Regulatory Impact Analysis

Rule Topic: **Amendment of Wastewater/Groundwater Laboratory Certification Rule**

Rule Citation: 15A NCAC 02H .0804 – Parameters for which Certification may be requested

DEQ Division: Division of Water Resources (DWR)

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Impact Summary:

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

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

1. Necessity for Rule Change

The scope of Parameter Methods for which the Wastewater/Groundwater Laboratory Certification Branch (WW/GW LCB) may offer certification is limited to those falling under the Parameters listed in Rule 15A NCAC 02H .0804. DEQ has begun to require some permitted facilities to test for the class of compounds broadly known as "Per- and Polyfluoroalkyl Substances (PFAS)." PFAS is not currently listed as a Parameter in Rule 15A NCAC 02H .0804. This precludes laboratories from producing certified regulatory data for this Parameter for North Carolina permits. As such, PFAS must be added as a Parameter to Rule 02H .0804 to enable permittees to comply with requirements for regulatory data to be produced by a certified laboratory in accordance with existing requirements in Rule 15A NCAC 02H .0804(a).

2. Regulatory Baseline

As part of the permanent rulemaking process, G.S. 150B-19.1 requires agencies to quantify to the "greatest extent possible" the costs and benefits to affected parties of a proposed rule. To understand what the costs and benefits of the proposed rule changes would be to regulated parties and the environment, it is necessary to establish a regulatory baseline for comparison. For the purpose of this regulatory impact analysis, the baseline is comprised of the following:

- current version of Rule 15A NCAC 02H .0804 (effective July 1, 2019) which lists Parameters for which laboratories may request state certification and which requires permitting data to be produced by certified laboratories; and
- FY 2023/2024 State budget (S.L. 2023-134) which increased some fees for certification and established separate fee structures for in-state versus out-of-state commercial laboratories.

3. Proposed Amendments

15A NCAC 02H .0804 (d) (20)

The proposed rule amendment adds the Per- and Polyfluoroalkyl Substances (PFAS) Parameter to the list of certifiable organic Parameters.

4. Impact Analysis

Impact on Regulated Community:

NPDES Permittees
In general, NPDES permittees include municipal and industrial entities. The proposed rule does not add additional requirements beyond what is or will be required in a regulated facility's permit; as such, there should be no costs to permittees associated with the proposed rule changes.

NPDES Permittees will benefit, however, in that the proposed amendment will allow facilities to comply with requirements that PFAS monitoring data reported to the State be performed by a certified laboratory. The adoption of this Parameter into state rule will allow permittees to avoid issues of noncompliance with their permits related to monitoring for PFAS. If the proposed Parameter is not adopted into state rule in a timely manner, permittees would be at risk of being out of compliance with their monitoring requirements. Permittees would still be required to perform monitoring, but their monitoring data would have to be reported as uncertified. Certified data would be preferable to uncertified data for making future permitting and enforcement decisions.

Commercial Laboratories

The proposed amendments will not require any commercial, municipal, or industrial laboratory to request certification; therefore, the proposed amendments will not necessarily result in any costs to laboratories. However, the amendments will create an opportunity for laboratories to get certified for this Parameter. Because of the interest in PFAS testing in North Carolina, we expect that a number of laboratories will seek certification. There are currently no municipal wastewater or water treatment facilities performing any organic analyses. All analytical work would likely be contracted to Commercial Laboratories.

To become certified, the cost to a laboratory would be $85.00 for each Parameter Method that the laboratory elects to add, assuming they are already a certified laboratory. Fees for becoming certified and/or adding Parameter Methods once already certified are detailed in Rule 15A NCAC 02H .0806 and S.L. 2023-134 (Section 12.14). There are currently 206 non-Field laboratories that would be eligible to add methods under the new Parameters. Of these 206 laboratories, 40 laboratories are currently certified for organic Parameters. Laboratories not currently certified would pay a $300 application fee and at least the minimum certification fee of $2,000 for Municipal and Industrial laboratories, $6,500 for in-state Commercial laboratories and $9,750 for out-of-state Commercial laboratories. Municipal and Industrial laboratories requesting more than 24 Parameters in an initial application would pay a minimum fee of $85 multiplied by the number of Parameters. In-state Commercial laboratories requesting more than 76 Parameters and out-of-state Commercial laboratories requesting more than 114 Parameters in an initial application would pay a minimum fee

of $85 multiplied by the number of Parameters.

The likelihood of Industrial and/or Municipal laboratories already having or investing in the equipment, software, and specialized staffing needed to perform analyses under this new Parameter is extremely low. The likelihood of Commercial laboratories having or investing in the needed equipment and staffing is higher but will likely still be limited to larger laboratories. Based on costs for the Water Sciences Section Chemistry Laboratory to get the PFAS analysis up and running, the initial cost of instrumentation and associated equipment could surpass $400,000. This doesn't include the cost of recurring supplies or costs associated with hiring staff with skills necessary to operate the instrumentation.

