Fiscal Analysis

Rule Citation Number: 15A NCAC 02H .0801, 15A NCAC 02H .0802, 15A NCAC 02H .0803, 15A NCAC 02H .0804, 15A NCAC 02H .0805, 15A NCAC 02H .0806, 15A NCAC 02H .0807, 15A NCAC 02H .0808, 15A NCAC 02H .0809 and 15A NCAC 02H .0810

Rule Topic: Revision of Rules 15A NCAC 02H .0801 to .0810 – Laboratory Certification

DEQ Division: Division of Water Resources (DWR)

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Impact Summary:

State government:	Yes
Local government:	Yes
Private entities:	Yes
Federal government:	No
Substantial Impact:	No

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

Necessity: N.C. Gen. Stat. §150B-21.3A requires state agencies to review existing rules every 10 years, determine which rules are still necessary, and either re-adopt or repeal each rule as appropriate. The proposed rulemaking satisfies these requirements for a portion of the Department's rules.

Laboratory Certification fees were last increased in 2002. Since that time, operating costs have grown due to inflation, an increase in the number of Certified laboratories and ever changing regulatory and analytical method requirements. These costs and added time requirements from the increase in laboratories, coupled with the loss of three auditor positions, has caused the Laboratory Certification Branch to struggle to maintain adequate inspection cycles and provide technical services to the laboratories and other stakeholders. Because the program is almost fully fee-funded (one position is funded by water quality permitting receipts), a fee increase will be required to maintain even our current level of services and staffing. It is the intent of the program that the fee increase will allow us to regain one of the lost auditor positions and provide a higher level of service than currently provided to, and which is desired by, the certified laboratory community, other outside stakeholders and our internal clients. The Division views a fee increase as the best-available option to meet those needs.

1. Summary

The Division of Water Resources ("Division") reviewed its Wastewater/Groundwater Laboratory Certification rules in accordance with G.S. §150B-21.3A and proposes to re-adopt all the rules.

The Division identified necessary technical changes in some rules, including:

- Correction of agency names;
- Revision and addition of definitions of terms used throughout the rules for clarity;
- Capitalization of terms defined within the rules;
- Minor clarifications; and
- Modification or removal of provisions superseded by statutes.

The Division anticipates that these technical changes are not going to have major impact on the rules.

In addition, the proposed rules would result in:

- Modifying the fee schedule. The program is fee-funded, and the proposed amendments to fee structure are required to ensure that fees generated by the program are sufficient to operate and support the compliance efforts of the Division of Water Resources and the Division of Waste Management;
- Appending the list of certifiable parameters. This will aid the compliance efforts of the Divisions of Water Resources and Waste Management;
- Codifying policies or providing additional quality control requirements where a rule does not exist. This will aid laboratories' efforts to produce court-defensible data, and it will help level the playing field for all laboratories by establishing baseline quality assurance (QA) requirements from a multitude of EPA-approved methodologies; and
- Requiring all laboratories to meet the same data quality standards. This will bring Field Laboratory QA requirements to the same level as Municipal, Industrial, Commercial and Other Laboratories.

Economic impacts are anticipated to occur because of necessary adjustments on its current fees and for a few changes to QA requirements. The total revenue from lab certification fees that the Division expects to have for the fiscal year that this rule will take effect is approximately $773,900. The net revenue as a result of the proposed fee increase is approximately $92,350.

The increased fee collections will allow the Laboratory Certification Branch to recreate 1 lost position. Current staffing level includes 8 positions plus 1 administrative position funded by Laboratory Certification fees who reports to the Water Sciences Section Chief. The current audit cycle is approximately 6 to 7 years. An optimal audit cycle would be 3 to 4 years to ensure laboratories are current with changes in federal regulations, state regulations, technology, methodology, etc. A 3-year audit cycle is federally mandated for drinking water laboratories.

The additional net revenue for collected fees ($92,350) would be sufficient to add 1 new position while accommodating future operating and growth and would help to decrease the audit cycle to 3 to 4 years. Currently, each auditor manages approximately 140 laboratories. Adding an additional auditor position would reduce the burden by at least 20 laboratories per person,

affording each auditor more time which they can use to increase the number of on-site inspections each year. This would also allow other auditors more time to provide technical assistance and other services to their assigned laboratories and other stakeholders.

The estimated *quantifiable* impacts to regulated persons (~700 laboratories) on the whole is conservatively estimated to be between net costs of $14,022 to net benefits of $98,923 in each year. Approximately half of these regulated laboratories are municipal-owned laboratories; as such, some of the economic impact will be to municipal government entities. However, several expected costs and benefits could not be quantified. The most likely outcome is that the regulated persons (laboratories) will realize a positive economic benefit even with the modest fee increase. This is because the lower range of benefits estimated in this analysis is very conservative, and the unquantifiable costs are not expected to be substantial.

The Division anticipates indirect environmental benefits will be observed as a result of these proposed rule changes, while no negative environmental impact is anticipated.

2. Background

The North Carolina Wastewater/Groundwater Laboratory Certification (NC WW/GW LC) program is a Branch of the Water Sciences Section and is a vital component in the process to ensure the quality of analytical data used for regulatory purposes by a diversity of programs within the Department of Environmental Quality (DEQ). Various Divisions within DEQ rely on the services of the Laboratory Certification Branch to support a multitude of scientific, regulatory and administrative decisions. The purpose of Certification is to determine that a laboratory has the necessary technical competence, facilities and equipment to perform the required laboratory analytical procedures. Key elements of this certification include:

- use of approved methodology and associated quality control by competent laboratory personnel;
- use of adequate facilities and equipment;
- continuing acceptable performance on proficiency testing samples; and
- periodic on-site evaluation of laboratory operations.

Efforts to improve the quality of monitoring data rank among the most important functions of the Laboratory Certification Branch staff. In addition to Certification, staff also provide technical support and training to environmental laboratory personnel to assist in improvement of laboratory operations, quality systems and understanding of the framework of regulatory requirements which govern laboratory operations. The program prides itself on helping clients identify areas where they can leverage efficiencies and implement cost reduction strategies while maintaining operational excellence.

