measured. One of the standards must have a concentration equal to or less than the laboratory's lowest reporting concentration for the parameter involved. All data sets must reference the corresponding calibration. Analyze and/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 must be analyzed initially (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 carry over and calibration drift.

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

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

(iii) For electrode analyses, a minimum two-point calibration is required.

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

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

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

Commented [DS114]: Added specific items for clarity – no new requirement – Has always been enforced using .0805 (a) (7) - Supporting Records shall be maintained as evidence that these practices are being effectively carried out.

Commented [DS115]: Provides clarity – no effect

Commented [DS116]: Provides clarity - No new requirement - Has always been enforced using .0805 (a) (7) - Supporting Records shall be maintained as evidence that these practices are being effectively carried out.

Commented [DS117]: Added to ensure accurate and legally defensible data at the lower reporting concentration – May potentially impact some labs that cite methods that do not already require this, but adding the option to back-calculate rather than analyze a standard alleviates that impact in some cases.

Commented [DS118]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/Calibration%20Verification%20Mid.%20Std.%20and%20Blk%20After%2010%20Policy02_2014.pdf

Commented [DS119]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/BlankAcceptanceCriterion50Policy02_14.pdf

Commented [DS120]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/Second%20Source%20Standard%20Policy-20100708-DWQ-LAB-CERT.pdf

Commented [DS121]: Adds clarity – no effect

Commented [DS122]: Added clarity – no effect

Commented [DS123]: Provides clarity by addressing new technology and equipment that have factory-set calibrations.

Commented [DS124]: Provides clarity by specifically addressing this technology – no effect

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

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

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

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

(M) Sample preservation must be verified and documented. At any time a laboratory receives samples subject to G.S. 143-215.1 and 143-215.63, et seq. which do not meet sample collection, holding time, or preservation requirements, the laboratory must document the incident, notify the sample collector or client and secure another sample, if possible. If another viable sample cannot be secured, the original sample may be analyzed but the results reported must be qualified with the nature of the infraction(s) and the laboratory must notify the State Laboratory of the infraction(s). The notification must include a statement indicating corrective action taken to prevent the problem for future samples.

(N) All temperature sensing devices must meet National Institute of Standards and Technology (NIST) specifications for accuracy or be checked, at a minimum every twelve months, against a NIST traceable, or equivalent, temperature sensing device and proper corrections made. Temperature sensing devices used only to verify other laboratory temperature sensing devices may be checked every 5 years against a NIST traceable, or equivalent, temperature sensing device and proper corrections made. All temperature sensing devices must have accuracy appropriate for its intended use. All temperature sensing devices must be properly used, stored and maintained.

Commented [DS125]: This alleviates the burden of staffing on weekends – may potentially have a negative impact on labs

Commented [SD126]: Provides clarity – no effect

Commented [SD127]: Provides clarity - No new requirement - Has always been enforced using .0805 (a) (7) - Supporting Records shall be maintained as evidence that these practices are being effectively carried out.

Commented [SD128]: Updated to current weight classifications – no effect

Commented [SD129]: Added to ensure accurate and legally defensible data – May potentially impact some labs; however, vendors will often provide this service at no charge.

Commented [SD130]: Increased the frequency of balance checks across the range of use from quarterly to monthly to ensure accurate and legally defensible data. Minimal effect since the weights are already on hand.

Commented [SD131]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/Analytical%20Balance%20Service%20Policy.pdf

Commented [SD132]: Added "containers" to provide clarity – no effect

Commented [SD133]: Added "containers" to provide clarity – no effect

Commented [SD134]: Added to provide clarity – no effect

Commented [SD135]: Added to provide clarity – no effect

Commented [SD136]: Provides clarity - No new requirement - Has always been enforced using .0805 (a) (7) - Supporting Records shall be maintained as evidence that these practices are being effectively carried out.

Commented [SD137]: Added to provide clarity – no effect

Commented [SD138]: Provides clarity – no effect

Commented [SD139]: Provides clarity - No new requirement - Has always been enforced using .0805 (a) (7) - Supporting Records shall be maintained as evidence that these practices are being effectively carried out.

Commented [SD140]: Changed from "thermometers" to cover other technologies used to sense temperature to ensure accurate and legally defensible data – provides clarity – no effect

Commented [SD141]: Changed from "annually" to provide clarity – no effect

Commented [SD142]: Added a less frequent requirement for limited use thermometers to alleviate burden on labs – May potentially have a negative impact on some labs.

Commented [SD143]: **Added for clarity – no new requirement – enforced by 15A NCAC 2H .0805 (a) (6) (H) - *Glassware, chemicals, supplies, and equipment required to perform all analytical procedures included in their certification.***

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

(P) Each laboratory must develop and implement a documented training program which includes, at a minimum, documentation of the following:

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

(ii) staff have read the laboratory Quality Assurance Manual and/or applicable Standard Operating Procedures;

(iii) staff have obtained acceptable results on unknown performance evaluation samples or other demonstrations of proficiency.

~~(8) Decertification Requirements. Municipal and industrial laboratories that cannot meet initial certification requirements must comply with the Decertification Requirements as set forth in Rule .0807(e) of this Section.~~

(b) Issuance of Certification.

(1) Upon compliance with these Rules, ~~certification~~Certification shall be issued by the Director, ~~Division of Water Quality, Department of Environmental Quality~~ or ~~his~~ assigned delegate, for each of the applicable ~~parameters~~ Parameter Methods requested within 30 days of receipt of the initial Certification invoice payment.

(2) Initial ~~certifications~~Certifications shall be valid for the remainder of the applicable Certification cycle. ~~issued for prorated time periods to schedule all certification renewals on the first day valid for one year.~~

(c) Maintenance of Certification.

(1) To maintain ~~certification~~Certification for each ~~parameter~~ Parameter Method, a certified laboratory must analyze ~~up to four performance evaluation~~ a minimum of one Proficiency Testing sample ~~samples~~ per ~~parameter~~ Parameter Method per ~~year~~year. ~~submitted by an accredited vendor as an unknown. Laboratories submitting unacceptable results on a performance evaluation samples may be required to analyze more than four samples per year.~~A laboratory may be asked to analyze additional Proficiency Testing samples for a Parameter Method whenever a question about the accuracy of data produced arises, when there are changes in equipment or personnel, when inaccurate information is reported with Proficiency Testing results, or when Unacceptable Proficiency Testing results are submitted.

