## CHAPTER 42 - LABORATORY SERVICES

## SUBCHAPTER 42A - GENERAL POLICIES

### 10A NCAC 42A .0101 SCOPE

The following are the general purposes of the State Laboratory of Public Health:

(1) This laboratory analyzes specimens and samples for physicians, health clinics, other laboratories and other agencies, (federal, state, local and private) to aid in the diagnosis, treatment and monitoring of individual, community, or environmental health problems.

(2) It strives to improve the quality and relevance of health related laboratory services performed in the state.

(3) It provides, at cost, vaccines and other biologicals such as antirabic treatments and kits for the collection and shipment of specimens and samples.

*History Note:* *Authority 130A-88;*
*Eff. February 1, 1976;*
*Readopted Eff. November 15, 1977;*
*Amended Eff. September 1, 1990; October 1, 1985;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

### 10A NCAC 42A .0102 DEFINITIONS

The following definitions shall apply throughout this Chapter:

(1) "Laboratory" refers to the State Laboratory of Public Health as described in G.S. 130A-88.

(2) "The laboratory" refers to any other health related laboratories in North Carolina.

(3) "Specimen" refers to material collected from human beings, animals and insects.

(4) "Sample" refers to material collected from the environment and includes milk and other food although these may be animal products.

(5) "CDC" refers to the Centers for Disease Control in Atlanta, Georgia.

(6) "Authorized sender of specimens" refers to any individual who is authorized to manipulate a patient for the purpose of collecting blood, spinal fluid, and other body materials for analysis, or to an agency such as a hospital, local health department, or clinic which employs persons to perform such services under the direction of a licensed individual, when submitting specimens for types of analyses that have been approved by the Department for submission to the Division or which are required by law or rule to be submitted to the Division.

(7) "Authorized sender of samples" is any individual who has been designated by law, rules and regulations, or professional position to collect and submit environmental material for analysis when submitting specimens for types of analyses that have been approved by the Department for submission to the Division or which are required by law or rule to be submitted to the Division.

*History Note:* *Authority G.S. 130A-88;*
*Eff. February 1, 1976;*
*Readopted Eff. November 15, 1977;*
*Amended Eff. September 1, 1990; October 1, 1985; October 1, 1984;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

### 10A NCAC 42A .0103 FORMS

The following types of forms are available from this laboratory:

(1) Identification forms which must accompany specimens or samples; These request the full name and address of the sender, the name of the patient (if applicable), the source of the specimen or sample, and other specific information necessary for intelligent analysis or for epidemiological data gathering;

(2) Forms which sender uses in ordering specimen or sample collection kits or biologicals; These forms contain lists of material available, cost of each, and space for sender to indicate quantity ordered;

(3) Application which must be submitted by any laboratory wishing to be certified under any of the certification programs described in this Chapter;
(4) Application for Admission to Training Courses includes spaces for applicants name, address, training and experience and name of course;
(5) Forms for participating laboratories to report the results of analysis of proficiency testing specimens or samples; The forms are designed according to the type of specimen or sample and the complexity of the expected results;
(6) Forms used by public water systems to contract with this laboratory to perform analyses required by G.S. 130A-311 to 130A-332.

*History Note:* *Authority G.S. 130A-88;*
*Eff. February 1, 1976;*
*Readopted Eff. November 15, 1977;*
*Amended Eff. October 1, 1985; October 1, 1984;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42A .0104 ACQUIRING SERVICES OF CDC**

Unless prior approval has been obtained from the State Laboratory of Public Health and the Centers for Disease Control (CDC), all specimens submitted to CDC must be submitted through this laboratory and the results returned to sender through this laboratory. Applications to CDC training courses for laboratories anywhere in the state must be approved by the person in charge of this laboratory and forwarded to CDC.

*History Note:* *Authority G.S. 130A-88;*
*Eff. February 1, 1976;*
*Readopted Eff. November 15, 1977;*
*Amended Eff. September 1, 1990;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42A .0105 SUBMITTING SPECIMENS OR SAMPLES AND RECEIVING RESULTS**

(a) For specific information on individuals or agencies to whom the services described in this Chapter are available, type of specimen or sample to submit, when and how to collect proper specimen or sample, how to ship specimen or sample, test procedures to request, information to submit with specimen or samples, when to expect results, aid in interpretation of results, persons to contact for information or consultation, location and hours this laboratory is open, order forms for kits and biologicals and their current prices, and other pertinent information, please refer to the "laboratory services" manual which is available to authorized senders of specimens or samples and may be obtained from this laboratory.
(b) Private citizens may submit specimens or samples to this laboratory in only one circumstance, animals or animal heads for rabies examination.
(c) Individuals will be given the results of analysis made on specimens in the circumstances described in (b) of this Rule but in all other instances may receive the results only upon written request of the authorized sender.
(d) Upon request of the person who sends a specimen to this laboratory for testing, copies of the laboratory results may be furnished to another authorized sender. Copies of laboratory results shall also be furnished to the Department's health divisions for follow-up or tracking of communicable diseases or conditions in accordance with applicable laws or rules.

*History Note:* *Authority G.S. 130A-88;*
*Eff. February 1, 1976;*
*Amended Eff. May 1, 1977;*
*Readopted Eff. November 15, 1977;*
*Amended Eff. September 1, 1990; October 1, 1985;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42A .0106 FEES**

(a) Upon request, the State Laboratory of Public Health furnishes to authorized senders of specimens and samples kits and materials for collecting and submitting specimens and samples. The fees for these kits and materials are based on cost and are subject to change as costs change.
(b) Upon request, the State Laboratory of Public Health furnishes, to persons authorized to administer them vaccines and other biologicals such as antirabic treatments. The prices for these are based on cost and cost of shipment and are subject to change as these costs change.
(c) An individual is eligible to receive rabies vaccine and immune globulin without charge for rabies post-exposure treatment when the individual meets all of the following criteria:

(1) the individual's family income is at or below the federal poverty level in effect on July 1 of each fiscal year as determined by the local health department;
(2) the individual meets the residency and other requirements set forth in 10A NCAC 45A .0200, except that the individual shall not be eligible for Medicaid or health insurance reimbursement for rabies post-exposure treatment as determined by the local health department; and
(3) the treatment is recommended by a physician licensed to practice medicine.

(d) The State Laboratory of Public Health provides laboratory analysis services to assist owners and operators of public water systems in complying with the North Carolina Drinking Water Act. These services must be contracted for on a yearly basis and must be paid for in advance. Refunds of prepayments will be made only when:

(1) The water system ceases to exist as a public water system or merges with a larger water system;
(2) The water system changes in status from a community to a non-community water system or from a non-community to a community water system;
(3) There has been an overpayment of fees; or
(4) The laboratory fails to perform an analysis in accordance with the contract.