The program has grown significantly since its inception and currently certifies more than 700 laboratories in 25 states under the following categories:

- Municipal Laboratory;
- Industrial Laboratory;
- Commercial Laboratory;
- Other Laboratory;

- Field Laboratory; and
- Field Commercial Laboratory.

Laboratories (both in-state and out-of-state) performing physical, chemical and microbiological testing for compliance monitoring under many of DEQ's covered programs are required to be certified pursuant to Rule 15A NCAC 2H .0800. The program offers accreditations designed to accommodate the needs of many DEQ programs operating under the federal regulatory umbrella including testing under the Clean Water Act and the Resource Conservation and Recovery Act. Two levels of accreditation are offered to Commercial, Municipal, Industrial and Other Laboratories. These include certification of Field Laboratories (i.e., those analyzing the following Field Parameters: Total Residual Chlorine, Conductivity, pH, Temperature, Dissolved Oxygen, Settleable Residue) and certification of Non-Field Laboratories (i.e., those analyzing both Field and Non-Field Parameters).

The Laboratory Certification Branch operates pursuant to authority contained in North Carolina General Statute 143-215.3(a)(1) and 143-215.3(a)(10). Rule 15A NCAC 2H .0800 sets the scope of the available parameters of accreditation, provides procedures for laboratories applying for certification, details the appropriate methods, references quality assurance procedures for evaluating laboratory competence, and outlines the fee schedules for the two levels of accreditation.

Laboratories may be certified for multiple methods and technologies for each available parameter. This allows a laboratory some flexibility in choosing the analyses and technologies/methods for which they wish to be accredited, thereby limiting their accreditation costs. The fees charged to laboratories participating in the North Carolina program are considerably lower than similar programs in other states, including those participating in the National Environmental Laboratory Association Program (NELAP). The accreditation period is for one year, running from January 1 of the current year to December 31 of the same year.

The Laboratory Certification Program is almost entirely supported by program revenue generated through annual accreditation. These fees provide funding for salary and operating cost to administer the program as required by G.S. 143-215.3(a) (10). All laboratories are billed in July for the upcoming certification period. The billing cycle was changed in 2013 to adjust our fees receipts to the state fiscal year cycle.

Each year, laboratories are required to pass the necessary performance evaluation and pay the appropriate annual fee prior to Certification renewal. Laboratories which do not meet the criteria for renewal are contacted by program staff, and a resolution is usually quickly achieved.

The annual cost for administering the program varies from year to year based on the number of laboratories certified and the scope of their accreditation, the number of compliance/enforcement audits, follow-up or remedial inspections, and the number of technical assistance visits. Staff vacancies and the variability of personnel fringe costs also influence the cost.

G.S. §150B-21.3A requires the Department to evaluate each of its existing rules and make an initial determination as to whether the rules are:

1. Necessary with substantive public interest – the agency has received public comment on the rule within the past two years or the rule affects the property interest of the regulated public, and the agency knows or suspects that any person may object to the rule.

2. Necessary without substantive public interest – the agency determines that the rule is needed, and the rule has not had public comment in the last two years. This category includes rules that identify information that is readily available to the public, such as an address or telephone number.
3. Unnecessary – the agency determines that the rule is obsolete, redundant or otherwise not needed.

The Department must then determine which rules are still necessary and propose to re-adopt, with or without modifications, or to repeal each rule as appropriate. The Division categorized all the subject rules as 'Necessary with substantive public interest'. The Rules Review Commission reviewed and approved these determinations, as did the General Assembly's Joint Legislative of Administrative Procedure Oversight Committee (JLAPO), and the Review Process was completed in December 2014.

The Division prepared draft rules and solicited input on the proposed actions from stakeholders during outreach meetings on April 7, 2015 and April 19, 2017. In addition to the two stakeholder meetings hosted by the Division, the Laboratory Certification Branch held stakeholder meetings at three locations across the state and gave presentations on the proposed changes at various laboratory analyst association meetings and conferences. The meetings gave stakeholders the opportunity to review the Division's draft rules and submit comments on the proposed rules. The draft rules were posted on the Division's webpage and on the Laboratory Certification webpage at least 30 days prior to the meetings. The draft rules were also mailed or emailed to every laboratory certified pursuant to the rules. Stakeholders voiced and submitted comments to the Division during or after the meetings.

3. Rule Analysis

The following table and text briefly describe the proposed rule changes and summarize the anticipated economic and environmental impact of each.

For the purpose of this fiscal analysis, the following items are considered to comprise the baseline for this rulemaking package:

- The current version of 15A NCAC 2H .0800 rules;
- Current NC general statute and session law;
- Director's Approval Letters issued between 2001 and 2012 which approved the addition of multiple parameters to the Laboratory Section Wastewater/Groundwater Certification Program under authority granted G.S. 215.3(a)(10), which requires the Department to establish an accreditation program for environmental laboratories and to establish fees for certification program support, and 15A NCAC 02H .0805(a)(1) which authorizes the Division Director to approve analytical procedures.

Table 1: Subchapter 02H – Wastewater/Groundwater Laboratory Certification Impact Summary

Rule	Proposed Change	Source of Change	Economic Impact	Environment Impact
15A NCAC 02H .0801 Purpose	Repeal	Staff Review and RRC Input	None	None
15A NCAC 02H .0802 Scope	Repeal	Staff Review and RRC Input	None	None
15A NCAC 02H .0803 Definitions	Added definitions and revised definitions for clarity and improved legal defensibility.	Staff Review, Legal Counsel and Stakeholder Input	Positive and/or Negative	Positive
15A NCAC 02H .0804 Parameters	Added parameters, most of which are currently approved by Director's letter. Made editorial changes and added language clarification.	Staff Review and Stakeholder Input	Positive and/or Negative	None
15A NCAC 02H .0805 Certification and Renewal	Made editorial changes. Added new Requirements and codified policies. Included less stringent language to give laboratories more flexibility.	Staff Review and Stakeholder Input	Positive and/or Negative	Positive
15A NCAC 02H .0806 Fess Associated with Certification Program	Increased annual fees and added new requirement to cover administrative fees for processing Parameter additions. Clarification of language.	Staff Review and Stakeholder Input	Positive and/or Negative	Positive
15A NCAC 02H .0807 Decertification and Civil Penalties	Editorial and technical corrections. Provided clarification and removed language to reduce or eliminate burden to the laboratories.	Staff Review and Stakeholder Input	Positive	Positive
15A NCAC 02H .0808 Recertification	Added language and clarification. Reduced the decertification period for unacceptable PT results.	Staff Review and Stakeholder Input	Positive	Positive
15A NCAC 02H .0809 Reciprocity	Grammatical correction and added language. New requirement added for tracking purposes.	Staff Review and Stakeholder Input	Positive	Positive
15A NCAC 02H .0810 Administration	Repeal	Staff Review and RRC Input	None	None

3.1 Proposed Rules with Economic and/or Environmental Impact

The following section provides details on the positive (beneficial) and negative (detrimental) economic and environmental impacts of each rule.