(2) In addition, if a Proficiency Testing sample is not readily available, the State Laboratory may request the analysis of Split samples, ~~that samples be split into two equal representative portions, one part going to the State and the other to the certified laboratory for analysis.~~Acceptable Split

Commented [SD144]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/Pipettor%20Calibration%20Policy%20-%2003_09.pdf

Commented [SD145]: Added to ensure accurate and legally defensible data – should have minimal effect since it is documentation-oriented

Commented [SD146]: Removed obsolete language that was meant to grandfather labs in when the Rules were originally written– not necessary

Commented [SD147]: Provides clarification – no effect

Commented [SD148]: Simplified language for clarity – no effect

Commented [SD149]: Reworded to provide clarification – many stakeholders thought this meant they had to analyze 4 samples per year – no new requirement

sample results will be determined by the State Laboratory using scientifically valid statistical methodology.

(3) The State laboratory may submit or require ~~clients~~certified laboratories to ~~submit~~analyze blind ~~performance~~ Proficiency Testing samples or ~~split~~Split samples under direction of State Laboratory personnel.

(4) A certified laboratory shall be subject to periodic announced or unannounced inspections during the ~~certification~~Certification period and shall make time and all relevant records available for ~~inspections~~ inspection. ~~and must supply copies of records for any investigation upon written request by the State Laboratory.~~

~~(5) A certified laboratory must provide the State Laboratory with written notice of laboratory supervisor or laboratory manager changes within 30 days of such changes.~~

~~(6) A certified laboratory must submit written notice of any changes of location, ownership, address, name or telephone number within 30 days of such changes.~~

~~(7) A certified laboratory must submit a written amendment to the certification application each time that changes occur in methodology, reporting limits, and major equipment. The amendment must be received within 30 days of such changes.~~

(5) A certified laboratory must supply copies of all relevant records for any investigation upon written request by the State Laboratory.

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

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

(d) Certification ~~Renewals~~ Renewals.

(1) Certification renewals ~~of laboratories~~ shall be issued for one year.

(e) Data ~~reporting.~~Reporting.

(1) Certified ~~commercial laboratories~~Commercial Laboratories must provide ~~make~~ data reports to their clients that are signed by the laboratory supervisor. This duty may be delegated in writing; however, the responsibility shall remain with the supervisor.

(2) Whenever a certified ~~commercial laboratory~~Laboratory refers or subcontracts samples to another laboratory certified ~~laboratory~~ for ~~analyses,~~ the Parameter, the referring laboratory must supply the date and time samples were collected to insure holding times are met. Subcontracted samples must clearly indicate the State of North Carolina as the collection site on all record transcriptions. Laboratories may subcontract sample fractions, extracts, leachates and other sample preparation products provided that evidence of adherence to all Rules and requirements of 15A NCAC 02H .0800 ~~are~~is documented. The initial client requesting the analyses must receive the original or a copy of the report made by the laboratory that performs the analyses. Each reported result must be unequivocally traceable to the laboratory that performed the analysis on the final report.

Commented [SD150]: Reworded to provide clarification – no new requirement

Commented [SD151]: Reworded for clarity – no new requirement

Commented [SD152]: Reworded for clarity – no new requirement

Commented [SD153]: Moved to .0805 (c) (6)

Commented [SD154]: Moved to .0805 (c) (7)

Commented [SD155]: Removed – not necessary

Commented [SD156]: Changed from "amendment" so as not to imply they must complete an amendment form. Reduces paper waste and burden.

Commented [SD157]: Removed "Commercial" to clarify that any certified laboratory may refer or subcontract samples to another certified laboratory

Commented [SD158]: grammatical correction - no effect

Commented [SD159]: Provides clarity – no effect

(3) All ~~uncertified data~~Uncertified Data must be clearly 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, must be appropriately characterized as an estimated value by qualification.

(5) Reported data associated with Quality Control failures, improper sample collection, holding time exceedances or improper preservation must be appropriately characterized by qualification.

(f) Discontinuation of Certification.

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

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

(g) Prerequisites and Requirements~~requirements~~ for Field Laboratory ~~Parameter~~ Certification. Only the following requirements must be met prior to ~~certification~~Certification for Field ~~Parameter~~ Laboratories. Once certified, failure to comply with any of the following items will be a violation of ~~certification~~Certification requirements.

~~(1) Data pertinent to each analysis must be maintained for five years. Certified Data must consist of date collected, time collected, sample site, sample collector, and sample analysis time. The field benchsheets must provide a space for the signature or initials of the analyst, and proper units of measure for all analyses.~~

~~(2) A record of instrument calibration where applicable, must be filed in an orderly manner so as to be readily available for inspection upon request.~~

~~(3) A copy of each approved analytical procedure must be available to each analyst.~~

~~(4) Each facility must have glassware, chemicals, supplies, equipment, and a source of distilled or deionized water that will meet the minimum criteria of the approved methodologies.~~

~~(5) Supervisors of laboratories certified for Field Parameters only must meet the requirements of Subparagraph (a)(3)(A) or (a)(3)(B) of this Section, or possess a chemistry or related degree with two years of related environmental experience, or hold any Biological Water Pollution Control System Operator's Certification as defined by 15A NCAC 08G.~~

~~(6) Application: Each Field Parameter Laboratory shall submit an application in duplicate.~~

~~(7) Performance Evaluations. Each Field Parameter Laboratory must participate in an annual quality assurance study by analyzing performance evaluation samples obtained from an accredited vendor as unknowns. If performance evaluations are not available for a parameter, certification for that parameter may be based on the proper use of the approved procedure as determined by an announced or unannounced on-site inspection.~~

~~(8) Decertification and Civil Penalties. A laboratory facility can be decertified for infractions as outlined in Rule .0807 of this Section.~~

Commented [SD160]: Added to ensure accurate and legally defensible data – this is an industry standard – added for clarity since there are a few states/programs that do not require this – no effect

