**Regulatory Impact Analysis**

**Rule Citation Number:** 15A NCAC 02H .1101 thru .1111
**Rule Topic:** Amendment and Readoption of Biological Laboratory Certification Rules

**DEQ Division:** Division of Water Resources (DWR)

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**Impact Summary:**

| | |
|---|---|
| State government: | No |
| NC DOT: | No |
| Local government: | Yes |
| Private entities: | Yes |
| Substantial Impact: | No |
| Federal government: | No |

**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.

## 1. Summary

The Division of Water Resources ("Division") reviewed the Environmental Management Commission's General Requirements for Biological Certification rules in accordance with G.S. §150B-21.3A and proposes to re-adopt or repeal the subject rules.

The Division identified necessary changes in some rules, including:

- Correction of agency names and addresses;
- Correction of cross-references and other regulatory citations;
- Correction of spelling and typographical errors;
- Minor clarifications;
- Codifying established, specific standards and procedure modifications already in force via the Document authorized by existing Rule 15A NCAC 02H .1111.

Several minor, but substantive changes are also proposed that could be considered less stringent than the baseline in that they give regulated persons more options. However, none of these changes will require regulated persons to revise their existing procedures or to procure additional staff. As such, as measured from the baseline conditions, the Division anticipates that these rule changes will have no economic impact on the regulated community or government agencies. In

addition, the proposed rule changes will maintain existing environmental protections at an equivalent level.

## 2. Background

### *Aquatic Toxicology Branch (ATB)*

The ATB serves the state of North Carolina through its support of the EPA mandated National Pollutant Discharge Elimination System (NPDES) program as it pertains to the Clean Water Act. The ATB performs three main functions in support of the NPDES program:

- NPDES Compliance and Enforcement – All permitted dischargers of complex wastewaters are required to perform monitoring of aquatic toxicity in their wastewater. Currently, there are over 500 subject industrial and municipal facilities in North Carolina. The ATB reviews all toxicity data reported by these facilities to verify data quality, track compliance with permit limits and make enforcement recommendations;
- Biological Laboratory Certification and Inspection – All toxicity analyses reported by dischargers are required by rule to be performed by a biological laboratory certified by the state of North Carolina. The ATB operates this certification program which includes laboratory inspections, data tracking and performance evaluation testing; and
- Whole Effluent Toxicity (WET) Testing and Bioassay Organism Culture – The ATB uses modified EPA methods for measuring the acute and chronic toxicity of wastewater and surface waters to freshwater and marine organisms. The ATB maintains in-house cultures for WET testing and special toxicity studies.

### *Rules Review and Readoption Process*

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; or
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 Division prepared draft rules and solicited input on the proposed actions from stakeholders in outreach meetings on March 24, 2015 in Raleigh, April 1, 2015 in Burlington, NC, April 9, 2015 in Wilson, NC and April 16, 2015 in Asheville, NC. The meetings gave stakeholders the opportunity to review and submit comments on the Division's draft proposed rules. The draft rules were posted on the Division's webpage at least 30 days prior to the meetings. Stakeholders voiced and submitted comments to the Division on/before the meeting.

The Division presented the proposed draft rules to the Water Quality Committee (WQC) of the Environmental Management Commission (EMC) on May 10, 2017. The WQC approved the proposed rule changes. The Rules Review Committee performed a pre-review of the rules and the Division has edited the rules in accordance with the pre-review comments.

## 3. Economic Impact Analysis

For purposes of this RIA, the following items are considered to comprise the baseline for this regulatory impact analysis:

- the current version of the Section 02H .1100 rules;
- current NC general statute and session law; and
- the current version of the "Biological Laboratory Certification/Criteria Procedures Document," hereafter referred to as the "Document." The Document is a technical manual that describes specific scientific reporting units, forms, test methods, and procedures pertaining to certification. The Document is created and maintained by the Division and is authorized by Rule 15A NCAC 02H .1111 and G.S. 143-215.3(a)(10). The procedures contained in the Document were initially approved by the US Environmental Protection Agency (EPA) in 1986. In 2015, US EPA again acknowledged its prior approval of NC Alternative WET test procedures. NPDES permits that have the WET testing requirement for monitoring reference procedures contained in the Document; as such, permitted facilities are required to adhere to the procedures listed in the Document, and the procedures listed in the Document are enforceable by the Division. NPDES permit conditions require that NC certified biological labs perform the procedures specified in NPDES permits.

The following table contains brief descriptions of the proposed rule changes and anticipated economic and environmental impact of each.

**Table 1: Subchapter 02H – Biological Certification**
**Section .1100 – General Requirements for Laboratory Certification**

| Rule | Proposed Change | Proposed Action | Economic Impact | Environment Impact |
|---|---|---|---|---|
| 15A NCAC 02H .1101 Purpose | Technical changes for clarity. | Readopt w/ Amendment | None | None |
| 15A NCAN 02H .1102 Scope | Repeal. Scope language not necessary. | Repeal | None | None |
| 15A NCAC 02H .1103 Definitions | Updated definitions for clarity;<br><br>Removed unnecessary definitions;<br><br>Added definitions for "Aquatic population survey and analysis" and "Approved Procedure;"<br><br>Changed term "Evaluation sample" to "Proficiency Testing sample" for consistency with Chemistry Lab rules. | Readopt w/ Amendment | None | None |