(e) Fees for the analysis of public water supplies shall be as follows:

| PARAMETER | FEE |
|---|---|
| Inorganic Chemistry | $200.00 |
| Organic Chemistry | $190.00 |
| Coliform | $ 20.00 |
| Trihalomethanes | $ 60.00 |
| Sodium and Corrosivity | $ 60.00 |
| Radiochemistry: | |
| gross alpha and beta | $ 50.00 |
| radium 226 | $ 65.00 |
| radium 228 | $ 50.00 |
| uranium | $ 75.00 |
| Any single organic or inorganic parameter | $ 15.00 |

*History Note:* *Authority G.S. 130A-5(12); 130A-326;*
*Eff. February 1, 1976;*
*Readopted Eff. November 15, 1977;*
*Amended Eff. February 1, 1991; September 1, 1990; April 1, 1987;*
*Temporary Amendment Eff. August 9, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*
*Amended Eff. January 1, 1994;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42A .0107 PAP SMEAR FEES**

*History Note:* *Authority G.S. 130A-5;*
*Temporary Adoption Eff. January 1, 2004;*
*Eff. May 1, 2004;*
*Expired Eff. January 1, 2018 pursuant to G.S. 150B-21.3A.*

## SUBCHAPTER 42B - LABORATORY SECTIONS

### 10A NCAC 42B .0101 CANCER CYTOLOGY

*History Note:* *Authority G.S. 130A-88;*
*Eff. October 1, 1985;*
*Expired Eff. January 1, 2018 pursuant to G.S. 150B-21.3A.*

### 10A NCAC 42B .0102 NEWBORN SCREENING

(a) The State Laboratory of Public Health will conduct screening for the core conditions listed on the Recommended Uniform Screening Panel developed by the Secretary of the United States Department of Health and Human Services and the Advisory Committee on Heritable Disorders of Newborns and Children (the "RUSP"), which is hereby incorporated by reference, including any subsequent editions and amendments, and available free of charge at https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html. Specimens shall be submitted to this laboratory for screening in accordance with the procedures set forth in 10A NCAC 43H .0314.
(b) The process to develop and implement new screening for the conditions described in Paragraph (a) of this Rule shall begin after:

(1) the screening fee set out in Rule .0108 of this Section is adjusted, as permitted by G.S. 130A-125(c);
(2) funds exist to acquire instrumentation, equipment, Program supplies, and Program personnel; and
(3) the Program performs assay validations, implements preventative follow-up interventions, secures necessary infrastructure, and meets all federal, State, and local requirements.

*History Note:* *Authority G.S. 130A-88; 130A-125;*
*Eff. October 1, 1985;*
*Amended Eff. September 1, 1990;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;*
*Amended Eff. January 1, 2021.*

### 10A NCAC 42B .0103 ENVIRONMENTAL SCIENCES

(a) This laboratory examines samples of drinking water and other environmental materials for evidence of microbiological, chemical or other contamination. No test will be performed on a sample from an open well or an unprotected spring because such supplies are unsafe to drink regardless of laboratory findings.
(b) This laboratory examines samples for monitoring man-made and natural radiochemical levels in air, water, soil, animal and vegetable material, milk and other foods.
(c) This laboratory examines samples of drinking water, samples from industrial environments and other environmental material for the presence of excess levels of inorganic or organic compounds which are deemed detrimental to human health. Sample containers supplied by this laboratory must be used to collect samples.

*History Note:* *Authority G.S. 130A-88;*
*Eff. October 1, 1985;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

### 10A NCAC 42B .0104 LABORATORY IMPROVEMENT

(a) Participation in the proficiency testing offered by this laboratory is mandatory for laboratories certified in milk and for laboratories funded through the federal gonorrhea grant to culture females for gonorrhea. Participation in other proficiency testing or by other laboratories is voluntary.
(b) Formal training courses in laboratory procedures and laboratory management are presented by this laboratory for health related laboratorians in the state. Courses are announced in the bulletin, LABORATORY, and are planned in response to requests and needs demonstrated by proficiency testing results.
(c) The bulletin, LABORATORY, is published quarterly and includes announcements of courses offered and information important to laboratory scientists and managers. The bulletin is available to any health related laboratory.

*History Note:* *Authority G.S. 130A-88;*
*Eff. October 1, 1985;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42B .0105 MICROBIOLOGY**

(a) This laboratory isolates and identifies anaerobic organisms and serves as a reference laboratory for confirmation of further identification of anaerobic bacteria.

(b) The laboratory examines fecal specimens for enteric pathogens from symptomatic patients, typhoid carriers, and contacts of such individuals. Environmental samples, such as food and water from aquariums or turtle bowls are examined if they are implicated as vehicles of infection. This laboratory is the designated serotyping center for the state of all isolates of salmonella and shigella for confirmation and surveillance purposes.

(c) This laboratory isolates and identifies pathogenic fungi from body tissues and fluids and serves as a reference laboratory for confirmation or further identification of fungi.

(d) This laboratory examines fecal and other specimens from symptomatic patients for the eggs, cysts, and larvae of the intestinal parasitic worms and protozoa. Blood smears are examined for parasitic blood diseases, such as malaria. Reference specimens or prepared stained slides from preserved material, biopsy material and tissue aspirates for tissue parasites are also accepted. Identification of arthropods is made.

(e) This laboratory accepts a wide variety of bacteria which have been isolated by hospital or other laboratories, which are unusual, difficult to identify, fastidious, or infrequently encountered, thereby serving as a reference laboratory for other laboratories.

(f) Sputa and specimens from other sources are examined for mycobacteria, including MYCOBATERIUM TUBERCULOSIS and all isolates are tested for drug susceptibility using the drugs most commonly used for treating tuberculosis.

(g) This laboratory may examine, upon request of an authorized sender of specimens, a variety of other specimens as the public health may require.

*History Note:* *Authority G.S. 130A-88;*
*Eff. October 1, 1985;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42B .0106 VIROLOGY/SEROLOGY**

(a) The services available for the laboratory diagnosis of viral infections are based on the following general approaches:

(1) the examination of serum for the demonstration of a significant increase in antibody titer to a given virus;

(2) the examination of pathological fluids, tissue, and other suitable material for the isolation and identification of the viral agent; and

(3) the examination of infected tissue to demonstrate the presence of viral material or for changes which are characteristic of a particular viral disease.

(b) Several types of serological procedures and variations of those are used to study and detect evidence of rickettsial, bacterial, fungal and parasitic diseases as well as viruses.

(c) Only the head of animals larger than the common gray squirrel shall be accepted. Gray squirrels and small animals, including bats, shall, when possible, be submitted intact.

*History Note:* *Authority G.S. 130A-88;*
*Eff. October 1, 1985;*
*Amended Eff. September 1, 1990;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42B .0107 NEWBORN SCREENING FOR POMPE DISEASE, MPS-1, AND X-ALD**

Pompe disease, Mucopolysaccharidosis Type I (MPS I), and X-Linked Adrenoleukodystrophy (X-ALD) are added to the Newborn Screening Program. The process to develop and implement new tests for these conditions shall begin after the fee is established and adequate funds exist to acquire instrumentation, equipment, Program supplies,

Program personnel, perform assay validations, implement preventative follow-up interventions, secure necessary infrastructure, and with the assurance that the laboratory has met all federal, State, and local requirements.