Commented [SD161]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/QualifyingDataPolicy20110406.pdf

~~(9) Recertification. A laboratory facility can be recertified in accordance with Rule .0808 of this Section.~~

(1) All analytical records, including original observations and information necessary to facilitate historical reconstruction of the calculated results, must be maintained so as to ensure their security and integrity for five years. All analytical data and records pertinent to each certified analysis must be accurate and filed in an orderly manner so as to be readily available for inspection upon request. All analytical records must be legible and safeguarded against unauthorized amendment, obliteration, erasures, overwriting and corruption. Records which are stored only on electronic media must be securely maintained throughout the five year retention period and supported in the laboratory by all hardware and software necessary for immediate data retrieval and review. All documentation errors must 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. Write the correction adjacent to the error. The correction must be initialed by the responsible individual and the date of change documented. All manual data and log entries must be written in indelible ink. Pencil entries are not acceptable.

(2) All laboratories must use printable laboratory benchsheets. Certified Data must be traceable to the associated sample analyses and must consist of the method or Standard Operating Procedure, laboratory identification, instrument identification, sample collector, signature or initials of the analyst, date of collection, time of collection, date of analyses, time of 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), sample identification, sample preparation where applicable, volume of sample analyzed where applicable, proper units of measure, dilution factor where applicable, all manual calculations, quality control assessments, value from the measurement system, final value to be reported and any other data needed to reconstruct the final calculated result. Each item must be recorded each time samples are analyzed. Analyses must conform to methodologies found in Rule .0805 (a) (1) of this Section.

(3) A record of instrument calibration or calibration verification, where applicable, must be documented and filed in an orderly manner so as to be readily available for inspection upon request.

(4) Laboratory Procedures. Laboratory procedures must be in accordance with Rule .0805 (a) (1) of this Section. A copy of each analytical method and/or Approved Procedure and Standard Operating Procedure must be available to each analyst and available for review upon request by the State Laboratory. Standard Operating Procedure documentation must clearly indicate the effective date of the document and must be reviewed at least every two years and updated as needed. Each laboratory must have a formal process to track and document review dates and any

Commented [SD162]: Expanded to provide clarity and consistency with Non-field lab rule – no effect - *Data pertinent to each analysis must be maintained for five years.*

Commented [SD163]: No new requirement - http://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/quality_assurance_policies_for_field_laboratories_10_01_2013.pdf

Commented [SD164]: Expanded to provide clarity – No new requirement - Has always been enforced using .0805 (g) (1) - Data pertinent to each analysis must be maintained for five years. Certified Data must consist of date collected, time collected, sample site, sample collector, and sample analysis time. The field benchsheets must provide a space for the signature or initials of the analyst, and proper units of measure for all analyses.

Commented [SD165]: Provides clarity – no effect

Commented [SD166]: Gives greater flexibility to use procedures developed by Certification and based on approved reference methods – May potentially have a negative impact on some laboratories since it may alleviate having to purchase reference methods.

revisions made in all of their Standard Operating Procedure documents. Supporting Records shall be maintained as evidence that these practices are being effectively carried out.

(5) Each laboratory must develop and implement a documented training program which includes, at a minimum, documentation of the following:

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

(ii) staff have read the laboratory Quality Assurance Manual and/or applicable Standard Operating Procedures;

(iii) staff have obtained acceptable results on unknown performance evaluation samples or other demonstrations of proficiency.

(6) Each facility must have glassware, chemicals, supplies, properly maintained equipment, and a source of water that will meet the minimum criteria of the approved methodologies. A best effort must be made to perform analyses in a manner where possible sources of contamination or error will not be introduced.

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

(8) Any time quality control results fall outside established limits or indicate an analytical problem, the laboratory must take steps to identify the root cause of the failure. The problem must be resolved through corrective action, the process documented and any samples involved must 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 must be appropriately characterized by qualification.

(9) All temperature sensing devices must meet National Institute of Standards and Technology (NIST) specifications for accuracy or be checked, at a minimum every twelve months, against a NIST traceable, or equivalent, temperature sensing device and proper corrections made. Temperature sensing devices used only to verify other laboratory temperature sensing devices may be checked every 5 years against a NIST traceable, or equivalent, temperature sensing device and proper corrections made. All temperature sensing devices must have accuracy appropriate for its intended use. All temperature sensing devices must be properly used, stored and maintained.

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

Commented [SD167]: Added to ensure accurate and legally defensible data and to be consistent with Non-field lab requirements – Minimal effect is anticipated – our program intends to help with this by providing SOP templates for the Field Parameters.

Commented [SD168]: Added to ensure accurate and legally defensible data – should have minimal effect since it is documentation oriented.

Commented [SD169]: Added for clarity – no effect

Commented [SD170]: No new requirement - http://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/quality_assurance_policies_for_field_laboratories_10_01_2013.pdf

Commented [SD171]: No new requirement - http://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/quality_assurance_policies_for_field_laboratories_10_01_2013.pdf

Commented [SD172]: No new requirement - http://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/quality_assurance_policies_for_field_laboratories_10_01_2013.pdf

Commented [SD173]: Added to ensure accurate and legally defensible data – May potentially impact some laboratories if they choose to have a vendor verify traceability.

Commented [SD174]: No new requirement - http://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Policies/quality_assurance_policies_for_field_laboratories_10_01_2013.pdf

(11) Supervisors of laboratories certified for Field Parameters only must meet the requirements of Subparagraph (a) (3) (A) or (a) (3) (B) of this Section, or possess a chemistry or related degree with two years of related environmental experience, or an equivalent combination of education and work experience, or hold any Water Pollution Control System Operator's Certification as defined by 15A NCAC 08G or subsequent Rules. All laboratory supervisors are subject to review by the State Laboratory. The supervisor shall provide personal and direct supervision of the technical personnel and be held responsible for the proper performance and reporting of all analyses made for these Rules. If the supervisor is to be absent, the supervisor shall arrange for a substitute capable of insuring the proper performance of all laboratory procedures, however, the substitute supervisor cannot be in charge for more than twelve consecutive weeks.

