15A NCAC 02H .0801 – is proposed for amendment as follows:

15A NCAC 02H .0801 PURPOSE

The purpose of these Rules is to set out 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 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.
15A NCAC 2H.0802 is proposed for amendment as follows:

15A NCAC 02H.0802  SCOPE

These Rules shall 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., 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 shall 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.
1 15A NCAC 02H .0803 is proposed for amendment as follows:

2

3 15A NCAC 02H .0803  DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

35 (14) "State Laboratory" means the Laboratory Section of the North Carolina Division of Water Quality,
36 or its successor.
(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 with analytical chemistry has been considered and found to be
acceptable pursuant to these Rules.

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


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

(8) Decertification means loss of Certification.

(9) Director means the 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 mischaracterized by omission or substitution,
such that the value or information reported is incorrect, incomplete, or inaccurate.

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

(13) Field Parameters 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.
Inaccurate Data or Other Information means data or information that is in any way incorrect, or mistaken.

Industrial Laboratory means a laboratory, including its agents or employees, operated by an industry to analyze samples in a chemistry laboratory or in a field setting under the scope of these Rules.

In-situ means in the original or natural place or site.

Matrix Spike means an additional aliquot of an environmental sample to which a known concentration of the analytes 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.

Mobile Laboratory means a collection of analytical equipment and instruments contained in an environmentally controlled vehicle that can be deployed to a project site for other than Field Laboratory Certification purposes.

Municipal Laboratory means a laboratory, including its agents or employees, operated by a municipality or other local government to analyze samples in a chemistry laboratory or in a field setting 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.

NPDES means National Pollutant Discharge Elimination System.

Other Laboratory means a facility that is not required to obtain State Laboratory Certification as part of its routine operation and does not analyze samples in a chemistry laboratory or in a field setting for a fee, or is doing business as a non-profit facility.

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

Parameter Method means a type of analytical technique, including materials and tools, used to measure a parameter.

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.

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.

Recertification means re-instating Certification at the end of the Decertification period imposed by the Division pursuant to 15A NCAC 02H.0807 by showing that it has corrected all deficiencies.

Reference Temperature-measuring Device means a National Institute of Standards and Technology (NIST) traceable temperature-measuring device used only to verify the calibration of other temperature-measuring devices.

Second Source means reference solutions from a different manufacturer or from the same manufacturer and identified by a different lot number.
(29) Split sample means two or more representative portions taken from a sample or subsample and analyzed by two or more laboratories approved by the State Laboratory.

(30) Standard Operating Procedure (SOP) means a laboratory’s analytical or operational procedures described with adequate detail to allow someone similarly qualified to reproduce the procedures used to generate the test or desired result.

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

(32) 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.

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

(34) 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.

(35) 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; analytical results produced by a laboratory for an analysis not within the Scope of these Rules pursuant to Rule .0802 of this Section; or analytical results produced by a laboratory without proper Certification.

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

(37) Vector Attraction Reduction Option refers to an option for demonstrating a reduction in vector attraction of sewage sludge listed in 40 CFR Part 503.33(b)(1) through (b)(12).

(38) 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.
15A NCAC 02H .0804 is proposed for amendment as follows:

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

(a) Commercial laboratories are required to obtain certification for parameter Methods used to generate data which will be reported by the client to the State in accordance with Rule .0802 of this Section. Municipal and Industrial Laboratories are required to obtain certification for 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 shall 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)
19. Nitrate plus Nitrite Nitrogen
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<th>Parameter</th>
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<tr>
<td>1</td>
<td>Acidity:</td>
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<td>2</td>
<td>Alkalinity:</td>
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<tr>
<td>3</td>
<td>Biochemical Oxygen Demand:</td>
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<td>4</td>
<td>Bromide:</td>
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<td>5</td>
<td>Carbonaceous Biochemical Oxygen Demand:</td>
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<td>Chemical Oxygen Demand:</td>
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<td>Chlorine, Free Available:</td>
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<td>Chlorine, Total Residual:</td>
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<td>10</td>
<td>Chlorophyll:</td>
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<td>Coliform, Fecal:</td>
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<td>Color:</td>
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<td>Conductivity/Specific Conductance:</td>
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<td>15</td>
<td>Cyanide:</td>
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<td>16</td>
<td>Dissolved Organic Carbon:</td>
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<td>Dissolved Oxygen:</td>
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<td>Total Residue, Total Dissolved 180°C:</td>
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<td>Total Residue, Total Suspended:</td>
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<td>23</td>
<td>Phenols:</td>
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<td>24</td>
<td>Orthophosphate:</td>
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<td>Nitrate Nitrogen:</td>
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<td>Turbidity:</td>
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<td>Total Residue, Total Suspended:</td>
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<td>Temperature:</td>
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<td>36</td>
<td>Total Organic Carbon (TOC):</td>
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<td>37</td>
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<td>Leachate Procedures:</td>
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<td>39</td>
<td>Vector Attraction Reduction – All Options:</td>
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(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;
(49) Vector Attraction Reduction: Option 1;
(50) Vector Attraction Reduction: Option 2;
(51) Vector Attraction Reduction: Option 3;
(52) Vector Attraction Reduction: Option 4;
(53) Vector Attraction Reduction: Option 5;
(54) Vector Attraction Reduction: Option 6;
(55) Vector Attraction Reduction: Option 7;
(56) Vector Attraction Reduction: Option 8; and
(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 analysis: One or more Parameter Methods shall 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);
(10) Chromium, Total;
Chromium, Trivalent (Chromium III);
Cobalt;
Copper;
Hardness, Total (Calcium + Magnesium);
Iron;
Lead;
Lithium;
Magnesium;
Manganese;
Mercury;
Molybdenum;
Nickel;
Potassium;
Phosphorus;
Selenium;
Silica;
Silver;
Sodium;
Strontium;
Thallium;
Tin;
Titanium;
Vanadium; and
Zinc.

(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 shall 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
(7) Nitrosamines
(8) Organochlorine Pesticides
(9) Polychlorinated Biphenyls
(10)  Nitroaromatics and Isophorone
(11)  Polynuclear Aromatic Hydrocarbons
(12)  Halothers
(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
(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);
(2)  Acetonitrile;
(3)  Acrolein, Acrylonitrile;
(4)  Adsorbable Organic Halides;
(5)  Base/Neutral and Acid Organics;
(6)  Benzidines;
(7)  Chlorinated Acid Herbicides;
(8)  Chlorinated Hydrocarbons;
(9)  Chlorinated Phenolics;
(10)  Explosives;
(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; and
(29) Volatile Petroleum Hydrocarbons.

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 .0805 is proposed for amendment as follows:

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

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

(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 method for Total Petroleum Hydrocarbons is available from the State Laboratory at no cost. 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.

(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) The procedures and methods listed in this Subparagraph (a) (1) are incorporated by reference, including subsequent amendments and editions.

(H) This material is available for inspection at the State Laboratory, 4405 Reedy Creek Road, Raleigh, North Carolina, 27607 or may be obtained from:
  (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/.
  (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. Wall Experiment Station, 37 Shattuck Street, Lawrence, MA, 01843-1398 and free of charge on the
(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.

(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 shall demonstrate acceptable performance on a minimum of one evaluation sample for each Parameter Method listed on their Certified Parameters Listing for which Proficiency Testing samples are available from more than one vendor, as required by these Rules. When two Proficiency Testing samples for the same Parameter Method are analyzed and submitted at the same time, an unacceptable result on one or both samples shall be considered the first unacceptable result for Certification purposes. A laboratory that submits Unacceptable Proficiency Testing Results for two Proficiency Testing samples for the same Parameter Method submitted at the same time shall analyze a remedial Proficiency Testing sample to 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 actions taken to prevent recurrence. Proficiency Testing samples shall be analyzed in the same manner that routine samples are analyzed using the same staff, sample tracking, sample preparation procedures, analytical methods, standard operating procedures, calibration techniques, quality control procedures, and acceptance criteria.