*History Note:* *Authority G.S. 130A-125;*
*Eff. September 1, 2018.*

**10A NCAC 42B .0108 FEES**
(a) The State Laboratory of Public Health shall charge a fee of one hundred thirty-two dollars ($132.00) to cover the programmatic costs of the newborn screening performed by the State Laboratory of Public Health under 10A NCAC 42B .0102(a).
(b) In accordance with G.S. 130A-125, the Commission for Public Health, in consultation with the Secretary of the North Carolina Department of Health and Human Services, has determined that the fee listed in Paragraph (a) of this Rule is necessary to offset the cost of incorporating the conditions identified in 10A NCAC 42B .0102(a) in the Newborn Screening Program.

*History Note:* *Authority G.S. 130A-125;*
*Eff. January 1, 2021.*

## SUBCHAPTER 42C - MILK AND WATER LABORATORY CERTIFICATION

**10A NCAC 42C .0101 MILK LABORATORY CERTIFICATION**
Milk laboratories are certified by this laboratory in cooperation with the United States Food and Drug Administration to perform bacteriological examinations on milk or milk products shipped interstate, as required by the United States Public Health Service Standard Milk Ordinance and Code, which is adopted by reference in 02 NCAC 09G .2000. A certified laboratory may be one under the direct supervision of the state or a local health department, or may be a milk plant laboratory, if the request for certification is made through the local health department. Certification is based on periodic laboratory surveys and on test results of split samples sent to each participating laboratory.

*History Note:* *Authority G.S. 130A-88;*
*Eff. July 1, 1985;*
*Amended Eff. September 1, 1990;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42C .0102 WATER LABORATORY CERTIFICATION**
Water laboratories in local health departments, commercial laboratories, and industrial laboratories are certified by this laboratory to perform bacteriological, chemical, and radio-chemical examinations for determining the sanitary quality of water in accordance with United States Environmental Protection Agency (EPA) Safe Drinking Water Act and 15A NCAC 18C.

*History Note:* *Authority G.S. 130A-88;*
*Eff. July 1, 1985;*
*Amended Eff. December 1, 1991; September 1, 1990;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

## SUBCHAPTER 42D - CERTIFICATION AND IMPROVEMENT

### SECTION .0100 - LABORATORY CERTIFICATION

**10A NCAC 42D .0101 CERTIFICATION FOR LABORATORIES CONDUCTING HIV TESTING**

*History Note:* *Authority G.S. 130A-148(a);*
*Temporary Rule Eff. February 1, 1988, for a period of 180 Days to expire on July 29, 1988;*
*Eff. March 1, 1988;*
*Transferred and Recodified from 10 NCAC 9D .0104 Eff. April 4, 1990;*
*Amended Eff. July 1, 1995;*
*Expired Eff. January 1, 2018 pursuant to G.S. 150B-21.3A.*

## SECTION .0200 - LABORATORY CERTIFICATION

**10A NCAC 42D .0201 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0202 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0203 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0204 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0205 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0206 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0207 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0208 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0209 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0210 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0211 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0212 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0213 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0214 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0215 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0216 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0217 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0218 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0219 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0220 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0221 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0222 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0223 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0224 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0225 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0226 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0227 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0228 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0229 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0230 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 42D .0231 SCOPE**

A laboratory wishing to perform analyses of public water systems pursuant to 15A NCAC 18C .1500 shall be certified by the State Laboratory of Public Health and shall meet the minimum requirements for certification contained in Rules .0231 through .0261 of this Section for each test category it wishes to perform. A laboratory may also be certified by the State Laboratory of Public Health if certified by the United States Environmental Protection Agency (EPA).

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0232 NOTICE AND PROCEDURE**

(a) A laboratory seeking certification shall request in writing an application for certification from the State Laboratory of Public Health. The application for certification shall include:

(1) Name and address of the laboratory and its owner(s) or directors;
(2) Names and qualifications of the laboratory personnel;
(3) Test categories for which certification is requested;
(4) Description of facilities, equipment, and methodologies;
(5) Such other information as the State Laboratory of Public Health deems necessary for certification purposes.

(b) Upon review of the application by a state laboratory certification evaluator, and successful analyses of water performance samples, an on-site visit shall be scheduled to evaluate the laboratory premises.

(c) A written report describing deviations from minimum requirements shall be prepared by the laboratory certification evaluator and submitted to the laboratory director or other responsible person. Within 30 days of receiving the written report, the laboratory shall submit a letter with supporting documents (records, reports, data, purchase orders, or other documents) showing the action taken to comply with the minimum requirements. The letter shall be sent to the laboratory certification evaluator for review.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0233 CERTIFICATION, CERTIFICATION RENEWAL AND FEES**

(a) The State Laboratory of Public Health shall grant certification for the test categories requested upon finding that a laboratory meets the minimum requirements set forth in this Section.

(b) A laboratory may renew its certification every year by payment of the certification fee by December 1 of the preceding year. A laboratory which renews its certification shall continue to meet the minimum requirements of this Section in accordance with 10A NCAC 42D .0234.

(c) The certificate and information pertaining to certification shall remain the property of the State Laboratory of Public Health and shall be surrendered upon decertification pursuant to Rule .0234 of this Section. All certification information shall be available for public access pursuant to Chapter 132 of North Carolina General Statutes.
(d) The certification fee shall be twenty dollars ($20.00) per analyte. The minimum and maximum fee per analyte group shall be as set out in G.S. 130A-326(7). The analyte groups are as follows:

(1) inorganic chemistry;
(2) organic chemistry I (synthetic organic chemicals);
(3) organic chemistry II (volatile organic chemicals);
(4) total coliforms, fecal coliforms, heterotrophic plate count; and
(5) radiochemistry.

The certification fee shall not be prorated nor refunded. Twenty percent shall be due at the time of the application.

*History Note:* *Authority G.S. 130A-315; 130A-326;*
*Eff. December 1, 1991;*
*Amended Eff. January 1, 1996; April 1, 1993;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0234 CRITERIA AND PROCEDURES: DECERT./DENIAL/DOWNGRADING**

(a) The State Laboratory of Public Health or its delegate may decertify, downgrade or deny laboratory certification if the laboratory:

(1) Failed to train or supervise employees in laboratory methodologies required by 15A NCAC 18C .1500;
(2) Failed to report analytical results of performance evaluation samples or compliance samples or maintain records as required by this Section and the Rules Governing Public Water Supplies in 15A NCAC 18C .1500;
(3) Failed to maintain facilities and equipment in accordance with the minimum requirements of this Section;
(4) Failed to notify the certification evaluator within 30 days of major changes such as personnel, equipment, or laboratory location;
(5) Violated or aided and abetted in the violation of any provisions of the rules of this Section; or
(6) Failed to correctly analyze on-site evaluation performance samples during the initial on-site evaluation.