(12) A certified Field Laboratory will be subject to periodic announced or unannounced inspections during the Certification period and must make all relevant records available for inspection.

(13) A certified Field Laboratory must supply copies of all relevant records for any investigation upon written request by the State Laboratory.

(14) A certified Field Laboratory must 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.

(16) Proficiency Testing. Each certified Field Laboratory must be in accordance with Rule .0805 (a) (2) of this Section.

(17) Data Reporting. Each certified Field Laboratory must be in accordance with Rule .0805 (e) of this Section.

(18) Issuance of Certification. A Field Laboratory may be issued Certification in accordance with Rule .0805 (b) of this Section.

(19) Maintenance of Certification. A certified Field Laboratory must submit written notice of any material 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 will be issued in accordance with Rule .0805 (d) of this Section.

(21) Discontinuation of Certification. A certified Field Laboratory may discontinue Certification in accordance with Rule .0805 (f) of this Section.

(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 which violates or fails to act in accordance with any of the terms, conditions, or requirements of the Rule .0807 of this Section or of the State Laboratory. A laboratory is subject to both civil penalties and Decertification.

Commented [SD175]: Reduces regulatory burden – increases flexibility in meeting Supervisory requirements

Commented [SD176]: Reduces regulatory burden – increases flexibility in meeting Supervisory requirements by allowing Physical/Chemical Operator's license in addition to the Biological Operator's license.

Commented [SD177]: Added for clarity – no effect

Commented [SD178]: Made language consistent with Non-field lab rule – no new requirement .0805 (g) (7) - If performance evaluations are not available for a parameter, certification for that parameter may be based on the proper use of the approved procedure as determined by an announced or unannounced on-site inspection.

Commented [SD179]: **Made language consistent with Non-field lab rule – no new requirement .0805 (g) (2) - *A record of instrument calibration where applicable, must be filed in an orderly manner so as to be readily available for inspection upon request.***

Commented [SD180]: Provides clarity – no effect

Commented [SD181]: Removed requirement to submit it in duplicate to reduce paper waste

Commented [SD182]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Technical%20Assistance%20Documents/PTRequirementsDocument20120120Revision%201.2F.pdf

Commented [SD183]: Provides clarity – no effect

Commented [SD184]: Provides clarity – no effect

Commented [SD185]: Added this requirement to be consistent with Non-field lab rule and for tracking purposes– minimal effect

Commented [SD186]: Provides clarity – no effect

Commented [SD187]: Provides clarity – no effect

Commented [SD188]: Expanded to provide clarity – no effect

(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)~~143-215.3(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.

15A NCAC 02H .0806 is proposed for readoption :

15A NCAC 02H .0806 FEES ASSOCIATED WITH CERTIFICATION PROGRAM

(a) An applicant for laboratory ~~certification,~~Certification, excluding those laboratories seeking Field Parameter Certification only, must submit to the Department of ~~Environment and Natural Resources, Laboratory~~Environmental Quality, Division of Water Resources~~,~~ Water Sciences Section, a non-refundable fee of three hundred dollars ($300.00) for the evaluation and processing of each application.

(b) Municipal, Industrial and Other ~~laboratories~~Laboratories must pay an annual fee of ~~fifty dollars ($50.00)~~eighty-five dollars ($85.00) for each ~~inorganic parameter plus one hundred dollars ($100.00) for each organic~~ parameter ~~and metals analyte~~; however, the minimum fee will be one thousand ~~three~~seven hundred fifty dollars ~~($1,350.00)~~($1750.00) per year.

(c) Commercial ~~laboratories~~Laboratories must pay an annual fee of ~~fifty dollars ($50.00)~~eighty-five dollars ($85.00) for each ~~inorganic parameter plus one hundred dollars ($100.00) for each organic~~ parameter ~~and metals analyte~~; however, the minimum fee will be ~~two~~three thousand ~~seven~~five hundred dollars ~~($2,700.00)~~($3500.00) per year.

(d) Prior to receiving initial ~~certification,~~Certification, a Field Laboratory must pay the required fee as specified in Paragraph (k) or (l) of this Rule and all other laboratories ~~laboratory~~ must pay the required fee as specified in Paragraph (b) or (c) of this Rule. ~~Initial certification~~Excluding Field Laboratories, Certification fee will be prorated on a ~~semi-annual~~ quarterly basis to make all ~~certification~~Certification renewals due on the first day of January.

(e) Once certified, ~~a~~ Field Laboratories must pay a fifty dollar ($50.00) administrative fee for each Parameter Method added to their Certified Parameters Listing and all other laboratories~~laboratory~~ must pay the full annual parameter fee for each ~~parameter~~Parameter Method added to their ~~certificate.~~Certified Parameters Listing.

(f) A laboratory decertified for all parameters must pay initial ~~certification~~Certification fees prior to ~~recertification.~~Recertification.

(g) A laboratory decertified for one or more ~~parameters~~Parameter Methods must pay a fee of two hundred dollars ($200.00) for each ~~parameters~~Parameter Method for which it was decertified prior to ~~recertification.~~Recertification.

(h) Out-of-state laboratories shall reimburse the ~~state~~State for actual travel and subsistence costs incurred in ~~certification~~Certification and maintenance of ~~certification.~~Certification. Out-of-state laboratories will also be assessed for expenses for an on-site inspection based on the hourly rate of the laboratory certification officer(s), rounded to the nearest hour and inclusive of preparation time, travel time and inspection time.

(i) Annual ~~certification~~Certification fees are due 60 days after receipt of invoice.

(j) A fifty dollar ($50.00) late payment fee must be paid by Field Laboratories when annual Certification fees are not paid by the date due. ~~A~~For all other laboratories, a two hundred fifty dollar ($250.00) late payment fee must be paid when annual ~~certification~~Certification fees are not paid by the date due.

(k) Commercial ~~facilities~~Laboratories analyzing samples for ~~field parameters~~Field Parameters only must pay an annual fee of ~~two~~three hundred dollars ~~($200.00)~~($300.00) per year.