(A) 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 shall participate annually in an evaluation studies by analyzing Proficiency Testing samples obtained from a State Laboratory approved Vendor as unknowns, and arranging with the Vendor to send the graded results directly to the State Laboratory by the date due. A laboratory that submits Unacceptable Proficiency Testing Results shall analyze a remedial Proficiency Testing sample using the same Parameter Method to 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 actions 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 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 Method for which performance samples are available. Laboratories shall analyze Proficiency Testing samples obtained from a State Laboratory-approved Vendor as unknowns and arrange with the Vendor to send the graded results directly to the State Laboratory. Laboratories that submit two consecutive unacceptable Proficiency Testing Results for a particular Parameter Method must then submit two consecutive acceptable results from the most recent attempt analyzed within the six months prior to initial Certification for that Parameter Method prior to initial certification.

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

(3) Supervisory Requirements.

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

(B) The supervisor of a municipal or industrial waste water treatment plant non-Commercial Municipal, Industrial, Mobile or Other Laboratory must have a minimum of a B.S. or A.B. Bachelor’s degree in chemistry or a closely-related science curriculum from an accredited college or university plus a minimum of six months of laboratory experience in analytical chemistry or an equivalent combination of education and work experience, or a two-year associate degree from an accredited college,
university, or technical institute in chemistry technology, environmental sciences, or a closely-related science curriculum plus a minimum of two years of experience in analytical chemistry or an equivalent combination of education and work experience. Non-degree supervisors must have at least six years of 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 of this supervision. 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. 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, 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 shall submit an application in duplicate, accompanied by the application fee and the laboratory's Quality Assurance Manual, including Standard Operating Procedures for all requested Parameter Methods, to the State Laboratory. Separate application and Certification shall be required for each Mobile Laboratory and the applicant shall supply the vehicle make, vehicle identification number, and license number. Separate application and certification shall be required for all stationary laboratories maintained on separate premises even though operated under the same management; however, separate 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 shall be permitted without separate Certification. After receiving a
completed application and prior to issuing certification, a representative of the State Laboratory may visit each laboratory to verify the information in the application and the adequacy of the laboratory.

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

(A) A 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.

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

For analysis of Field Parameters, a certified laboratory shall follow the quality assurance and quality control requirements in Paragraphs (g) (1) through (9) of this Rule.

(A) — Unless specified by the method or this Rule, each laboratory shall establish performance acceptance criteria for all Quality Control analyses. Each laboratory shall calculate and document the precision and accuracy of all Quality Control analyses with each sample set.

When the method of choice specifies performance acceptance criteria for precision and accuracy, and the laboratory chooses to develop laboratory-specific limits, the laboratory-specific limits shall not be less stringent than the criteria stated in the approved method.

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

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

(D) Unless the referenced method states a greater frequency or the parameter is not amenable to spiking, laboratories shall spike 5% of samples monthly. Laboratories analyzing fewer than 20 samples per month shall analyze one Matrix Spike during each month that samples are analyzed.

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

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

(i) the method or Standard Operating Procedure;
(ii) the laboratory identification;
(iii) the instrument identification;
(iv) the sample collector;
(v) the signature or initials of the analyst;
(vi) the date and time of sample collection;
(vii) the date of sample analyses.
(viii) the time of sample analyses (when required to document a required holding time
or when time critical steps are imposed by the method, a federal regulation or this
Rule):
(ix) sample identification;
(x) sample preparation, where applicable;
(xi) the volume of sample analyzed, where applicable;
(xii) the proper units of measure;
(xiii) the dilution factor, where applicable;
(xiv) all manual calculations;
(xv) all quality control assessments;
(xvi) the value from the measurement system;
(xvii) the final value to be reported; and
(xviii) any other data needed to reconstruct the final calculated result.
Each item shall be recorded each time samples are analyzed. The date and time samples
are placed into and removed from ovens, water baths, incubators and other equipment shall
be documented if a time limit is required by the method.