15A NCAC 2H .0803 (3) and 15A NCAC 2H .0805 (a) (1) (F)

The proposed rule defines Approved Procedure as "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*." The Laboratory Certification Branch provides Approved Procedures for the current Field Parameters and will continue this practice with the newly defined Field Parameters. This has saved Field Laboratories the cost of purchasing the

methods or method compendiums. There is also potential for future savings in that the purchased methods are eventually replaced with newer revisions by periodic changes in federal regulation. When such changes are made, the laboratories would have to obtain the approved version of the method or method compendium. An estimation of the potential positive fiscal impact is provided in Table 2.

Table 2. Potential Field Laboratory Savings from Providing Approved Methods

Standard Methods Costs	Impact[1]
SM online subscription – 1 seat/year = $346	461*$346 = **$159,506**
On line cost per method[2] = $75	461*$150 = **$69,150**[3]
Book = $395	461*$395 = **$182,095**

[1]At the time of writing, there are 461 Field Laboratories in the program. The amount is this column represents gross potential savings of Field Laboratories resulting from this proposed rule.
[2]The accompanying Quality Control chapters would also need to be purchased as a separate method.
[3]The total in this cell is based on a minimum of one method plus the associated Quality Control chapter. Most Field Laboratories would require more than 1 method; up to as many as 15 methods, based on the proposed rule.

15A NCAC 2H .0803 (13)

The proposed rule revises the definition of Field Parameter(s) to include the following additional parameters: Free Available Chlorine, Salinity, Sulfite, Turbidity, and Vector Attraction Reduction Options 5, 6 and 12. Table 3 illustrates the number of laboratories that are currently Certified for each of these parameters. The table does not include Salinity and Free Available Chlorine, which were included as Field Parameters under the Division Director's authority in 2007 and 2012; respectively, and would therefore have no impact since this authority has the force of rule as permitted in 15A NCAC 2H .0805(a)(1).

Table 3. Laboratories Certified for the Proposed Field Parameters

Parameter	Current # of Municipal & Industrial Laboratories	Current # of Commercial Laboratories
Turbidity	47	42
Sulfite	0	4
VAR Option 5	5	0
VAR Option 6	14	1
VAR Option 12	3	0

The proposed rule has the potential for both positive and negative economic impact to laboratories.

The impact to current Field Laboratories would be that they would then have the option to perform these analyses themselves and save the cost of having to subcontract the analyses to a Commercial Laboratory.

The impact to current Field Commercial Laboratories would be an opportunity to increase the number of parameters they could analyze and thereby increase services to existing clients and/or gain new clients.

There would be no impact to current Municipal and Industrial Laboratories since they are all Certified for additional Non-Field Parameters that preclude them undergoing a laboratory status change.

The impact to current Commercial Laboratories would be the potential loss of revenue created by having current Field Laboratories begin to analyze these parameters themselves.

15A NCAC 2H .0803 (18) and 15A NCAC 2H .0805 (a) (5)

The proposed rule defines Mobile Laboratory as "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. All Mobile Laboratories will be considered separate laboratories and will require separate Certification. The current rule did not define Mobile Laboratories.

There are only two companies that operate as Mobile Laboratories currently certified by our program. We don't believe there will be any economic impact to these laboratories according to their current operation practices, but could potentially have a negative economic impact if they choose to deploy more than one mobile unit.

15A NCAC 2H .0803 (23) and 15A NCAC 2H .0807 (b)

The proposed rule defines Parameter Method as "a type of analytical technique, including materials and tools, used to measure a parameter which is different from other analytical methods used to measure the same parameter." By changing this definition, laboratories that are decertified for Unacceptable PT Sample results will not necessarily lose certification for the parameter; as a whole, under the proposed rule. The decertification will only impact the associated Parameter Method. This will have a potential positive economic impact to laboratories that are certified by more than one Parameter Method in that they can continue to report data for the parameter by another certified method without incurring the costs to contract or subcontract analyses during the decertification period.

15A NCAC 2H .0803 (34)

The proposed rule defines "Unacceptable Proficiency Testing Results" as "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." This change is for clarification purposes

only. It will not require a lab to revise its existing procedures; as such, no economic impact is anticipated.

15A NCAC 2H .0804 (b) (20)

Laboratories are currently certified for Flash Point under the Ignitability parameter. The proposed rule makes a technical correction by separating Flash Point from the Ignitability parameter since Flash Point is an entirely different method-defined parameter. This may potentially impact some laboratories that elect to maintain Certification for both parameters since they will be charged separately; however, this will only affect laboratories that already must pay greater than the annual base fee. At the time of writing, this may potentially negatively impact 9 laboratories at an additional cost of $85 per year. This could result in a maximum aggregate potential cost of $765.

15A NCAC 2H .0804 (b) (49 through 57)

The current rule offers Certification for *Vector Attraction Reduction – All Options*. The proposed rule lists each Option individually and excludes Options 9, 10 and 11. This leaves a total of 9 Options. This change may potentially negatively impact 11 laboratories that are above the minimum annual fee and who might elect to maintain Certification of multiple options since they will be charged separately at an additional cost of $85 per parameter per year. This could result in a maximum potential cost per laboratory of $765 if all 9 Options are requested, with a maximum aggregate potential cost to all laboratories of $8,415. It is anticipated that the cost will be less since currently, no laboratory is certified for more than 4 Options.

15A NCAC 2H .0804 (b) (38)

The proposed rule strikes *Leachate Procedures* as a Certifiable Parameter since the rule does not include separate Certification for any other preparation procedure. The table below outlines the net fiscal savings for the laboratories currently certified for the Leachate Procedures parameter per year.