(l) ~~Municipal and Industrial facilities~~Municipal, Industrial and Other Laboratories analyzing samples for ~~field parameters~~Field Parameters only must pay an annual fee of one hundred fifty dollars ~~($100.00)~~($150.00) per year.

Commented [SD189]: We are asking for a modest and what we feel is a fair fee increase. After no increase in 14 years, receipts no longer adequately support this program. We are only hoping to regain the 3 positions that were lost to help provide the oversight and technical support of over 700 client laboratories. [see attached fee justification] It should be noted that the increase in annual minimum fees will only affect laboratories that are above the minimum. The change in Parameter addition fee is more for some additions and less for others.

Commented [SD190]: Increases minimum annual fee $400 – changes all Parameter addition fees to $85.00 [currently inorganics were $50 and metals/organics were $100]

Commented [SD191]: Increases minimum annual fee $800 – changes all Parameter addition fees to $85.00 [currently inorganics were $50 and metals/organics were $100]

Commented [SD192]: Provides clarity – no effect

Commented [SD193]: Potentially reduces existing impact for new labs that seek certification in the second and fourth quarters of the year – no effect if adding in first and third quarters.

Commented [SD194]: New requirement to cover administrative fees for processing Parameter additions – May impact a lab only if they add Parameter Method(s).

Commented [SD195]: New requirement – Impacts the lab only when audited and helps offset a business advantage that out-of-state labs have over the in-state labs that must pay state taxes.

Commented [SD196]: New requirement – Will only impact laboratories if they do not pay annual fees within 60 days of receipt per .0806 (i).

Commented [SD197]: $100 increase in annual fee for Commercial Field labs

Commented [SD198]: $50 increase in annual fee for Field labs

(m) A laboratory that voluntarily discontinues Certification must pay all Certification fees as specified in Paragraphs .0806 (a) (b) (c) (d) (k) or (l) of this Rule prior to regaining Certification.

Commented [SD199]: Added to provide clarity – no effect

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10);*
Eff. February 1, 1976;
Amended Eff. November 2, 1992; December 1, 1984;
Temporary Amendment Eff. October 1, 2001;
Amended Eff. August 1, 2002.

15A NCAC 02H .0807 is proposed for readoption:

15A NCAC 02H .0807 DECERTIFICATION AND CIVIL PENALTIES

(a) Laboratory Decertification. ~~A laboratory may be decertified, for any or all parameters, for up to one year for any of the following infractions:~~The following infractions may result in a laboratory being decertified for any or all parameters for up to one year:

(1) Failing to maintain the facilities, or records, or personnel, or equipment, or quality control program as set forth in the application, and these Rules; ~~or~~

(2) Submitting inaccurate data or other information; ~~or~~

(3) Failing to pay required fees by the date due; ~~or~~

(4) Failing to discontinue supplying data for clients or programs described in Rule .0802 of this Section during periods when a ~~decertification~~Decertification is in effect; ~~or~~

(5) Failing to submit a ~~split~~Split sample to the State Laboratory as requested; ~~or~~

(6) Failing to use approved methods of analysis; ~~or~~

(7) Failing to report laboratory supervisor ~~or equipment~~ changes within 30 days of such changes; ~~or~~

(8) Failing to report analysis of required annual ~~performance evaluation~~ Proficiency Testing samples submitted by ~~an a EPA~~ State Laboratory approved ~~vendor~~Vendor within the specified time limit; ~~or~~

(9) Failing to allow an inspection by an authorized representative of the State Laboratory; ~~or~~

(10) Failing to supply all records and analytical data requested by the State Laboratory; ~~or~~

(11) Failing to submit a written notification ~~amendment to the certification application~~ within 30 days of applicable changes; ~~or~~

(12) Failing to meet ~~required~~ requirements for sample holding times and preservation; ~~or~~

(13) Failing to respond to requests for information by the date due; ~~or~~

(14) Failing to comply with any other terms, conditions, or requirements of this Section or of ~~a~~ laboratory ~~certification~~Certification;

(15) Altering or modifying the laboratory's certificate or Certified Parameters Listing;

(16) Sharing or conferring Proficiency Testing sample results with other laboratories prior to the study reporting deadline;

(17) Splitting, sending, or subcontracting a Proficiency Testing sample or a portion of a Proficiency Testing sample, to another laboratory for any analysis for which it is certified or seeking Certification unless the practice represents the routine analysis and reporting scheme utilized by the laboratory;

(18) Knowingly receiving and analyzing any Proficiency Testing sample or portion of a Proficiency Testing sample from another laboratory for which the results of the Proficiency Testing sample are intended for use for initial or continued Certification.

(19) Obtaining or attempting to obtain the assigned value of any Proficiency Testing sample used to satisfy initial or continued Certification requirements prior to the closing date of the study.

Commented [SD200]: Editorial – no new requirement added

Commented [SD201]: Removed – not necessary – reduces burden on labs

Commented [SD202]: Technical correction - EPA no longer approved PT vendors – no effect

Commented [SD203]: Capitalized a defined term for clarity - no effect.

Commented [SD204]: Provides clarification that records other than just the analytical data itself apply – No effect

Commented [SD205]: Allows for any form of written notification of including electronic to reduce burden on the labs

Commented [SD206]: Clarification – both preservation and holding time are requirements across all regulatory programs – no effect

Commented [SD207]: Provides clarity – falsification - Ensures laboratories do not misrepresent their scope of accreditation to stakeholders, clients and data receiving agencies – no impact

Commented [SD208]: Ensures accurate representation of a laboratory's proficiency and that no bias is contributed to the reported results – no new requirement added - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Technical%20Assistance%20Documents/PTRequirementsDocument20120120Revision%201.2F.pdf

(20) Failing to correct findings in an inspection report.

(b) Parameter Method Decertification. ~~A laboratory may receive a parameter decertification for failing to:~~The laboratory may be decertified for a Parameter Method for:

(1) ~~Obtain acceptable results on two consecutive blind or announced performance evaluation samples submitted by an EPA accredited vendor or the State Laboratory; or~~Obtaining two consecutive Unacceptable Proficiency Testing sample results; or

(2) ~~Obtain acceptable results on two consecutive blind or announced split samples that have also been analyzed by the State Laboratory.~~Obtaining two consecutive unacceptable Split sample results.