(G) If certified for total suspended residue, total dissolved residue or total residue, laboratories
shall analyze one standard monthly during each month samples are analyzed.
(H) For analytical procedures requiring analysis of a series of standards, the concentrations of
these standards shall bracket the range of the sample concentrations measured. One of the
standards shall have a concentration equal to or less than the laboratory’s lowest reporting
concentration for the parameter involved. All data sets shall reference the corresponding
calibration. Laboratories shall analyze or back-calculate a standard at the same
concentration as the lowest reporting concentration each day samples are analyzed. A
calibration blank and calibration verification standard shall be analyzed prior to sample
analysis, after every tenth sample and at the end of each sample group, unless otherwise
specified by the method, to check for carry over and calibration drift.
(i) The concentration of reagent, method, and calibration blanks shall not exceed
50% of the lowest reporting concentration or as otherwise specified by the
reference method.
(ii) Laboratories shall analyze one known second source standard to verify the
accuracy of standard preparation if an initial calibration is performed and in
accordance with the referenced method requirements thereafter.
(iii) For electrode analyses, a series of two or more non-zero standards shall be used.
(iv) For metals analyses, a series of three or more non-zero standards or standards as
set forth in the analytical procedure shall be analyzed along with each sample set
shall be used.
(v) For colorimetric analyses, a series of five or more non-zero standards for a curve prepared every twelve months or three or more non-zero standards for curves established each day, or standards as set forth in the analytical procedure, shall be analyzed to establish a calibration curve. A manufacturer’s factory-set calibration (internal curve) shall be verified with the same number of standards and frequency as a prepared curve.

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

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

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

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

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

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

(N) All temperature-measuring devices shall have accuracy appropriate for its intended use.
All temperature-measuring devices shall be properly used, stored, and maintained.
(i) Reference Temperature-Measuring Devices shall meet National Institute of
Standards and Technology (NIST) specifications for accuracy and shall be
recalibrated in accordance with the manufacturer’s recalibration date. If no
recalibration date is given, the Reference Temperature-Measuring Device shall be
recalibrated every five years.
(ii) Excluding digital, incubator, and infrared temperature-measuring devices, all
non-Reference Temperature-Measuring Devices shall be verified every twelve
months against a Reference Temperature-Measuring Device and their accuracy
shall be corrected.
(iii) Digital temperature-measuring devices and temperature-measuring devices used
in incubators shall be verified at every three months against a Reference
Temperature-Measuring Device and their accuracy shall be corrected.
(iv) Infrared temperature-measuring devices shall be verified every three months at
three different temperatures over the temperature range of use against a Reference
Temperature-Measuring Device and their accuracy shall be corrected. Each day
of use, infrared temperature-measuring devices shall be verified against a non-
Reference Temperature-Measuring Device that meets NIST specifications for
accuracy. If the infrared temperature-measuring device does not agree within 0.5
degrees Celsius during the daily verification, corrective action must be taken.

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

(P) Each laboratory shall develop and implement a documented training program that includes
documentation that:
(i) staff have the education, training, experience, or demonstrated skills needed to
generate quality control results within method-specified limits and/or that meet
the requirements of these Rules;
(ii) staff have read the laboratory Quality Assurance Manual and/or applicable
Standard Operating Procedures; and
(iii) staff have obtained acceptable results on Proficiency Testing samples pursuant to
15A NCAC 2H .0803 (1) 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 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 shall be valid for the remainder of the applicable Certification cycle that begins on January 1 and is valid for one year, 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 for each parameter Parameter Method, a certified laboratory must analyze up to four performance evaluation one Proficiency Testing sample samples per parameter Parameter Method per year. 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 if a question about the accuracy of data produced arises, if there are changes in equipment or personnel, if inaccurate information is reported with Proficiency Testing results, or if Unacceptable Proficiency Testing Results are submitted.