Table 4. Impact of Removing Leachate Procedures

Number of Applicable Parameters	Number of Laboratories Certified	Cost Per Laboratory	Net Fiscal Savings
1	6	$85	$510
2	19	$85 *2 = $170	$3230
3	1	$85 *3 = $255	$255
4	21	$85 *4 = $340	$7140
		Grand Total Net Savings	**$11,135**

15A NCAC 2H .0804 (c) (14)

The proposed rule includes the addition of Total Hardness under the Metals subsection (this is in addition to Total Hardness in the Inorganics subsection of the current rule). This change was needed for clarity to better characterize the more complex method of derivation. This may negatively impact laboratories that elect to maintain or add this parameter to their scope; however, this will only affect laboratories that are already above the minimum annual fee. There are currently 14 laboratories certified for Total Hardness methods that would be included in both the Inorganic and Metals subsections under the proposed rule, all of which were already above the minimum annual fee. The maximum net potential impact that this change may incur is $120 per year to applicable laboratories. This could result in a maximum aggregate potential cost of $1,680.

Table 5. Impact of Adding Total Hardness to the Metals Subsection

Current Rule	Proposed Rule	Net Fiscal Impact per Laboratory
Total Hardness - All Methods $50	Total Hardness - Metals Methods: $85 Total Hardness - Inorganic Methods: $85	$120

15A NCAC 2H .0804 (d) (1)

The proposed rule includes the addition of 1,2-Dibromo-3-chloro-propane (DBCP) and 1,2,3-Trichloropropane (TCP) to the 1,2-Dibromoethane (EDB) parameter to clarify the parameter covers certification for the additional constituents found in the 1,2-Dibromoethane (EDB) reference methods. This rule change will not require a lab to revise its existing procedures; as such, no economic impact is anticipated.

15A NCAC 2H .0804 (d) (2-3)

The proposed rule separates the parameter (Acrolein, Acrylonitrile, Acetonitrile) into two parameters (Acetonitrile and Acrolein, Acrylonitrile) to reflect current approved reference methods target analyte lists. Currently, there are no laboratories certified for this parameter. Laboratories generally elect to obtain certification for a single Gas Chromatography/Mass Spectrometry (GC/MS) parameter for analysis of these compounds rather than the two individual Gas Chromatography (GC) methods. If a lab elected to obtain certification for both parameters in the proposed rule, the cost differential to the lab would be $85. The number of labs that may choose to obtain certification for both parameters is unknown; as such the potential cost could not be quantified.

15A NCAC 2H .0804 (d) (10)

The proposed rule adds the Explosives parameter to support anticipated regulatory monitoring requirements. The impact is $85 to a lab that elects to add this parameter to the scope of their certification if they are already over the minimum annual fee. There are currently 52 laboratories

that are certified for organic parameters. The number of labs that may choose to obtain certification for the Explosives parameter is unknown; as such the potential cost could not be quantified.

15A NCAC 2H .0805 (a) (2) (A)

The proposed rule clarifies current requirements for maintaining all analytical data pertinent to each certified analysis, which must be filed in an orderly manner so as to be readily available for inspection upon request as it pertains to PT Samples by requiring laboratories to send a corrective action report to the State Laboratory that details the root cause of the [proficiency testing] failure and the corrective action(s) taken to prevent recurrence. This requirement was previously required through 15A NCAC 2H .0805 (a) (7) (A) and enforced per 15A NCAC 2H .0807 (a) (13) and is intended to provide evidence that the laboratory analysis is in control or to provide information so the Laboratory Certification Branch can offer technical assistance with troubleshooting analytical uncertainties. This rule change will not require a lab to revise its existing procedures; as such, no economic impact is anticipated.

15A NCAC 2H .0805 (a) (3) (C)

The current rule states that a supervisor must visit the laboratory each day of normal operations. To afford more flexibility, the proposed rule states that the supervisor must only contact (not visit) the laboratory each day, which potentially saves time and travel costs. In addition, the length of time that a substitute supervisor can remain in charge in the named supervisor's absence has been increased in the proposed rule from 6 to 12 weeks to align with the Family and Medical Leave Act (FMLA). This will potentially have a positive impact on some laboratories by saving them the replacement staffing costs for up to 6 additional weeks. In summary, benefits would be observed from savings associated with salaries and travel costs.

15A NCAC 2H .0805 (a) (5)

The proposed rule no longer requires applications to be submitted in duplicate. This is a potential positive impact for the laboratories and on the environment in terms of paper cost savings and reduced paper waste.

15A NCAC 2H .0805 (a) (6)

The proposed rule removes many prescriptive requirements on facility specifications such as minimum laboratory size and bench space. This allows greater flexibility for laboratories that do not need all the items to effectively analyze and report the parameters in the scope of their accreditation. This could potentially save laboratories money in facility and upkeep costs. We do not believe that these savings would be offset by the new requirement for properly maintaining facilities, supplies and equipment since this is paramount to meeting the quality control benchmarks in the approved reference methods or regulations. The net fiscal impact for laboratories is expected to be positive since they will be able to pare down the facilities, supplies and equipment needed to perform the analyses under the scope of their accreditation.

15A NCAC 2H .0805 (a) (7) (A)

The proposed rule adds the requirement to establish acceptance criteria for all Quality Control analyses. This was added to ensure that laboratories develop quality control practices where none

are prescribed by method or rule. 40 CFR Part 136 requires this, but not all the programs under the scope of the rule falls under these federal Clean Water Act requirements. In addition, the proposed rule provides consistency across all regulatory programs and helps to ensure data produced by laboratories can withstand scientific and legal scrutiny. This may potentially impact some laboratories due to minimal increases to staff time and materials needed to add additional quality control elements; however, most methods have quality control requirements already prescribed so we expect the negative economic impact to be negligible while the positive environmental impact could be significant for methodologies that do not have prescribed quality control procedures. On the environmental side, better-defined Quality Control measures will aid the data receiving agencies within state government by providing increased confidence in data used for regulatory decision-making. In consequence, the effectiveness of these actions helps protect human health and ecological life.