(b) A downgraded laboratory with provisional certification may continue to perform analyses. The provisional status shall continue for at least six months. At the end of the six months the laboratory certification shall be reinstated if the laboratory has made corrections and is in compliance with the minimum requirements for certification. If no corrections have been made the laboratory certification may be revoked.
(c) The State Laboratory of Public Health or its delegate may decertify or deny laboratory certification when a laboratory or its employees have done any of the following:

(1) Knowingly made false statements on any documents associated with certification;
(2) Falsified results of analysis;
(3) Submitted performance evaluation samples used for certification determination to another laboratory for analysis;
(4) Failed to employ approved laboratory methodology in the performance of the analyses required by 15A NCAC 18C .1500;
(5) Failed to correctly analyze performance evaluation samples including United States EPA water study, double blind, blind, and on-site samples or report the results within the specified time in accordance with the requirements of 15A NCAC 20D .0243 and .0251;
(6) Failed to report analytical results of performance evaluation samples or compliance samples or maintain records as required by this Section and the Rules Governing Public Water Supplies in 15A NCAC 18C;
(7) Failed to satisfy the certification evaluator that the laboratory has corrected deviations identified during the on-site visit within 30 days; or
(8) Violated or aided and abetted in the violation of any provisions of the rules of this Section.

(d) The State Laboratory of Public Health its delegate shall notify a laboratory of its intent to decertify, downgrade to provisional status or deny certification. The notice shall be in writing and include reasons for the decision and shall be delivered by certified mail.
(e) This Rule shall not preclude informal conferences concerning a decision to decertify, downgrade to provisional status or deny certification.
(f) If a laboratory is denied initial certification for failure to satisfy this Rule, the laboratory may request another evaluation which shall be scheduled between 15 days and 30 days after the initial on-site evaluation. If the laboratory is denied certification during the second on-site evaluation, the laboratory shall satisfy the initial certification criteria as stated in Rule .0232 of this Section before another evaluation is scheduled.
(g) The State Laboratory of Public Health or its delegate may decertify or deny laboratory certification if the laboratory has been decertified by another certifying agency for committing any of the items contained in Subparagraphs (c)(1)-(3) of this Rule.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Amended Eff. January 1, 1996; October 1, 1994; May 1, 1993;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0235 RECERTIFICATION**

(a) A laboratory is eligible for recertification six months after decertification, except in the following instances:
(1) A laboratory which lost certification for false statements on documents, falsified analytical results, or submitted official performance samples to another laboratory, is eligible for recertification one year after decertification. Application for recertification shall be made in the same way as application for certification as contained in Rule .0233 of this Section;
(2) A laboratory which lost certification for failure to correctly analyze performance evaluation samples is eligible for recertification 30 days after decertification and after satisfying Rule .0243(b)(4) or .0251(3), or both of this Section.
(b) A laboratory for which certification was not renewed for failure to pay the certification fee by the date required in Rule .0233 of this Section is eligible for recertification 60 days after paying the overdue fee.

*History Note:* *Authority G.S. 130A-315; 130A-326;*
*Eff. December 1, 1991;*
*Amended Eff. April 1, 1993;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0236 CERTIFICATION OF OUT-OF-STATE LABS**

(a) An out-of-state laboratory shall meet all the following conditions to obtain North Carolina certification to perform analyses for compliance with 15A NCAC 18C .1500:
(1) The laboratory shall be certified under a program administered by the state in which facility is located or by the United States Environmental Protection Agency (EPA). If a state has no program for certifying drinking water laboratories, an on-site evaluation may be performed and certification granted by the North Carolina Drinking Water Certification Branch for the analysis of drinking water in the state of North Carolina.
(2) The laboratory shall provide this office with its EPA performance evaluation data within 30 days of the receipt of those data;
(3) An initial on-site inspection shall be conducted by one or more laboratory certification evaluators at the requesting laboratory's expense. The Department shall not be required to conduct follow-up inspections more than once per year. Follow-up inspections shall be conducted at the requesting laboratory's expense.
(4) The laboratory shall pay fees as prescribed in Rule .0233 of this Section; and
(5) The laboratory shall notify the North Carolina Department of Environment and Natural Resources within 30 days of any changes in its certification status pursuant to the actions of another agency.

(b) The laboratory's failure to comply with any or all of the conditions in Paragraph (a) of this Rule will prevent the laboratory from obtaining certification in North Carolina or result in downgrading or decertification in North Carolina.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Amended Eff. January 1, 1996;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0237 CONTRACT LABORATORIES**

(a) A laboratory may sub-contract analytical work to another laboratory if the sub-contracting laboratory has been certified by the State Laboratory of Public Health as required in Rule .0231 of this Section.
(b) Any data generated through a sub-contract shall be reported on the report form of the laboratory that performed the sub-contracted analyses and shall be signed by the responsible person.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0238 CHEMISTRY FACILITIES**

The laboratory facilities shall be clean, be temperature and humidity controlled in the instrument areas to allow proper operation and have sufficient lighting at the bench top to perform the required procedures.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0239 CHEMISTRY EQUIPMENT AND INSTRUMENTATION**

The laboratory is required to have those instruments that are needed to perform the approved methods for which certification has been requested.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0240 CHEMISTRY LABORATORY PRACTICES**

The following chemistry laboratory practices shall apply:

(1) General:
  (a) Chemicals and reagents. Analytical reagent grade (AR) chemicals or better grade shall be used for analyses. Individual analytical methods in the approved references may specify additional requirements for the reagents to be used.
  (b) Laboratory safety. Where safety practices are included in an approved method, they shall be strictly followed.
(2) Inorganic Contaminants:
  (a) Reagent water. The laboratory shall have a source of reagent water having a resistivity value of at least 0.5 megohms (less than 2.0 micromhos) at 25°C. Quality checks to meet these specifications shall be made at planned intervals of at least once per month.
  (b) Glassware preparation. Glassware shall be washed in a warm detergent solution and thoroughly rinsed first with tap water and then with reagent water. This cleaning procedure is sufficient for general analytical needs, but the individual procedures shall be referred to for precautions to be taken against contamination of glassware.
(3) Organic Contaminants:

(a) Reagent water. Reagent water for organic analysis shall be free of interferences for the analytes being measured. Water shall be treated when necessary to eliminate interferences.

(b) Glassware preparation. Glassware and sample bottles shall be washed in a detergent solution and thoroughly rinsed first in tap water and then in reagent water. Glassware shall have a final organic solvent rinse or shall be baked at 400°C for 30 minutes and then dried or cooled in an area free of organic contamination. Glassware shall be covered with organic-free aluminum foil during storage. Bottles and cap liners, used for collection of samples for determination of volatile organic chemicals (VOCs) shall be dried at 105°C for one hour, sealed, and stored in an area free of volatile organics.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0241 CHEMISTRY METHODOLOGY**

Minimum equipment requirements and methodology for individual parameters of chemical analyses shall be in accordance with methods adopted in 40 C.F.R. 141.23, 141.24, 141.30, 141.40(n)(11), and 143.4(b) which is hereby incorporated by reference including any subsequent amendments and editions. A list of methods may be obtained from the Division of Laboratory Services.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Amended Eff. January 1, 1996;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0242 CHEMISTRY SAMPLE COLLECTION, HANDLING, AND PRESERVATION**

(a) A written sampling protocol with specific sampling instructions shall be available to sample collectors and available for inspection by the certification officer.