(2) In addition, if a Proficiency Testing sample is not available, the State Laboratory may request the analysis of Split samples 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 sample results shall 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 if there is a question about the accuracy of data produced, if Proficiency Testing samples are not available or if analysis of Proficiency Testing samples does not represent the entire analytical process.

(4) A certified laboratory shall be subject to periodic announced or unannounced inspections during the certification period and shall make time and all records pursuant to 15A NCAC 2H .0805(a)(7)(E) available for inspections 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.
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.

A certified laboratory shall supply copies of all records pursuant to 15A NCAC 2H .0805(a)(7)(E) for any investigation upon written request by the State Laboratory.

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

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

Certification Renewals.

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

(e) Data reporting.

(1) Certified commercial laboratories must 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 refers or subcontracts analysis of samples to another laboratory for analyses, the referring laboratory must supply the date and time samples were collected to insure holding times are met. Subcontracted analyses must clearly indicate that the collection site is in 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 adherence to all Rules and requirements of 15A NCAC 02H .0800 are 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 shall be traceable to the laboratory that performed the analysis on the final report.

(3) All uncertified data must be clearly documented as such on the benchesheet and on the final report.

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

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

(f) Discontinuation of Certification.

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

(2) After discontinuation of certification, a laboratory shall be recertified by meeting the requirements for initial certification; however, laboratories that discontinue certification during any investigation shall be subject to Rule .0808 of this Section.
(g) Prerequisites and Requirements for Field Laboratory Parameter Certification. Only the following requirements must be met prior to certification for Field Parameter Laboratories. Laboratories that meet the requirements of this Paragraph shall be certified as Field Laboratories. Once certified, failure to comply with any of the following items shall be a violation of Certification requirements.

(1) 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 benchesheets 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.

(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, shall be maintained for five years. All analytical data and records pertinent to each certified analysis shall be accurate and filed in an orderly manner so as to be readily available for inspection upon request. All analytical records shall be legible and safeguarded against unauthorized amendment, obliteration, erasures, overwriting and corruption. Records which are stored only on electronic media shall 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 shall be corrected by drawing a single line through the error so that the original entry remains legible. Entries shall not be obliterated by erasures or markings. Wite-Out®, correction tape or similar products designed to obliterate
documentation are not to be used. Write the correction adjacent to the error. The correction shall be
initialed by the responsible individual and the date of change documented. All manual data and log
entries shall be written in indelible ink. Pencil entries are not acceptable.

(2) All laboratories shall use printable laboratory benchesheets. Certified Data shall be traceable to the
associated sample analyses and shall consist of:
(i) the method or Standard Operating Procedure;
(ii) the laboratory identification;
(iii) the instrument identification;
(iv) the sample collector;
(v) the signature or initials of the analyst;
(vi) the date and time of sample collection;
(vii) the date of sample analyses;
(viii) the time of sample analyses (when required to document a required holding time or when
time critical steps are imposed by the method, a federal regulation or this Rule);
(ix) sample identification;
(x) sample preparation, where applicable;
(xi) the volume of sample analyzed, where applicable;
(xii) the proper units of measure;
(xiii) the dilution factor, where applicable;
(xiv) all manual calculations;
(xv) the quality control assessments;
(xvi) the value from the measurement system;
(xvii) the final value to be reported; and
(xviii) any other data needed to reconstruct the final calculated result.
Each item shall be recorded each time samples are analyzed. Analyses shall conform to
methodologies found in Rule .0805 (a) (1) of this Section.

(3) A record of instrument calibration or calibration verification shall be documented, filed in an orderly
manner, and available for inspection upon request.