15A NCAC 2H .0805 (a) (7) (F)

The proposed rule changes the word *printed* benchsheets to *printable* benchsheets. This affords laboratories more flexibility in electronic reporting and potentially reduces paper costs. Reduced paper waste is also a positive impact on the environment.

15A NCAC 2H .0805 (a) (7) (G)

The analysis frequency of a standard for residue parameters (excluding Settleable Residue) was increased from quarterly to monthly in the proposed rule. This is anticipated to have a minimal negative economic impact on laboratories in staff time. Laboratories may make a standard in-house from ashless cellulose powder. We could not find this product in quantities less than 500 mg. The average cost for 500 mg is $75.00. If a lab makes a 100 mg/L TSS standard, they would go from using 400 mg per year to 1200 mg (1.2 g) per year. Multiplying this by 3 to include the other residue parameters would total 3.6 g per year. At either the monthly or quarterly rate, the lab would need to replace the bottle due to the expiration date before all the product is used. The rule revision would only result in negligible cost in terms of staff time.

15A NCAC 2H .0805 (a) (7) (I)

The proposed rule stipulates that incubators, ovens, waterbaths, refrigerators or other temperature-controlled devices in use must only be checked *during normal business operations*. This change alleviates the burden of staffing on weekends which may potentially have a positive economic impact on laboratories in terms of human resources savings.

15A NCAC 2H .0805 (a) (7) (N)

A less frequent calibration requirement for limited use reference thermometers was added to the proposed rule to reduce the burden to laboratories. This would potentially save laboratories money since this service is contracted to other entities. Added more frequent verification requirement for digital, incubator and infrared thermometers because electronic and infrared thermometers do not hold their calibration as long as liquid-in-glass thermometers and incubators require a strict operating temperature tolerance to produce reliable and accurate data. The requirement is expected to have minimal negative economic impact on laboratories since these verifications can be performed in-house and would only result in negligible cost in terms of staff time.

15A NCAC 2H .0805 (a) (7) (P)

The proposed rule includes a requirement for a documented training program for each laboratory. The purpose is to ensure accurate and legally-defensible data, which potentially has a positive impact on the environment. This requirement is expected to have minimal negative economic impact on laboratories since it is requiring only that laboratories formally document staff training that is most likely already taking place.

15A NCAC 2H .0805 (c) (7) and 15A NCAC 2H .0807 (a) (11)

The phrase *written amendment* was changed to *written notice* so as not to imply laboratories must complete an amendment form for notification of changes in location, ownership, address, name or telephone number. This proposed change reduces paper waste which could save laboratories money.

15A NCAC 2H .0805 (g) (4)

The proposed rule requires Field Laboratories to develop and use Standard Operating Procedures (SOPs) consistent with Non-Field Laboratory requirements. This requirement will have a negative economic impact in the form of personnel time costs on Field Laboratories. This cost will mainly be an initial one-time cost, and the Laboratory Certification Branch intends to develop template SOPs for Field Parameters that will minimize the time and resources needed to write SOPs. SOP template development will take approximately 3 hours for each SOP. A total of 13 Field parameter SOPs will be developed at an approximate cost of $1,067, based on an average hourly Certification staff salary of $27.36. This should have a positive impact on the environment as it helps ensure accurate and legally-defensible data.

15A NCAC 2H .0805 (g) (11)

The proposed rule reduces regulatory burden by increasing flexibility in meeting Supervisory requirements for Field Laboratories. The rule allows for an equivalent combination of education and work experience and possession of a Physical/Chemical Operator's license in addition to the Biological Operator's license.

15A NCAC 2H .0806

See Table 7 below, in Methodology and Assumptions for the proposed changes to the fee schedule.

15A NCAC 2H .0807 (a) (7)

The proposed rule removes the requirement that laboratories must notify the State Laboratory of equipment changes. This will reduce regulatory burden on laboratories.

15A NCAC 2H .0808 (b)

The proposed rule reduces the decertification period for unacceptable PT results from 60 to 30 days. This will potentially have a positive economic impact on laboratories by reducing the amount of time they would have to subcontract or contract analyses during the decertification period. Using the North Carolina Division of Water Resources Water Sciences Section cost-per-analysis fee schedule which was derived by averaging the fees charged by a pool of certified commercial

environmental laboratories, examples of the range of potential net savings for laboratories are depicted below.

- A Municipal, Industrial or Field Laboratory analyzing pH 5 days a week may potentially save at least $197.40 [$6.58 * fee per pH analysis x 30 days] for a single parameter decertification by reducing the decertification period to 30 days. The fee schedule used to derive these figures did not consider the additional savings to these labs by avoiding fees commercial labs charge to perform this analysis on-site. This analysis must be performed within 15 minutes of collection.

- A Commercial Laboratory, assuming an average 1 soil semivolatile organics analysis per day, may potentially save $22,611.60 [$753.72 fee per SVOA extraction and analysis x 30 days] for a single parameter decertification by reducing the decertification period to 30 days.

Between 2015 and 2017, laboratories were decertified for 27 parameters per year on average. If none of the 27 parameters were SVOA extractions, the potential cost savings to laboratories would be approximately $5,330 in total [27 parameters * $197.40 savings for shorter decertification period]. The potential cost savings would be considerably higher if some of the affected parameters were SVOA extractions.

15A NCAC 2H .0808 (c)

Table 6 represents examples of possible net savings to a laboratory resulting from the proposed rule 15A NCAC 2H .0808 (c). The parameters chosen represent the lowest to highest possible net savings to a laboratory based on one approved vendor's current proficiency testing sample pricing. The current rule requires that when a laboratory is Decertified for a Parameter Method for obtaining Unacceptable Results on two consecutive Proficiency Testing (PT) Samples, the laboratory must obtain acceptable results on two consecutive PT samples to meet Recertification requirements. The laboratory must also pay a $200 Recertification fee. The proposed rule requires, "After two years, a Parameter Method Recertification will be treated as an initial Certification in accordance with Rule .0805 of this Section." This means that after two years, only one PT and an $85 additional parameter fee is required to add the Parameter Method back to the laboratory's Certified Parameter Listing (observed data shows that; on average, we have 11 laboratories applying for this administrative procedure for inorganic parameters, 6 for metals parameters and 1 for organic parameters per year). Total annual savings are estimated at $3,573.