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| 15A NCAC 02H .1104 Fees Associated with Certification Program | Technical changes for clarity. | Readopt w/ Amendment | None | None |
| 15A NCAC 02H .1105 Certification | Technical changes for clarity. | Readopt w/ Amendment | None | None |
| 15A NCAC 02H .1106 Decertification | Technical changes for clarity;<br><br>02H .1106(b)(1) – Revised acceptable range for proficiency testing samples to allow outside vendors which sometimes use other ranges for pH, conductivity, etc. | Readopt w/ Amendment | Benefit | None |
| 15A NCAC 02H .1107 Recertification | Technical changes for clarity. | Readopt w/ Amendment | None | None |
| 15A NCAC 02H .1108 Reciprocity | Technical changes for clarity. | Readopt w/ Amendment | None | None |
| 15A NCAC 02H .1109 Administration | Technical changes for clarity. | Readopt w/ Amendment | None | None |
| 15A NCAC 02H .1110 Implementation | Updated language for clarity, and technical changes. Added methodology references that had been identified in the Document.<br><br>02H .1110(e) – Changed to allow outside vendors to provide proficiency testing samples to improve options for labs.<br><br>02H .1110(f)(6) – Clarify that records must be maintained for five years. | Readopt w/ Amendment | Benefit | None |
| 15A NCAC 02H .1111 Biological Procedures Document | Codifying requirements of the Biological Laboratory Certification/Criteria Document:<br>- minimum laboratory facilities and equipment requirements required for certification;<br>- minimum quality assurance requirements required to be eligible for certification; and<br>- approved modifications to methods referenced in 40 CFR 136.<br><br>02H .1111(c)(7) – Reduced requirement to taxonomically identify test organism from quarterly to annually. | Readopt w/ Amendment | Benefit | None |

***Costs and Benefits Analysis***

**State Government**

None of these proposed rule changes will require the State implementing agency DEQ to revise their existing procedures or to procure additional staff. As such, there will be no economic cost or benefit to state agencies.

These changes will not affect environmental permitting of NC Department of Transportation (NCDOT); as such, there will be no economic cost or benefit to NCDOT.

**Regulated Persons**
Biological laboratories performing analyses in support of NPDES permit requirements are the regulated persons primarily impacted by the proposed rule changes. These laboratories are required to comply with Section 15A NCAC 02H .1100, which includes requirements for certification, test methods, lab equipment and staff, and quality assurance. A small percentage of certified laboratories are operated by municipalities/counties; as such, there could be some impact on local government agencies.

Proposed rule changes are largely administrative in nature and are for the purpose of providing clarity to the regulated community thereby making the rules easier to understand. This should translate into less time spent by laboratories on understanding lab certification requirements for biological toxicity testing and aquatic population surveys of water and wastewater as required for NPDES permits and/or EMC rules. The amount of time saved will be negligible and is not expected to provide a significant economic benefit; however, it is noted here for completeness.

Rule 02H .1106(b)(1) is proposed to be changed such that the acceptance range for proficiency testing samples will fall within the specified acceptable range as established by the State Laboratory or State Laboratory approved vendor. The current rules specify that acceptable values must vary by less than two standard deviations of the value established by the Division. This change is proposed to accommodate outside approved vendors which sometimes use other ranges, such as ±10% of the mean value for conductivity and ± 0.2 pH units for pH. . This change allows the use of proficiency test results from State Laboratory vendors, but it does not require laboratories to change their existing practices. Additionally, the State Laboratory has found that the use of ± two standard deviations as too restrictive for pH. The use of ± 0.2 pH units is less restrictive and more appropriate for pH measurements.

Rule 02H .1110(e) is proposed to be changed to allow proficiency samples to be provided by either the State lab or a State lab-approved vendor. The current requirement is that the State lab provide proficiency samples to the contract labs. This change was made based on the requests of stakeholders and provides additional flexibility to laboratories. It does not require laboratories to change their existing practices. It is not known how many laboratories would take advantage of this option; therefore, an economic benefit could not be quantified.

Rule 02H .1110(f)(6) is proposed to be changed to clarify that laboratories must maintain records for five years. Currently, there is no stated time limit, which could be interpreted to mean that records must be kept indefinitely. This change could result in a savings of storage space (virtual or physical) for laboratories; however, the change does not require laboratories to change their existing practices. It is not known how many laboratories would benefit from this clarification; therefore, an economic benefit could not be quantified.

Rule 02H .1111(c)(7) is proposed to be changed to reduce the frequency of taxonomic identification of representative test organisms from quarterly to annually. This change could result in savings to laboratories in terms of staff time used on taxonomic identification. Taxonomic identification takes relatively little time and does not require costly laboratory resources; as such, the potential cost and time savings is expected to be negligible. It is not known how many laboratories will choose to reduce the frequency of taxonomic identification; as such an economic benefit could not be quantified.

**Environment**

As measured from baseline conditions, the proposed changes will maintain existing environmental protections at an equivalent level with no cost or benefit to the environment.

**4. Total Economic Impact**

As measured from the baseline conditions, none of these changes will require regulated persons or government agencies to deviate from current practices. The few substantive changes represent a slight relaxation of current requirements and could have a positive, albeit minimal, economic impact on regulated persons. It is not known how many laboratories will take advantage of the additional flexibility. As such, the economic impacts of the proposed rule changes, both in terms of cost and benefit, are not monetarily quantifiable as measured from the baseline conditions. Consequently, there were no specific cost or benefit estimations to report in this analysis. The proposed rulemaking will not meet or exceed the $1,000,000 threshold for substantial economic impact as defined in G.S. 150B-21.4.

The subject rules are attached.