(4) Laboratory Procedures. Laboratory procedures shall comply with Rule .0805 (a) (1) of this Section.
A copy of each analytical method or Approved Procedure and Standard Operating Procedure shall
be available to each analyst and available for review upon request by the State Laboratory. Standard
Operating Procedure documentation shall indicate the effective date of the document and shall be
reviewed every two years and updated if changes in procedures are made. Each laboratory shall
have a formal process to track and document review dates and any revisions made in all of their
Standard Operating Procedure documents. Supporting Records shall be maintained as evidence that
these practices are implemented.
Each laboratory shall develop and implement a documented training program that includes the following:

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

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

(iii) that staff have obtained acceptable results on Proficiency Testing samples pursuant to 15A NCAC 2H .0803 (1) or other demonstrations of proficiency.

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

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

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

All temperature-measuring devices shall have accuracy appropriate for its intended use. All temperature-measuring devices shall be properly used, stored, and maintained.

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

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

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

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

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

(A) meet the requirements of Subparagraph (a) (3) (A) or (a) (3) (B) of this Section;

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

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

Supervisors shall provide personal and direct supervision of the technical personnel and be held responsible for the proper performance and reporting of all analyses governed by 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 shall not be in charge for more than twelve consecutive weeks.

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

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

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

(15) Application. Each Field Laboratory requesting initial Certification shall submit an application to the State Laboratory.

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

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

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

(19) Maintenance of Certification. A certified Field Laboratory shall submit written notice of any material changes in the laboratory supervisor, location, ownership, address, name and telephone number within 30 days of such changes.
Certification Renewals. Certification renewals of certified Field Laboratories shall be issued in accordance with Rule .0805 (d) of this Section.

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

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

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.

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

15A NCAC 02H .0806 is proposed for amendment as follows:

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

(a) An applicant for laboratory certification, excluding those laboratories seeking only 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 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 parameter; however, the minimum fee will be one thousand three hundred fifty dollars ($1,350.00) ($1750.00) per year. Municipal Laboratories may cost-share among Municipal Laboratories or charge a cost recovery fee or surcharge to operate their Pretreatment Program.

(c) Commercial 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 thousand seven hundred fifty dollars ($2,700.00) ($3500.00) per year.

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

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

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

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

(h) Out-of-state laboratories shall reimburse the state for actual travel and subsistence costs incurred by laboratory certification staff in certification and maintenance of certification including travel to provide technical assistance or complaint investigations. Out-of-state laboratories shall also be assessed for expenses for an on-site inspection based on the hourly rate of the laboratory certification staff, rounded to the nearest hour and inclusive of preparation time, travel time, and inspection time.

(i) Annual certification fees shall be due 60 days after receipt of invoice.

(j) A fifty dollar ($50.00) late payment fee shall be paid by Field Laboratories when annual Certification fees have not been paid by the date due. For all other laboratories, a two hundred fifty dollar ($250.00) late payment fee shall be paid when annual certification fees are not paid by the date due.
(k) Commercial facilities laboratories analyzing only samples for field parameters Field Parameters only must shall 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 only samples for field parameters Field Parameters only must shall pay an annual fee of one hundred fifty dollars ($100.00) ($150.00) per year.

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

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 amendment as follows:

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 pursuant to Paragraph (d) of this Section for any or all parameters for up to one year:

1. Failing to maintain the facilities, records, personnel, equipment, or quality control program as set forth in the application, and these Rules; or
2. Submitting inaccurate data or other information subject to these rules; 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 is in effect; or
5. Failing to submit a split sample to the State Laboratory as requested; or
6. Failing to use approved methods of analysis; or
7. Failing to report a change of laboratory supervisor or equipment changes within 30 days of such changes; or
8. Failing to report an analysis of required annual performance evaluation Proficiency Testing samples submitted by an EPA State Laboratory-approved 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 pursuant to 15A NCAC 2H .0805(a)(6) and (7) and 15A NCAC 2H .0805(g)(19); or
12. Failing to meet 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; or
15. Altering or modifying the laboratory’s certificate or Certified Parameters Listing; or
16. Sharing or comparing Proficiency Testing sample results with other laboratories prior to the study reporting deadline; or
17. Splitting, sending, or subcontracting a Proficiency Testing sample or a portion of a Proficiency Testing sample to another laboratory unless the practice represents the routine analysis and reporting scheme utilized by the laboratories; or
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 by that laboratory 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.

(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 pursuant to Paragraph (d) of this Section 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 pursuant to Paragraph (d) of this Section for all parameters for up to two years and may be recertified per Rule .0808 of this Section.

(d) Decertification Factors. In determining a period of decertification, the Director shall recognize that any harm to the natural resources of the State arising from violations of these 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 one or a combination of the following factors to be considered:

(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/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.
A decertified laboratory is not to shall not analyze samples for the decertified parameter Method for programs described in Rule .0802 of this Section or for clients reporting to these programs or other programs requiring Certified Data pursuant to this Section.

A decertified commercial laboratory shall supply written notification of the decertification to clients with Division of Water Quality that are required to report to the Department of Environmental Quality reporting requirements under G.S. 143 Article 21. Within 30 days of Decertification, the decertified laboratory shall provide the State Laboratory with a list of such clients involved and copies of the notices sent to each.

A commercial laboratory that has received a parameter decertification may make arrangements to supply analysis through another certified laboratory certified by the State Laboratory for the contracted parameters during any decertification period. The decertified laboratory must supply the State Laboratory, by written notice, the name of the laboratory to be used. Within 30 days of Decertification, the decertified laboratory shall 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 to be used during the Decertification period.

A commercial laboratory decertified for all parameters cannot subcontract samples for analyses to other certified laboratories during the Decertification period.

A decertified municipal or industrial laboratory that has received a Parameter Method Decertification shall 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 period and supply the State Laboratory, by written notice, the name of the certified laboratory to be used. Within 30 days of Decertification, the decertified laboratory shall supply the State Laboratory with the name and Certification number of the certified laboratory 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. In determining the civil penalties assessed, the Director shall recognize that any harm to the natural resources of the State arising from violations of 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 documents. Civil penalties up to the maximum may be based on any one or a combination of the factors in Section .0807(d) of this Rule.

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.
15A NCAC 02H .0808 is proposed for amendment as follows:

15A NCAC 02H .0808  RECERTIFICATION

(a) A laboratory decertified in accordance with Paragraph (a) of Rule .0807 of this Section shall be recertified at the end of the 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 deficiencies 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 showing 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 shall 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 shall be requested in writing following Decertification;

(3) The decertified laboratory shall supply the State Laboratory with the name, certification number, and address of the certified subcontract laboratory and a list of impacted clients and their contact information;

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

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

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

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

(d) A laboratory decertified for submitting Falsified Data or Information shall 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);
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 amendments follows:

15A NCAC 02H .0809  RECIPROCY

(a) Laboratories certified under other state certification programs of other states or other certification or accreditation bodies shall may be given reciprocity where such programs or certification or accreditation bodies meet the requirements of this Section. In requesting reciprocity 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 body, the laboratory’s response to the audit report, the laboratory’s scope of accreditation, and applicable regulations 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, if a laboratory’s certification by another state’s program or another certification or accreditation body is discontinued, the State Laboratory shall be notified and the 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;
15A NCAC 02H .0810 is proposed for repeal as follows:

15A NCAC 02H .0810 — ADMINISTRATION
(a) The Director of the Division of Water Quality, Department of Environment and Natural Resources or his delegate, is authorized 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 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) The State Laboratory will maintain a current list of certified commercial laboratories.
(d) Implementation of the October 1, 2001 changes 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.