Table 6. 15A NCAC 2H .0808 (c) Economic Benefit Examples

Current rule – no cap	Proposed rule – 2-year cap	Impact differential
Inorganic – Ammonia Nitrogen		
2 PTs required ($66 each)[1]	1 PT required ($66)	$66
$200 recertification fee	$85 additional parameter fee	$115
	Net savings to the laboratory	**$181**

Metals – Aluminum		
2 PTs required ($93 each)[1]	1 PT required ($93)	$93
$200 recertification fee	$85 additional parameter fee	$115
	Net savings to the laboratory	**$208**
Organic – Diesel Range Organics		
2 PTs required ($219 each)[1]	1 PT required ($219)	$219
$200 recertification fee	$85 additional parameter fee	$115
	Net savings to the laboratory	**$334**

[1] Based on 2017 pricing from Environmental Resource Associates (ERA), Inc. ERA is an approved commercial PT vendor used by many of our certified laboratories.

A laboratory may elect to obtain recertification in less than 2 years by meeting the requirements in .0808 (a) and (b). If the laboratory has clients for the decertified parameter, the laboratory is likely to regain certification as soon as the decertification period has expired to retain those clients. If a laboratory does not have clients for the decertified parameter, the laboratory may regain certification quickly so that they may use their scope of certification for marketing or they may elect to not to regain certification until there is a demand for the decertified parameter. The 2-year cap on recertifying a parameter versus treating it as an initial certification was added because personnel, equipment, methodology and regulatory requirements often change during that span of time and submitting an application will ensure accurate and current information is evaluated.

3.2 Methodology and Assumptions for 15A NCAC 2H .0806

Certification is required by state statute. All laboratories that are reporting data to the State pursuant to G.S. 143 Article 21 must be certified and must pay certification fees annually. General Statute 143-215.3 (a) (10) provides the Department of Environmental Quality with the power and duty to establish an accreditation program for environmental laboratories and to establish fees for certification program support. The Laboratory Certification Rule provides that the program shall require a fee for the processing of an application, including the issuance, annual renewal (this is the primary source of receipts), modification, recertification of parameter(s), late payment penalty fees and travel reimbursement for out-of-state laboratories. These fees shall be in an amount sufficient to pay the Department's cost of implementing and administering the accreditation program.

3.2.1 Points for Raising Laboratory Certification Fees

- The rules and fees were last revised in August 2002.
- The proposed fee increase is about 11% less than the cumulative rate of inflation over the past 16 years for Municipal/Industrial, and Commercial labs.
- Current receipts are approximately $681,550 (based on 2015) and are all allocated to salary for 8 positions – table 11 provides a breakdown of the fees collected for the 2015 certification cycle compared to the proposed fee schedule. It is the intent of the Laboratory Certification Branch to restore program staff levels. This will include recreating 1 lost position.
- Current staffing level includes 8 positions plus 1 administrative position funded by Laboratory Certification fees but reports to the Water Sciences Section Chief. In recent years 3 auditor positions were lost to Reduction in Force (RIF), being held vacant too long due to insufficient funds and the Division of Waste Management Underground Storage Tank program pulled their funding of 1 position.
- The current audit cycle is approximately 6 to 7 years. An optimal audit cycle would be 3 years to ensure laboratories are current with changes in federal regulations, state regulations, technology, methodology, etc. A 3 to 4-year audit cycle is federally mandated for drinking water laboratories.
    - There are approximately 700 laboratories with 5 Auditors and 2 Technical Assistance and Compliance Specialists. Small laboratory audits = 1 person and 1 day. Larger laboratories require 3-7 auditors to complete in 2 or more days plus pre- and post-audit processes by all.
    - In addition to performing inspections, the auditors are also:
        - Managing approximately 3 times the workload since the program's inception in terms of number of laboratories, daily technical assistance, paperwork, proficiency testing evaluations, etc.
        - Working to update inspection checklists, policies, guidance documents, etc. to accurately reflect changes in state and federal regulations.
        - Providing on-site technical assistance and troubleshooting consultation.
        - Providing more in-depth audits. The audits drill down to specific analyses rather than take a broader quality systems approach.
        - Re-adopting/Revising the rules and preparing a fiscal impact analysis.
        - Performing paper trail investigations related to Discharge Monitoring Reports for the Division's Regional Offices. Since we find so many issues that affect data quality and defensibility during this process, we do not want to discontinue this review.

        - Participating in training and outreach presentations and programs. Last year the program participated in at least 25 training and outreach events.
        - Conducting internal training.
        - Consulting, providing data assessment, compliance investigation and enforcement assistance to internal Departmental staff.
        - Conducting an internal assessment of the State chemistry laboratories.
    - Out of state laboratories have not been audited for at least 3 years. While they may be certified by other states, those certifications do not always cover what is required in North Carolina. There is also a national certification that has different requirements than NC and is very expensive.
        - Out-of-state laboratories are charged for per diem for audits.
        - In-state laboratories are not charged per diem for audits; however, they do pay state taxes that are used to support state programs.
        - We have proposed additional charges for on-site audits of out-of-state laboratories to offset this disparity.

- The Laboratory Certification program was granted primacy by EPA over the NPDES DMRQA-PT program and as a result, NPDES facilities are not required to participate in EPA's DMR-QA PT study program. This has increased auditor workload because EPA implemented additional proficiency testing sample evaluation criteria, but it saves those stakeholder facilities significant money and any inconvenience that might be associated with participating in EPA's program. Failure to continue meeting our program's high standards could jeopardize that exemption.

- Further increases in the number of certified laboratories with no increases in staff will result in a more "regulatory focused program" where Division staff may only have the resources to take enforcement actions rather than providing technical assistance and customer services to enable the regulated community to comply with the rules and regulations. This is not our preferred method of dealing with customers and it will potentially result in a program that does not have the focus on data accuracy and defensibility that is expected of us by stakeholders.