(c) Falsified Data. A laboratory that submits falsified data or other information may be decertified for all parameters for up to two ~~years.~~years and may be recertified per Rule .0808 of this Section.

(d) Decertification Factors. In determining a period of ~~decertification,~~Decertification, the Director shall recognize that any harm to the natural resources of the State arising from violations of ~~these~~the Rules in this Section may not be immediately observed and may be incremental or cumulative with no damage that can be immediately observed or documented. Decertification for periods up to the maximum may be based on any ~~and~~one or a combination of the ~~following factors to be considered:~~factors set forth at G.S. 143B-282.1(b).

~~(1) The degree and extent of harm, or potential harm, to the natural resources of the State or to the public health, or to private property resulting from the violation;~~

~~(2) The duration, and gravity of the violation;~~

~~(3) The effect, or potential effect, on ground or surface water quantity or quality or on air quality;~~

~~(4) Cost of rectifying any damage;~~

~~(5) The amount of money saved by noncompliance;~~

~~(6) As to violations other than submission of falsified data or other information, whether the violation was committed willfully or intentionally;~~

~~(7) The prior record of the laboratory in complying or failing to comply with any State and~~and/or ~~Federal laboratory Rules and regulations;~~

~~(8) The cost to the State of investigation and enforcement procedures;~~

~~(9) Cooperation of the laboratory in discovering, identifying, or reporting the violation;~~

~~(10) Measures the laboratory implemented to correct the violation or abate the effect of the violation, including notifying any affected clients;~~

~~(11) Measures the laboratory implemented to correct the cause of the violation;~~

~~(12) Any other relevant facts.~~

(e) Decertification Requirements.

(1) A decertified laboratory is not to analyze samples for the decertified ~~parameters~~Parameter Method for programs described in Rule .0802 of this Section or clients reporting to these programs or other programs requiring Certified Data pursuant to this Section.

(2) A decertified ~~commercial laboratory~~Commercial Laboratory must supply written notification of the ~~decertification~~Decertification to clients with ~~Division of Water Quality~~ Department of

Commented [SD209]: Ensures data is of known and documented quality and that all requirements of 15A NCAC 2H .0800 are met – no effect

Commented [SD210]: Added the "Parameter Method" distinction to reduce regulatory burden on laboratories. Would only be decertified for a single method when a lab is certified for multiple methods under one parameter category. Currently wording required all methods would be decertified for that parameter category. Potential negative impact.

Commented [SD211]: Editorial – no effect

Commented [DS212]: Adds clarification – no effect

Commented [SD213]: Covered in the G.S. - unnecessary and duplicative - no effect

Commented [DS214]: Provides clarification – no effect

Environmental Quality reporting requirements. Within 30 days, the decertified laboratory must supply the State Laboratory with a list of clients involved and copies of the notices sent to each.

(3) A ~~commercial laboratory~~Commercial Laboratory that has received a ~~parameter decertification~~Parameter Method Decertification may make arrangements to supply analysis through another ~~certified~~ laboratory certified by the State Laboratory for the contracted parameters during any ~~decertification~~Decertification periods. ~~The decertified laboratory must supply the State Laboratory, by written notice, the name of the laboratory to be used.~~ Within 30 days the decertified laboratory must supply the State Laboratory with a list of clients involved, copies of the notices sent to each, and the name and Certification number of the certified laboratory(ies) to be used during the Decertification period.

(4) A ~~commercial laboratory~~Commercial Laboratory decertified for all parameters cannot subcontract samples for analyses to other certified laboratories during the ~~decertification~~Decertification period.

(5) A ~~decertified municipal or industrial laboratory~~ Municipal or Industrial Laboratory that has received a Parameter Method Decertification must have ~~its~~ samples requiring that Parameter Method analyzed by another ~~certified~~ laboratory certified by the State Laboratory for the contracted Parameter Method during any ~~decertification~~Decertification period ~~and supply the State Laboratory, by written notice, the name of the certified laboratory to be used~~. Within 30 days, the decertified laboratory must supply the State Laboratory with the name and Certification number of the certified laboratory(ies) to be used during the Decertification period.

(f) Civil Penalties. Civil penalties may be assessed against a laboratory which violates or fails to act in accordance with any of the terms, conditions, or requirements of the Rules in this Section ~~or of a laboratory certification.~~ A laboratory is subject to both civil penalties and ~~decertification.~~Decertification.

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.6A;*
Eff. February 1, 1976;
Amended Eff. November 2, 1992; December 1, 1984;
Temporary Amendment Eff. October 1, 2001;
Amended Eff. August 1, 2002.

Commented [DS215]: Provides clarification – no effect

Commented [DS216]: Added additional information we ask for when a lab is decertified – no new requirement – see LC-22 Form

Commented [DS217]: Editorial – no effect

Commented [DS218]: Added additional information we ask for when a lab is decertified – no new requirement – see LC-22 Form

Commented [DS219]: Removed redundant language – no effect

15A NCAC 02H .0808 is proposed for readoption:

15A NCAC 02H .0808 RECERTIFICATION

(a) A laboratory decertified in accordance with Paragraph (a) of Rule .0807 of this Section ~~may~~shall be recertified at the end of the Decertification~~decertification~~ period imposed by the Division pursuant to 15A NCAC 02H .0807 (a) and (d) by showing to the satisfaction of the State Laboratory that it has corrected the ~~deficiency(ies).~~deficiency(ies) on the basis for which it was decertified.