(b) The following handling and preservation requirements of samples shall apply:

(1) Rejection of samples. The laboratory shall reject any samples taken for compliance purposes that do not meet the criteria in Subparagraphs (b)(2) - (b)(5) of this Rule, and shall notify the system or individual requesting the analyses.

(2) Sample containers and preservation. The type of sample container and the required preservative for each inorganic contaminant shall meet the criteria adopted in 40 C.F.R. 141.23(k)(5), and 141.86(b)(2) which is hereby incorporated by reference including any subsequent amendments and editions. The type of sample container and required preservative for organic contaminants shall meet the criteria in the approved methods adopted in 40 C.F.R. 141.24, 141.30 and 141.40(n)(11) which is hereby incorporated by reference including any subsequent amendments and editions. A copy is available for inspection at the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915. Copies of 40 C.F.R. 141-143 may be obtained by contacting the EPA Drinking Water Hotline at 800-426-4791 at no charge.

(3) Maximum Holding Times. Samples shall be analyzed within the maximum holding times listed in 40 C.F.R. 123(k)(5) and 141.86(b)(2) and those listed in the methods adopted in 40 C.F.R. 141.24, 141.30 and 141.40(n) which is hereby incorporated by reference including any subsequent amendments and editions. A copy is available for inspection at the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915. Copies of 40 C.F.R. 141-143 may be obtained by contacting the EPA Drinking Water Hotline at 800-426-4791 at no charge.

(4) Sample collection and transport. The laboratory shall accept only those samples which have been collected, identified, and transferred to the laboratory in accordance with the rules of this Section and 15A NCAC 18C .1500.

(5) Sample report form. The sample report form shall contain the location; date; and time of collection; collector's name; preservative added; and any other special remarks concerning the

sample. Sample report forms shall be approved by the State Laboratory of Public Health. Indelible ink shall be used to complete the form.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Amended Eff. January 1, 1996;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0243 CHEMISTRY QUALITY ASSURANCE**

(a) Certified laboratories must meet the following general requirements for chemistry quality assurance (QA):
- (1) All quality control information shall be available for inspection by the certification officer.
- (2) A manual of analytical methods and the laboratory's QA plan shall be available to the analysts.
- (3) Class S weights or higher quality weights shall be available to make periodic checks on the accuracy of the balances. Checks shall be within range of the manufacturer's guidelines. A record of these checks shall be available for inspection. The specific checks and their frequency shall be as prescribed in the laboratory's QA plan or the laboratory's operations manual. These checks shall be performed at least once a month.
- (4) Color standards or their equivalent, such as built-in internal standards, shall be available to verify wavelength settings on spectrophotometers. These checks shall be within the manufacturer's tolerance limits. A record of the checks shall be available for inspection. The specific checks and their frequency shall be as prescribed in the laboratory's QA plan or the laboratory's operations manual. These checks shall be performed at least every six months.

(b) The laboratory shall analyze performance samples as follows:
- (1) US EPA approved performance evaluation samples shall be analyzed annually in the first calendar quarter for each analyte, and by each method, for which the laboratory is or wishes to be certified. Additionally, US EPA approved performance samples for nitrate and nitrite shall be analyzed annually in the first and third calendar quarters by each method for which the laboratory is or wishes to be certified. All results shall be within the EPA acceptable limits as established by the sample providers. For any result analyzed in the first quarter falling outside of the established limits, a make-up sample shall be analyzed for that analyte in the second quarter. For any result analyzed in the third quarter falling outside of the established limits, a make-up sample shall be analyzed for that analyte in the fourth quarter.
- (2) Double blind and blind samples shall be analyzed when submitted to a certified laboratory and results shall be within established control limits; these data shall be of equal weight to the EPA performance sample data and on site quality control sample data in determining the laboratory's certification status.
- (3) On-site quality control samples shall be analyzed when presented to the laboratory by the certification evaluator and results shall be within established control limits. These data shall be of equal weight to the EPA performance evaluation sample data and the double blind sample data in determining the laboratory's certification status.
- (4) A laboratory shall have correctly analyzed two out of the last three performance samples for each analyte for which it is certified. In the event that a laboratory is decertified for failing to correctly analyze two out of the last three performance samples, the laboratory shall correctly analyze two consecutive performance samples to have their certification reinstated. The performance samples shall be analyzed no less than 30 days apart. A laboratory with less than three performance samples shall have successfully analyzed a minimum of two performance samples before their certification status may be determined.
- (5) Unacceptable performance on any of the samples in Paragraph (b) of this Rule shall be corrected and explained in writing within 30 days and submitted to the certification evaluator.

(c) The minimum daily quality control (QC) for chemistry shall be as follows:
- (1) Inorganic Contaminants:
  - (A) Each laboratory analyzing samples for inorganic contaminants must prepare daily a standard curve composed of at least a reagent blank and three standards covering the sample concentration range. A standard curve is not required on each day of analysis for samples analyzed for Nitrate by manual cadmium reduction or for Cyanide. The standard

curve shall be verified each day by analyzing a calibration standard and a reagent blank. The calibration standard must be within ± 10 percent of its true value in order to use the standard curve. If it is not within 10 percent of the true value, a new standard curve shall be prepared.

(B) The laboratory shall analyze a QC sample (EPA QC sample or equivalent) at the beginning of the sample run, at the end of the sample run, and every 20 samples, with recoveries not to exceed ± 10 percent of the true concentration. The source of this QC sample shall be different from the source used for the calibration standards in Part (c)(1)(A) of this Rule.

(C) The laboratory shall run an additional standard or QC check at the laboratory's lowest detectable limit for the particular analyte. The laboratory shall not report a value lower than the lowest standard or QC check analyzed.

(D) The laboratory shall add a known spike to a minimum of 10 percent of the routine samples (except when the method specifies a different percentage, i.e. furnace methods) to determine if the entire analytical system is in control. The spike concentration shall not be less than the background concentration of the sample selected for spiking. The spike recoveries shall not exceed ± 10 percent of the true value.

(E) All compliance samples analyzed by graphite furnace shall be spiked to determine absence of matrix interferences with recoveries within ± 10 percent of the true value of the spike concentration.

(F) The laboratory shall run a duplicate sample every 10 samples with duplicate values within ± 10 percent of each other.

(G) Precision and accuracy data may be computed from the analyses of check samples of known value used in each analytical procedure. This data shall be available for inspection by the laboratory evaluator.

(2) Organic Contaminants:

(A) Quality control specified in the approved methods referenced in Rule .0241 of this Section shall be followed.