- Feedback from Certified Laboratories:
    - Some laboratories have requested audits and/or requested audits at more frequent intervals to protect themselves.
    - Some commercial laboratories see the audit process as a means to ensure that no competitor has an unfair business advantage.
    - Most laboratories would support a reasonable fee increase to continue the level of support our program provides in terms of services and technical assistance. During our stakeholder process, we held at least 5 meetings across the state, and solicited input both before and after incorporating stakeholder comments into the rules

revision. I am only aware of 2 instances where a laboratory commented adversely on raising the fees and these were both by small Field Commercial laboratories. We feel the increase we have proposed for these laboratories (i.e., increasing annual fees from $200 per year to $300 per year without a change in more than 14 years) is very modest.

- At recent stakeholder meetings, laboratory representatives indicated that the customer service is what matters most to them.
  - They appreciate being able to call with questions without fear of Notice of Violations (NOVs).
  - They appreciate the knowledge and attitudes of the staff that come to audit, answer their questions through email or phone, or come on-site to provide hands-on troubleshooting and technical assistance.
  - Some prefer our audits to those of the National Environmental Laboratory Association Program (NELAP), third party assessors and other state laboratory accreditation programs due to our level of detail which focuses on data accuracy and defensibility in addition to the broader quality systems approach of some of those programs. They feel this level of review better protects them and their clients and helps to ensure their data can withstand scientific and legal scrutiny.

- Many states (Florida is an example) are moving toward using third party assessors; however, third party assessors charge more than double our fees and don't perform as thorough an audit or provide the technical assistance we do. These audits simply often cite violations without offering troubleshooting or suggested corrective actions. Our stakeholders did not want to see the program move in that direction and so we struck proposed rules allowing the use of third party assessors as a result of stakeholder feedback.

3.2.2 Comparison to Other State Laboratory Certification Program Fees

The Laboratory Certification program surveyed the accreditation programs in other states. Each state program has a unique fee structure. However, from the information, the program could identify 4 basic models for establishing a fee structure. These options are:

a) Fixed fees: Establish a fee for each category or field of testing of accreditation. NOTE: A variation on this model is to establish a relative cost factor for each category. The relative cost factor is multiplied by a dollar amount that is dependent upon the actual costs of administering the program. The fee for each category may go up or down each year as the costs of administering the program change. States employing the fixed fees per category model are: Arizona, California, Florida, Maine, New Jersey, and Texas. An example of a state using the relative cost factor method is Wisconsin.

b) Application Fee plus Fixed On-site Assessment Fee: Establish base application fees based upon category of accreditation. The laboratory pays the same base application fee each year. Establish an on-site assessment fee for each specific category of accreditation. The costs are known to the laboratories and include the total of the application fee and the on-site assessment fee. The laboratory would pay different amounts each year. A higher

amount would be required each year the laboratory is required to have an on-site assessment. There may be as many different categories as necessary. A category may be a single method. Oregon uses this model.

c) Fixed Fees plus Recovery of On-site Assessment Costs: Establish base application fees based upon category of accreditation. The laboratory pays the same base application fee each year. Each laboratory must pay for the actual cost of the on-site assessment. The costs are unknown to the laboratory until on-site assessment is billed. The laboratory would pay different amounts each year. There may be as many different categories as necessary. A category may be a single method. Colorado and New Hampshire use this model.

d) Surcharge for Numbers of Tests: Establish a fee for each category of accreditation. The fee for each category remains the same until changed in regulation. An additional charge or surcharge is assessed against each laboratory for the number of tests or analyses performed on samples in that state. The laboratory would be required to track covered samples and report the number of the covered samples to the Department. The Department would calculate a surcharge based upon the actual costs of running the program and the aggregate numbers of samples. The costs would be allocated to the individual laboratories based upon the numbers of required samples performed by the laboratory. The different tests or analyses could have different costs per sample performed to reflect the complexity of the analysis and extent of Department oversight required. The yearly cost to the laboratories would not be known until the end of the year. New York employs this model.

North Carolina's WW/GW Laboratory Certification model is a straight fixed fee model. We believe it is the fairest and simplest model for both the laboratories and the Department. It allows the laboratory to plan in their budget the costs of accreditation for multi-year projections (i.e., the fees remain constant until changed in the regulations) and does not require overly burdensome tracking. We also believe that even with the proposed fee increase, the cost of North Carolina certification is less than other state accreditation programs, including those participating in the National Environmental Laboratory Association Program (NELAP). Some examples are listed below:

- **California ELAP** – base fee of $1003.00 plus $452.00 for each Field of Testing (there are up to 20 Fields of Testing yielding annual fees from a minimum of $1455.00 to a maximum of $10,043.00).

- **New Jersey NELAP** – base fee of $900 plus $540.00 inorganic category fees and $840 organic category fees yielding annual fees from a minimum of $1440.00 to a maximum of $7655.00.

- **Arizona** – charges a fee per method (range from $7 to $303 per method). Fees as high as $9,540.00 per year may be assessed.

- **Florida DEP** – charges by category – one category for $500 and four or more categories for $2000. These fees do not include the cost of third party assessment.

- **Texas NELAP –** charges by category – there are up to 12 categories and the fees per category range from $255 to $510. Fees as high as $10,000 per year may be assessed.

- **Oregon ELAP -** charges by category – there are up to 18 categories and the fees per category range from $100 to $550. Fees as high as $10,573 per year may be assessed.
- **New Hampshire ELAP -** charges by category – there are up to 9 categories and the fees per category range from $100 to $600. Fees as high as $10,573 per year may be assessed.
- **North Carolina –** the maximum annual fee that could be assessed to a laboratory under the proposed fee schedule would be $10,540 per year if a laboratory held certification for every parameter we offer, which is highly unlikely since no laboratory is currently or has ever been certified for every parameter offered. For the state programs that charge by category, it is very likely that laboratories would reach the maximum values listed above.

When fees are collected that exceed operating costs, salaries and fringe, the Laboratory Certification Branch will use that money for training to improve relevant knowledge, skills and abilities for performing the duties of this job and to provide training to the certified laboratory community. When fees are collected that do not cover operating costs, salaries and fringe, travel, training and technical assistance will be restricted.