~~(b) A laboratory decertified for a parameter due to unacceptable results on two consecutive performance evaluation samples submitted by an EPA accredited vendor, or on two consecutive split samples may be recertified after 60 days by reporting acceptable results on two consecutive performance evaluation samples submitted by an EPA accredited vendor. Recertification samples may be requested from an EPA accredited vendor at any time, however, recertification must be requested in writing at the end of the 60 day period immediately following the date of decertification.~~

~~(c) A laboratory decertified for submitting falsified data or other information may be recertified at the end of the decertification period by demonstrating compliance with all requirements of this Section.~~

(b) A laboratory decertified for a Parameter Method due to two consecutive Unacceptable Proficiency Testing results, or on two consecutive Split samples may be recertified at the end of the 30-day period by completing all of the following:

(1) Report acceptable results on two consecutive Proficiency Testing samples submitted by a State Laboratory approved Vendor or report acceptable results on two consecutive samples split with the State Laboratory. Recertification samples may be requested from a State Laboratory approved Vendor at any time;

(2) Recertification must be requested in writing following Decertification;

(3) The decertified laboratory must supply the State Laboratory with the completed decertified laboratory report form sent with the Decertification notice;

(4) The decertified laboratory must supply the State Laboratory with a report of the investigation of the root cause and corrective action taken;

(5) The laboratory must pay the required fee as specified in Rule .0806 (f) or (g) of this Section; and

(6) The laboratory has met all of the Decertification requirements in accordance with Paragraph .0807 (e) of this Section.

(c) After two years, a Parameter Method Recertification will be treated as an initial Certification in accordance with Rule .0805 of this Section.

(d) A laboratory decertified for submitting Falsified Data or Information may be recertified at the end of the Decertification period imposed by the Division pursuant to 15A NCAC 02H .0807 (c) and (d) by demonstrating compliance with all requirements of this Section.

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10);*

Commented [DS220]: Provides clarification – no effect

Commented [SD221]: Provides clarification - no effect

Commented [SD222]: Reducing the decertification period for unacceptable PT results reduces the burden on laboratories by reducing the amount of time they would have to subcontract or contract analyses during the decertification period. Potential negative impact on laboratories if they are decertified.

Commented [DS223]: No new requirement - https://ncdenr.s3.amazonaws.com/s3fs-public/Water%20Quality/Chemistry%20Lab/Certification/Technical%20Assistance%20Documents/PTRequirementsDocument20120120Revision%201.2F.pdf

Commented [DS224]: Provides clarification – no effect

Commented [DS225]: Added because personnel, equipment, methodology, etc. often change in this time period. Having to submit application after this point will ensure this information is captured and potentially reduces burden on the lab because they would only need to supply one PT result to regain certification and would not be charged the $00 recertification fee.

Commented [DS226]: This rule was simply re-lettered – no effect

Eff. February 1, 1976;
Amended Eff. November 2, 1992; December 1,1984;
Temporary Amendment Eff. October 1, 2001;
Amended Eff. August 1, 2002.

15A NCAC 02H .0809 is proposed for readoption :

15A NCAC 02H .0809 RECIPROCITY

(a) Laboratories certified under other state certification programs and/or certification (accreditation) bodies may be given ~~reciprocity~~reciprocal ~~certification~~Certification where such programs and/or certification (accreditation) bodies meet the requirements of this Section. In requesting reciprocity ~~certification,~~Certification, laboratories shall include with the application required by Rule .0805(a) of this Section a copy of their certification, a copy of the last audit report from the certifying agency, the laboratory's response to the audit report, the laboratory's scope of accreditation and ~~Regulation~~Regulation(s) from the certifying agency.

(b) Laboratories certified by reciprocity shall pay the fees required by Rule .0806 of this Section.

(c) Any time that a laboratory has its certification with the reciprocal program discontinued for any reason, the State Laboratory must be notified and Certification~~certification~~ under this Section shall be terminated at the same time.

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10);*
Eff. February 1, 1976;
Amended Eff. November 2, 1992; December 1, 1984.

Commented [DS227]: Added language to open up options to laboratories by including other accreditation bodies such as The NELAC Institute. Potentially has a negative impact on laboratories that could benefit from using another type of accreditation body for reciprocity and forego the expense of an initial on-site audit by our program.

Commented [SD228]: Grammatical correction - no effect

Commented [DS229]: No new requirement – no effect

Commented [DS230]: New requirement added for tracking purposes- No effect

15A NCAC 02H .0810 is proposed for readoption :

15A NCAC 02H .0810 ADMINISTRATION

(a) The Director ~~of the Division of Water Quality, Department of Environment and Natural Resources~~ or ~~his~~ their delegate, is authorized to issue Certifications,~~certification, to~~ reject applications for ~~certification,~~Certification, ~~to~~ renew ~~certification,~~Certification, ~~to~~ issue ~~recertification,~~Recertification ~~to~~ issue ~~decertification,~~Decertification, and ~~to~~ issue reciprocity ~~certification.~~Certification.

~~(b) Appeals. In any case where the Director of the Division of Water Quality, Department of Environment and Natural Resources or his delegate denies certification, or decertifies a laboratory, the laboratory may appeal to the N.C. Office of Administrative Hearings in accordance with Chapter 150B of the General Statutes.~~

~~(c)~~(b) The State Laboratory will maintain a current list of certified ~~commercial,~~Commercial, Municipal, Industrial, Mobile, Field and Other Laboratories. ~~laboratories.~~

~~(d) Implementation of the October 1, 2001changes to this Section.~~

~~(1) All requirements of the Rules in this Section are effective on the effective date of the amendments.~~

~~(2) Requests for the new parameters may be made by submitting a properly completed amendment form.~~

~~(3) Laboratories subject to the amended requirements of these Rules must submit a completed application, or amendment form, within three months of the effective date of the amendments. Laboratories submitting an application or amendment form for any of the newly certifiable parameters may analyze samples for these new parameters until the State Laboratory has issued or denied certification. Fees for parameter additions requested during the initial three month period will be calculated as initial certification fees.~~

~~(4) Laboratory facilities, not currently certified, that are performing analyses for Field Parameters only must submit an application within three months of the effective date of the amendments. After submitting an application, these laboratories may continue to analyze samples until the State Laboratory has issued or denied certification.~~

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 150B-23;*
Eff. February 1, 1976;
Amended Eff. November 2, 1992; July 1, 1988; December 1, 1984; November 1,1978;
Temporary Amendment Eff. October 1, 2001;
Amended Eff. August 1, 2002.

Commented [SD231]: Unnecessary - duplicative - no effect

Commented [DS232]: Added all types of laboratories – no new requirement - no effect - http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/certified-laboratory-listings

Commented [DS233]: Removed because it pertained to Implementation of the original rule and is not necessary

15A NCAC 02H .1100 is proposed for readoption:

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 aquatic 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.