(B) Analysis for regulated volatile organic chemicals under 15A NCAC 18C .1515 shall only be conducted by laboratories that have received conditional approval by EPA or the Department according to 40 C.F.R. 141.24(g)(10) and (11) which is hereby incorporated by reference including any subsequent amendments and editions. A copy is available for inspection at the Department of Health and Human Services, Division of Public Health, 306 North Wilmington Street, Raleigh, North Carolina. Copies of 40 C.F.R. 141-143 may be obtained by contacting the EPA Drinking Water Hotline at 800-426-4791 at no charge.

(C) Analysis for unregulated volatile organic chemicals under 15A NCAC 18C .1516 shall only be conducted by laboratories approved under Part (c)(2)(B) of this Rule. In addition to the requirements of Part (c)(2)(B) of this Rule, each laboratory analyzing for EDB and DBCP shall achieve a method detection limit for EDB of 0.00001 mg/l and DBCP of 0.00002 mg/l, according to the procedures in Appendix B of 40 C.F.R. Part 136 which is hereby incorporated by reference including any subsequent amendments and editions. A copy may be obtained at no charge by contacting the Department of Health and Human Services, Division of Public Health, 306 North Wilmington Street, Raleigh, North Carolina.

(D) The laboratory shall achieve the method detection limits as listed in 40 CFR 141.24(f)(18) according to the procedures in Appendix B of 40 CFR Part 136 which is hereby incorporated by reference including any subsequent amendments and editions. A copy may be obtained at no charge by contacting the Department of Health and Human Services, Division of Public Health, 306 North Wilmington Street, Raleigh, North Carolina.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Amended Eff. August 1, 1996; January 1, 1996; October 1, 1994; April 1, 1993;*
*Temporary Amendment Eff. January 1, 2003;*
*Amended Eff. August 1, 2004;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0244 CHEMISTRY DATA**

Records of chemical analyses shall be kept by the laboratory in accordance with the EPA "Manual for Certification of Laboratories Analyzing Drinking Water", Chapter 4, Section 8, Records and Data Reporting, which is hereby incorporated by reference including any subsequent amendments and editions. A copy is available for inspection at the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915. Nonprofit organizations or government agencies may obtain a copy by contacting the EPA Drinking Water Hotline at 800-426-4791. Other organizations may obtain a copy from the National Technical Information Service at 800-336-4700 for thirty five dollars ($35.00).

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0245 CHEMISTRY ACTION RESPONSE**

All laboratory results exceeding maximum contaminant levels shall be reported to the Public Water Supply Section of the Division of Environmental Health within 48 hours. All other laboratory results shall be reported in accordance with the Public Water Supply rules in 15A NCAC 18C.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0246 MICROBIOLOGY FACILITIES**

Laboratory facilities shall be clean, temperature and humidity controlled, and have sufficient lighting at bench tops to perform the required procedures. The laboratory shall have provisions for disposal of microbiological waste.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0247 MICROBIOLOGY EQUIPMENT/SUPPLIES/ASSOCIATED QUALITY CONTROL**

(a) A laboratory seeking certification for microbiological analyses of water shall have available, or have access to, the items required for the total coliform and fecal coliform procedures as listed in the EPA "Manual for the Certification of Laboratories Analyzing Drinking Water", Chapter 5, Section 3, Laboratory Equipment and Supplies which is hereby incorporated by reference including any subsequent amendments and editions, except that Sections 3.2.2, 3.5.4 and 3.11.6 are not incorporated by reference. A copy is available for inspection at the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915. Nonprofit organizations or government agencies may obtain a copy by contacting the EPA Drinking Water Hotline at 800-426-4791. Other organizations may obtain a copy from the National Technical Information Service at 800-336-4700 for thirty five dollars ($35.00).
(b) In addition to the items and procedures incorporated by reference in Paragraph (a) of this Rule the laboratory shall have available the items and follow the procedures listed in this Paragraph:

(1) Balance. Calibrate the balance monthly using class S or S-1 reference weights. Check the balance with a minimum of three traceable weights which bracket the laboratory weighing needs.
(2) Autoclave. The autoclave shall be checked at least weekly with a maximum registering thermometer. Heat sensitive tape or spore strips or ampules may be used during each autoclave cycle and results recorded.
(3) Fecal Coliform Waterbath:
    (A) A temperature of 44.5C □ 0.2C shall be maintained.
    (B) A thermometer graduated in 0.1C increments shall be used to monitor temperature.

(C) The water level shall be sufficient to reach the upper level of media in tubes.
(D) On days used, record temperature at least twice per day with readings separated by at least four hours.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Amended Eff. January 1, 1996;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0248 MICROBIOLOGY GENERAL LABORATORY PRACTICES**

(a) The general laboratory practices for microbiological analyses shall be in accordance with those listed in the EPA "Manual for the Certification of Laboratories Analyzing Drinking Water", Chapter 5, Section 4, General Laboratory Practices, which is hereby incorporated by reference including any subsequent amendments and editions, except that Sections 4.6.2-4.6.11 are not incorporated by reference. A copy is available for inspection at the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915. Nonprofit organizations or government agencies may obtain a copy by contacting the EPA Drinking Water Hotline at 800-426-4791. Other organizations may obtain a copy from the National Technical Information Service at 800-336-4700 for thirty five dollars ($35.00).

(b) The laboratory shall follow the additional laboratory practices:

(1) Membrane Filter Media:

Use m-Endo broth or agar or LES Endo broth or agar in the single step or enrichment techniques. Ensure that ethanol used in rehydration procedure is not denatured. Prepare medium in a sterile flask and use a boiling water bath or, if constantly attended, a hot plate with a stir bar to bring medium to the boiling point. Do not boil medium. Final pH shall be 7.2 0.2.

(2) Multiple Tube Fermentation (MTF) Media:
(A) Use double strength lauryl sulfate broth or lactose broth in the presumptive test and single strength brilliant green lactose bile (BGLB) broth in the confirmed test. Autoclave media at 121°C for 12 minutes. Final pH shall be6.8 0.2 or 7.2 0.2 for BGLB broth.
(B) If MTF media are refrigerated after sterilization, incubate overnight at 35°C 0.5°C before use. Discard tubes showing growth or bubbles. Use MTF media prepared in tubes with loose fitting closures within one week. Store broth media in screw cap tubes or bottles no longer than three months, provided media are stored in the dark. Discard media if evaporation exceeds 10 percent of original volume.
(C) LES Endo agar shall be used for the completed test. Refrigerate medium and use within two weeks.

(3) Clark's Total Coliform Medium:
(A) Autoclave for 12 minutes at 121°C. Allow space between bottles.
(B) Final pH shall be 6.8 0.2.
(C) Store prepared medium in screw capped culture bottle no longer than three months; discard if evaporation exceeds 10 percent of original volume.

(4) EC Medium (for fecal coliforms):
(A) Autoclave for 12 minutes at 121°C.
(B) Examine tubes after sterilization to insure that inverted inner tubes are free of air bubbles and that the vials are at least partially covered with medium.
(C) Incubate refrigerated sterilized medium overnight at 35°C 0.5°C; discard tubes that show growth or bubbles.
(D) Store prepared medium in screw cap tubes.
(E) Final pH shall be 6.9 0.2.