Table 7. Proposed Fee Schedule for North Carolina

Laboratory Type	Current	Proposed	Net Change
Field Municipal/Industrial/Other	$100.00 per year	$150.00 per year(1)	+ $50.00
Field Commercial	$200.00 per year	$300.00 per year(1)	+ $100.00
Municipal/Industrial/Other	$1350.00 min per year	$1750.00 minimum per year	+ $400.00
	$50.00 each inorganic parameter	$85.00 each inorganic parameter	+ $35.00
	$100.00 each metal / organic parameter	$85.00 each metal / organic parameter	- $15.00
Commercial(2)	$2700.00 min per year	$3500.00 minimum per year	+ $800.00
	$50.00 each inorganic parameter	$85.00 each inorganic parameter	+ $35.00
	$100.00 each metal / organic parameter	$85.00 each metal / organic parameter	- $15.00

(1) We are also proposing Field laboratories will be charged a $50.00 administrative fee to add parameters during the year just as all non-field laboratories will be charged $85.00.

(2) Out-of-state laboratories will also be assessed a fee for an on-site inspection based on the established hourly rate of the laboratory certification officer(s) inclusive of preparation time, travel time and inspection time

A table illustrating comparison of the fees collected during the 2015 cycle versus the projected fees for those laboratories based on the proposed fee schedule is shown below. The net change in annual fees is estimated at $92,350.

Table 8. Projected Fees using the Proposed Fee Schedule

Type of Laboratory	**Number of Laboratories**	**2015 Fees (using current fee schedule)**	**Projected Fees (using proposed fee schedule)[(1)]**
Commercial	95	$385,750	$432,155
Municipal/Industrial	140	$204,400	$258,945
Field Commercial	94	$18,600	$28,200
Field Municipal/Industrial	364	$36,800	$54,600
Total	**693**	**$681,550**	**$773,900**

(1) The projected fees (using the proposed fee schedule) assumes no changes in the number of labs or parameters.

4. Quantified and Unquantified Impact Summary

Table 9 shows a 3-year analysis of the quantifiable costs and benefits that the Division expects to generate by increasing the laboratory fees. The total revenue that the division expects to have for the fiscal year that this rule is put in place is around $773,900. The net revenue, equal to $92,350, could be used to hire one new staff position. A more conservative analysis for the total benefits of this proposed fees increase is around $176,093. The aggregate total impact (benefits + costs) is equal to $268,443.

Table 9. Annual Quantified Impact Summary Table[(1)]

Fiscal Year	**Annual Impact**
Costs	
Increased certification fees – cost to laboratories	$92,350
Rule 15A NCAC 02H .0804 – cost to laboratories	$10,860
Rule 15A NCAC 02H .0805 – cost to State	$1,067 (one-time cost)

Unquantified costs to laboratories	Section 5.1
Total costs	$103,210 *Annual* $1,067 *One-Time*
Benefits	
Rule 15A NCAC 02H .0803 (lower range)	$69,150
Rule 15A NCAC 02H .0803 (upper range)	$182,095
Rule 15A NCAC 02H .0804	$11,135
Rule 15A NCAC 02H .0808	$8,903
Increased certification fees – benefit to State to be used for creation of one DEQ position	$92,350
Unquantified benefits to laboratories and environment	Section 5.1
Total Benefits to All Parties (lower range -- more conservative)	$181,538
Total Benefits to All Parties (upper range – more likely)	$294,483
Net Total Impact to All Parties (benefit minus costs), lower range to upper range	$78,328 - $191,273
Net Total Impact to State Increased annual revenue to the State from increasing certification fees will be used to cover salary and overhead for one new position; as such, net annual benefit to the State for the fee increase is considered to be $0 for purposes of this analysis.	-$1,067 one-time cost/$0 thereafter
Net Total Impact to Regulated Persons (benefits minus costs), lower range to upper range	-$14,022 - $98,923

(1) These estimates assume no change in the number of laboratories or parameters or operating cost growth.

4.1 Summary of Unquantified Environmental and Economic Benefits and Costs

The proposed rule has the potential for positive economic impact to laboratories as well as environmental benefits which have not been quantified. Most unquantified environmental benefits stem from reduced paper waste and quality control measures to ensure more accurate and legally defensible data which should provide increased confidence in data used for regulatory decision-making.

For unquantified economic benefits, expanding the Field Parameter list could lead to more clients for Field Commercial Laboratories and allow Field Industrial and Field Municipal Laboratories to contract fewer parameter analyses to Commercial Laboratories. There are a few proposed changes that could save laboratories salary and/or man-hour costs. These include:

- the proposed change that a supervisor must only contact the laboratory each business day;
- increasing from 6 to 12 weeks the amount of time that a substitute supervisor may fill in; and
- clarifying that incubators and ovens must only be checked during normal working hours.

Proposed updates to definitions (23) and (33) could save laboratories costs associated with being decertified for certain methods which leads to either lost revenue (commercial labs) or additional costs to contract out the sample analysis. The same benefits could arise from decreasing the mandatory decertification period from 60 to 30 days. Operating costs could be saved by laboratories due to the specification that limited-use thermometers must only be recertified every five years instead of annually and less restrictive requirements for facilities and equipment. Increasing flexibility in meeting Supervisory requirements for Field Laboratories could save laboratories salary or training costs.

Many of the revisions involve codifying policies that were written to give additional information on how to meet an existing rule. Codifying policies will ensure strict compliance with quality assurance protocols that ensure accurate and legally defensible data. These codified policies will provide additional quality control requirements where a rule or method requirement does not exist and will aid laboratories' efforts to produce accurate and court defensible data. It will level the playing field for all laboratories by establishing baseline quality assurance (QA) requirements from a multitude of EPA-approved methodologies, and will require all laboratories to meet the same data quality standards for data used for regulatory decision-making. These policy requirements have already been in place; however, codifying them will require strict adherence and may lead to some economic cost as described previously

Some of the proposed rule changes could result in unquantified costs to laboratories. Most stem from increased man-hours needed to institute additional quality control and/or quality assurance. The applicable rules are those which increase the residue standard analysis from quarterly to monthly, require a documented training program and require Field Laboratories to maintain SOPs. Our office is developing template SOPs for Field Parameters to greatly reduce the time burden of that rule. Due to the increased frequency of residue standard analysis, affected laboratories should expect a slight cost increase for purchasing standard materials. There could be a negative economic impact to Commercial Laboratories through loss of revenue if Field Laboratories (of any type) gain certification for the newly proposed Field Parameters and no longer contract analysis of those parameters to a Commercial Laboratory.