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15A NCAC 02H .1102 is proposed for readoption:

15A NCAC 02H .1102 SCOPE

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

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

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Commented [HH2]: No new requirement added, done for clarification

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15A NCAC 02H .1103 is proposed for readoption:

15A NCAC 02H.1103 DEFINITIONS

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

(1) Aquatic population survey and analysis consists of field sampling, laboratory identification, analysis and metric derivation for determination of biological integrity, as defined in 15A NCAC 02B .0202(11) [if 02B is being changed, change this reference to the correct number], for fish, aquatic macroinvertebrates, phytoplankton and aquatic macrophytes using methods developed per 15A NCAC 02B .0103(b). Standard operating procedures used by the State are available for review on the Division's website.

~~(1)~~(2) 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 aquatic population survey techniques are contained within one category.

~~(2)~~(3) 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 applicant's applicants' proficiency has been considered and found ~~acceptable.~~ to comply with these Rules.

~~(3)~~(4) 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)~~(5) Decertification is the loss of certification.

~~(5)~~(6) Director means the Director of the North Carolina Division of ~~Environmental Management,~~ Water Resources, or his successor.

~~(6)~~(7) Division means the North Carolina Division of ~~Environmental Management,~~ Water Resources, or its successor.

~~(7)~~(8) Evaluation samples are known samples submitted by the State Laboratory to the commercial, 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)~~(9) Falsified data or information means data or information ~~that,~~ that, whether by intent, negligence, or reckless disregard for accuracy has been ~~made untrue by alteration, fabrication, intentional omission, substitution, or mischaracterization~~ altered, fabricated, or otherwise reported and/or recorded falsely or mischaracterized by omission or substitution, such that the value or information reported is incorrect, incomplete, and/or inaccurate. The agency need not prove intent to defraud to prove data is falsified.

~~(9)~~(10) Inaccurate data or other information means data or information that is in any way incorrect or mistaken.

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~~(10)~~(11) 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~~ waters or to conduct aquatic population surveys.

~~(11)~~(12) 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, aquatic macroinvertebrates, algae, phytoplankton, and aquatic ~~macrophytes, and zooplankton.~~macrophytes.

~~(12)~~(13) 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~~ installation, or any other governmental unit, to analyze samples from its wastewater treatment plant(s) for toxicity measurements or resultant impacts to ~~receiving waters.~~ waters or to conduct aquatic population surveys.

~~(13)~~(14) Recertification is reaffirmation of certification.

~~(14)~~(15) 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.~~sample for surface water effluent discharge, surface water, or phytoplankton means two or more representative portions taken from a single sampling device. For aquatic macrophytes or macroinvertebrates, the same sample is analyzed by the State Laboratory and the commercial, industrial, or public laboratory.

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

~~(17)~~(16) Toxicant ~~Any~~ means 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.

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15A NCAC 02H .1104 is proposed for readoption:

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 of five hundred dollars ($500.00) if only one category is certified. Renewal certification fees are due by November 1 annually.

(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, recertificationrecertification, 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.

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15A NCAC 02H .1105 is proposed for readoption:

15A NCAC 02H .1105 CERTIFICATION

(a) Certification is affirmation by the Director or his their 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, and public laboratories must obtain certification from the Division of ~~Environmental Management~~ Water Resources 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~~ Algal 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.~~ are listed in the certification application available on the Division's website.

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

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15A NCAC 02H .1106 is proposed for readoption:

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~~ 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~~ Certification/Criteria Procedures Document available on the Division's website;

(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~~ the laboratory's ability to perform a test category to the State Laboratory within 30 days of such change; ~~or~~

(6) Report ~~to the state laboratory~~ analysis of performance evaluation samples submitted by the Division to the State Laboratory 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~~ Certification/Criteria Procedures Document available on the Division's website;

(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~~ 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

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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.

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15A NCAC 02H .1107 is proposed for readoption:

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~~ 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 or their delegate 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~~ 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.

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15A NCAC 02H .1108 is proposed for readoption:

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.

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15A NCAC 02H .1109 is proposed for readoption:

15A NCAC 02H .1109 ADMINISTRATION

(a) The Director of the Division of ~~Environmental Management~~ Water Resources, Department of ~~Environment, Health, and Natural Resources,~~ Environmental Quality, or ~~his~~ their 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.

(b) Appeals. In any case where the Director or their delegate denies certification, or decertifies a laboratory, the laboratory may appeal to the N.C. Office of Administrative Hearings in accordance with Chapter 150B of the General Statutes.

(c) The State Laboratory will maintain a current list of certified commercial, industrial, or public laboratories laboratory.

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.

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15A NCAC 02H .1110 is proposed for readoption:

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~~ Document available on the Division's webpage. Deviations from these methods are acceptable only upon prior written approval from the ~~state laboratory~~ State Laboratory.

(c) In order to maintain certification, each laboratory will demonstrate satisfactory performance on evaluation samples submitted ~~by~~to 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.~~ 4 year 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,~~ population surveying, 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,~~ aquatic population surveying, 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 (as defined in (d)(1), above) 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,~~ pursuant to Rule .1104 of this Section. 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

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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~~lifestage determinations.

(6) Supporting records shall be maintained for a minimum of five years as evidence that these practices are being effectively carried out and shall be available to the ~~state laboratory~~ State Laboratory upon request.

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

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66;*
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15A NCAC 02H .1111 is proposed for readoption:

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 will be notified.~~

(a) The Biological Laboratory Certification/Criteria Procedures Document (also referred to as the Certification/Criteria Procedures Document or the document) describes specific scientific reporting units, forms, test methods and procedures pertaining to certification. This document is available on the Division's website.

(b) The document, and any addition thereto, shall be approved by the Director or their delegate before it is released to the public. The document shall be made available online to all certified biological laboratories and to any persons on the mailing list. To be placed on the mailing list, a letter or electronic request must be sent to the Director or their delegate.

(c) If the document is revised at any time, the certified biological laboratories and those persons on the mailing list will be notified.

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10); 143-215.66;*
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