(5) EC + MUG Medium (for detection of fecal coliforms-E. coli):
(A) Autoclave medium at 121°C (gas tubes shall not be used).
(B) Final pH shall be 6.9 0.2.
(C) Store prepared medium in screw cap tubes no longer than three months.

(6) MMO-MUG Test Medium (for Total Coliform and E. coli):
(A) The laboratory shall not prepare this medium from basic ingredients.

(B) Each lot purchased shall be tested for performance by inoculation with three control bacteria: Escherichia coli, a total coliform other than E. coli (e.g., Klebsiella pneumoniae) and a non-coliform (e.g. Pseudomonas aeruginosa).

These control organisms shall be stock cultures or commercially available discs impregnated with the organism. Incubate these controls at 35°C 0.5°C for 24 hours, and read and record result.

(C) Do not autoclave.

(7) Fecal Coliform Membrane Filter Medium (for enumeration of fecal coliform in source water) .

(A) Rehydrate medium in reagent water containing 10 ml of 1 percent rosolic acid in 2N NaOH. Bring it to the boiling point; do not autoclave.

(B) Autoclave for 12 minutes at 121°C.

(C) Final pH shall be 7.4 0.2.

(D) Refrigerate unused prepared medium; discard after 96 hours.

(8) Heterotrophic Plate Count (HPC) Medium:

(A) Autoclave HPC agar at 121°C for 15 minutes.

(B) Final pH shall be 7.0 0.2.

(C) Temper melted agar at 44°-46°C before pouring.

(D) Hold melted agar no longer than four hours. Do not melt sterile agar medium more than once.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Amended Eff. January 1, 1996; April 1, 1993;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0249 MICROBIOLOGY METHODOLOGY**

(a) Minimum equipment requirements and methodology for microbiological analyses shall be in accordance with the methods adopted in 40 CFR 141.21(f) which is hereby incorporated by reference including any subsequent amendments and editions, except that Nutrient Agar plus MUG in 40 CFR 141.21(f)(6)(11) is not incorporated by reference. A copy is available for inspection at the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915. Copies of 40 CFR 141-143 may be obtained by contacting the EPA Drinking Water Hotline at 800-426-4791 at no charge.

(b) For total coliform analysis the laboratory shall maintain certification for one or more of the approved methods as specified in this Paragraph:

(1) The Membrane Filter Procedure (MF) may be used for drinking water when the sample is free from interference (e.g. turbidity and particulates). A laboratory must be approved for a second analytical procedure when MF is used.

(2) The Multiple Tube Fermentation (MTF) procedure may be used for analyzing drinking water that contains particulates or other interfering substances and may be used as the back up or the sole approved method.

(3) The ONPG-MUG Test and the Colisure Test may be used for analyzing drinking water that contains particulates. These methods may be used as the back up or the sole approved method.

(c) A laboratory shall maintain certification for one of the approved methods for fecal coliform analysis.

(d) For all procedures in Paragraph (a) of this Rule the laboratory shall incubate inoculated culture within 30 minutes of inoculation.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Amended Eff. January 1, 1996;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0250 MICROBIOLOGY SAMPLE COLLECTION, HANDLING AND PRESERVATION**

(a) For sample collecting, handling, and preservation, there shall be strict adherence to correct sampling procedures, complete identification of the sample, and prompt transfer of the sample to the laboratory as described in "Standard

Methods for the Examination of Water and Wastewater", American Water Works Association, Part 9060, which is incorporated by reference including any subsequent amendments and editions. A copy is available for inspection at the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915. Copies may be obtained from the American Water Works Association, Customer Service, 6666 West Quincy Avenue, Denver, Colorado 80235 at the cost of one hundred twenty dollars ($120.00).
(b) Minimum sample frequency and sample location shall be that specified in 15A NCAC 18C .1534.
(c) The collector shall be trained in sampling procedures or written instructions shall be provided by the laboratory.
(d) The water shall be sampled after maintaining a steady flow for two or three minutes to clear service line. The tap shall be free of aerator, strainer, hose attachment, or water purification devices.
(e) The sample volume shall be a minimum of 100 ml. The sample bottle must be filled only to the shoulder to provide space for mixing.
(f) The sample report form shall be completed immediately after collection with location, date and time of collection, chlorine residual, collector's name, and remarks. The report shall be on a form provided by the North Carolina Public Water Supply Section.
(g) Date and time of sample arrival shall be added to the sample report form when the sample is received in the laboratory.
(h) Samples shall be received and analyzed within 30 hours of time of collection. Samples that are not analyzed within 30 hours must be rejected and a new sample must be collected.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Amended Eff. January 1, 1996; October 1, 1994;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0251 MICROBIOLOGY QUALITY ASSURANCE**
Requirements for quality assurance are as follows:

(1) A written quality assurance (QA) plan shall be available for review.
(2) Records on analytical quality control tests on media and equipment shall be prepared and retained for five years.
(3) A performance level of 75 percent shall be maintained for each method for which a laboratory is, or wishes to be certified. This 75 percent average shall be calculated from the 10 most recent performance sample data points from water performance studies, double blind, blind and on-site samples.
(4) The laboratory shall comply with all quality control requirements in Rules .0247 and .0248 of this Section.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Amended Eff. January 1, 1996;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0252 MICROBIOLOGY DATA**
(a) Where the laboratory has the responsibility for microbiological sample collections, the sample collector shall complete a sample report form immediately after each sample is taken. The information on the form includes sample identification number, sample collector's name, time and date of collection, arrival time and date in the laboratory and other information as required.
(b) Results of microbiological analyses shall be calculated and entered on the sample report form to be forwarded to the Public Water Supply Section of the Division of Environmental Health. A careful check shall be made to verify that each result was entered correctly from the bench sheet and initialed by the analyst.
(c) A copy of the microbiological sample report form shall be retained by the laboratory for five years. If results are entered into a computer storage system, a printout of the data shall be returned to the laboratory for verification with bench sheets.

*History Note:* *Authority G.S. 130A-315;*

*Eff. December 1, 1991;*
*Amended Eff. January 1, 1996;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0253 MICROBIOLOGY ACTION RESPONSE**

All laboratory results exceeding maximum contaminant levels shall be reported to the Public Water Supply Section of the Division of Environmental Health within 48 hours. All other laboratory results shall be reported in accordance with the Public Water Supply rules in 15A NCAC 18C.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0254 RADIOCHEMISTRY FACILITIES**

A laboratory seeking certification for performance of radiochemical analyses of public water supplies shall meet the following requirements:

(1) The counting instrument(s) required for measurement of those radionuclides described in 15A NCAC 18C .1500 shall be located in a separate room from rooms in which samples and standards are being prepared or other types of chemical analyses are being performed. The temperature of this room shall not exceed 27°C. Temperature variation under normal operating conditions shall not exceed 3°C.

(2) All instruments shall be properly grounded, and a regulated power supply, either external or internal, shall be available to each instrument.

(3) In areas where radioactive standards are being prepared, care shall be taken to minimize contamination of surfaces and personnel. Bench surfaces shall be an impervious material covered with absorbent paper, or trays (stainless steel, plastic, or fiberglass) lined with absorbent paper.

(4) Laboratory space shall be 200 square feet per person and shall contain no less than 6 linear feet of bench space per analyst and include the following:
    (a) sink with hot and cold running water;
    (b) electrical outlets (120 V a.c. grounded);
    (c) source of distilled or deionized water;
    (d) gas supply (natural gas or liquified petroleum); a propane cylinder with proper attachments may be permitted in laboratories doing limited amounts of analytical work;
    (e) vacuum line, pump, or aspirator; and
    (f) exhaust hood.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0255 RADIOCHEMISTRY EQUIPMENT**

(a) The only instruments required shall be those needed to perform the specific radiochemical analyses for which the laboratory is being certified. Those instruments shall meet the specifications as listed in the EPA "Manual for the Certification of Laboratories Analyzing Drinking Water", Chapter 6, Section 3, Laboratory Equipment and Supplies, which is hereby incorporated by reference including any subsequent amendments and editions. A copy is available for inspection at the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915. Nonprofit organizations or government agencies may obtain a copy by contacting the EPA Drinking Water Hotline at 800-426-4791. Other organizations may obtain a copy from the National Technical Information Service at 800-336-4700 for thirty five dollars ($35.00).
(b) In addition, the laboratory shall have the following instruments if they are required for the radiochemical analyses:

(1) Conductivity meter. Readable in ohms or mhos, with a range of 2 to 2.5 million ohms or equivalent mhos + 1 percent, and a sensitivity of 0.33 percent or better. Meter may be either line/bench or battery/portable.
(2) Fluorometer. Capable of detecting 0.0005 ug of uranium.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0256 RADIOCHEMISTRY GENERAL LABORATORY PRACTICES**

A laboratory seeking certification for performing radiochemical analyses shall meet the following requirements:

(1) Glassware preparations. All glassware shall be washed in a warm detergent solution and thoroughly rinsed in tap water. A distilled water rinse shall follow the tap water rinse. Additional cleaning procedures shall only by required if they are specified in an analytical method.
(2) Water quality. All water used in preparation of reagents, standards, and samples shall have resistance values greater than 0.5 megohms (less than 2.0 micromhos)/cm at 25□C.
(3) Chemicals and reagents. Analytical reagent grade (AR) chemicals shall be used for most analyses.
(4) Storage of radioactive standards and radioactive wastes. There shall be an enclosed and properly labeled area, either within the analytical laboratory or in a separate room, for the safe storage (in suitable containers) of standards, samples, and radioactive wastes.
(5) Standards and sample preparation. There shall be a designated area within the laboratory for preparation of radioactive standards and samples. Precautions shall be taken in this area to ensure against radioactive contamination. Provisions shall be made for safe storage and disposal of radioactive wastes and for monitoring of the work area.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
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**10A NCAC 42D .0257 RADIOCHEMISTRY METHODS**

Minimum requirements and methods for radiochemical analyses shall be made in accordance with methods adopted in 15A NCAC 18C .1522 and may be obtained from the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0258 RADIOCHEMISTRY SAMPLE COLLECTION/HANDLING/PRESERVATION**

(a) Minimum requirements of sample handling for radiochemical analyses including sample container, preservation, and major instrumentation shall meet the criteria in Table VI-I in the EPA "Manual for the Certification of Laboratories Analyzing Drinking Water", which is hereby incorporated by reference including any subsequent amendments and editions. A copy is available for inspection at the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915. Nonprofit organizations or government agencies may obtain a copy by contacting the EPA Drinking Water Hotline at 800-426-4791. Other organizations may obtain a copy from the National Technical Information Service at 800-336-4700 for thirty five dollars ($35.00).
(b) Samples shall be collected in containers provided by the laboratory.
(c) If composited samples are to be analyzed, the compositing shall be performed in the laboratory.
(d) Sample report form. The sample report form shall contain the location; date and time of collection; collector's name; preservative added; and any other special remarks concerning the sample. Sample report forms shall be approved by the N.C. Public Water Supply Section. Indelible ink shall be used to complete the form.

*History Note:* *Authority G.S. 130A-315;*

*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0259 RADIOCHEMISTRY QUALITY CONTROL**

Requirements for quality control of radiochemical analyses shall be as follows:

(1) Quality control data and records shall be available for inspection.

(2) The laboratory shall participate at least twice each year in those EPA laboratory intercomparison studies that include each of the analyses for which the laboratory is, or wants to be, certified. Analytical results shall be within control limits described in "Environmental Radioactivity Laboratory Intercomparison Studies" Program-FY-1977 (EPA-600/4-77-001), which is hereby incorporated by reference including any subsequent amendments and editions. A copy is available for inspection at the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915. A copy may be obtained by contacting the EPA Office of Research and Development at 513-569-7562 at no charge.

(3) The laboratory shall participate once each year in an appropriate unknown performance study administered by EPA. Analytical results shall be within control limits established by EPA for each analysis for which the laboratory is, or wants to be, certified.

(4) Operating manuals and calibration protocols for counting instruments shall be available to analysts and technicians.

(5) Calibration data and maintenance records on all radiation instruments and analytical balances shall be maintained in a permanent record.

(6) The following specifications shall be included in minimum daily quality control:

(a) To verify internal laboratory precision for a specific analysis, a minimum of 10 percent duplicate analyses shall be performed. The difference between duplicate measurements shall be less than two times the standard deviation of the specific analysis as described in EPA-600/4-77-001. If the difference exceeds two standard deviations, calculations and procedures shall be examined, and samples shall be reanalyzed.

(b) When 20 or more specific analyses are performed each day, a performance standard and a background sample shall be measured with each 20 samples. If less than 20 specific analyses are performed in any one day, a performance standard and a background sample shall be measured along with the samples.

(c) Quality control performance charts, or performance records, shall be available for inspection.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

**10A NCAC 42D .0260 RADIOCHEMISTRY DATA**

Records and data reporting shall be maintained in accordance with the EPA "Manual for the Certification of Laboratories Analyzing Drinking Water", Chapter 6, Section 8.2-8.3.6, which is hereby incorporated by reference including any subsequent amendments and editions. A copy is available for inspection at the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915. Nonprofit organizations or government agencies may obtain a copy by contacting the EPA Drinking Water Hotline at 800-426-4791. Other organizations may obtain a copy from the National Technical Information Service at 800-336-4700 for thirty five dollars ($35.00).

*History Note:* *Authority G.S. 130A-315;*
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**10A NCAC 42D .0261 RADIOCHEMISTRY ACTION RESPONSE**

All laboratory results exceeding maximum contaminant levels shall be reported to the Public Water Supply Section of the Division of Environmental Health within 48 hours. All other laboratory results shall be reported in accordance with the Public Water Supply rules in 15A NCAC 18C.

*History Note:* *Authority G.S. 130A-315;*
*Eff. December 1, 1991;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*