PFAS methods require an HPLC with tandem quadrupole mass spectrometers. The Certification Branch currently offers certification for three organic methods that utilize an HPLC, but they do not require it to be connected to tandem quadrupole mass spectrometers. This is a major difference with significant added cost. Currently there are only 40 laboratories that are certified to perform organic analyses (39 commercial; 1 non-commercial). The 39 currently certified Commercial laboratories were polled to gauge their interest in becoming certified for PFAS. Of those 39 laboratories, 36 provided responses. Of the 36 laboratories who responded, 11 expressed interest in becoming certified. Based on inquiries received by the Certification Branch, we also expect a small number of additional commercial laboratories that are not currently certified for any Parameters in North Carolina to request certification for PFAS. The costs to these currently uncertified laboratories to become certified for PFAS would be higher than for certified laboratories due to the minimum certification fee. Table 1 contains a summary of the potential likely costs to Commercial laboratories. These costs would largely be incurred in the first year following adoption of the rule.

Table 1: Estimated Initial Certification Costs Attributable to PFAS Certification for Commercial Laboratories

	Certified laboratory	**Non-certified laboratory**
Fees (per laboratory) as established in Rule 15A NCAC 02H .0806 and S.L. 2023-134 (Section 12.14)		
Parameter Method Addition Fee	$85 per Parameter method	N/A
Application Fee	N/A	$300
In-State Laboratory Certification Fee	N/A	$6,500, or $85 per Parameter if more than 76 Parameters
Out-of-State Laboratory Certification Fee	N/A	$9,750, or $85 per Parameter if more than 114 Parameters
Projections		
Projected # of Laboratories that will	To date, 11 certified laboratories have	To date, 3 non-certified laboratories (1 in-state; 2 out-

request certification for PFAS	expressed interest in adding PFAS certification.	of-state) have contacted the Certification Branch to express interest in pursuing PFAS certification.
Total projected # of Parameter Methods for which Labs will seek certification	Eleven (11) (11 labs x 1 Parameter)	Three (3) (3 labs x 1 Parameter)
Total initial cost to interested laboratories	**$935** (11 Parameter Methods x $85 fee)	**$26,900** (($300 Application fee * 3 labs) + ($9,750 out-of-state Certification fee x 2 out-of-state labs) + ($6,500 in-state Certification fee x 1 in-state lab))

In addition to the initial certification costs, there would be ongoing annual costs to certified labs that elect to remain certified. The ongoing future costs to certified laboratories would be based on the total number of Parameters for which they are certified. Because it is highly unlikely that Municipal and Industrial laboratories will seek certification for this Parameter, we focused on costs to Commercial laboratories. For in-state Commercial laboratories, the minimum annual fee is $6,500, unless they hold certification for more than 76 Parameters. Then the renewal fee would be $85 multiplied by the total number of certified Parameters. For out-of-state Commercial laboratories, the minimum annual fee is $9,750, unless they hold certification for more than 114 Parameters. Then the renewal fee would be $85 multiplied by the total number of certified Parameters.

Table 2 contains a summary of the annual fees for certified Commercial Laboratories that are attributable to PFAS certification. It should be noted that except for laboratories that are certified only for PFAS, the annual costs attributable to certification for PFAS would be between $0 and $85.

Table 2: Ongoing/Annual Costs Attributable to PFAS Certification for Certified Commercial Laboratories

	Laboratory certified for other Parameters in addition to PFAS	**Laboratory certified only for PFAS**
Fees (per laboratory) as established in Rule 15A NCAC 02H .0806 and S.L. 2023-134 (Section 12.14)		
Annual Fee (portion of annual fee that is attributable to PFAS certification)	Certified commercial labs <u>are not subject</u> to additional fees if the number of Parameters does not exceed the relevant Parameter threshold: $0 for those certified in-state for 76 or fewer Parameters; $0 for those certified out-of-state for 114 or fewer Parameters. Certified commercial labs <u>are subject</u> to additional fees if the number of Parameters exceeds the relevant threshold: $85 for those already over the minimum Parameter threshold and adding one Parameter (PFAS).	$6,500 in-state; $9,750 out-of-state
Projections		
Projected # of Laboratories that will request certification for PFAS	To date, 11 certified laboratories have expressed interest in adding PFAS certification.	To date, one(1) in-state lab and two (2) out-of-state labs have expressed interest in being certified in NC for the first time to provide PFAS testing.
Total additional annual cost to laboratories	**$0** None of the 11 certified labs who have expressed interest are approaching the Parameter thresholds. As such, we do not expect any of these 11 certified labs to pay additional annual fees as a result of adding PFAS.	**$26,000** ($9,750 annual fee x 2 out-of-state labs) + ($6,500 annual fee x 1 in-state lab)

It is also possible, although doubtful, that commercial laboratories who are not already equipped to analyze Organic Parameters will request certification. Analysis of Organic Parameters versus Inorganic Parameters requires an entirely different skill set. To become certified for this Parameter, these laboratories would have to invest a considerable amount of money to purchase instrumentation and consumable supplies. DEQ staff in the WSS Chemistry Laboratory report that the cost of the major equipment required for startup of PFAS analysis was approximately $400,000, not including consumable supplies and standards.

It is presumed that commercial laboratories that choose to become certified for this Parameter will likely receive benefits that exceed the costs; otherwise, they wouldn't pursue certification. These benefits would be in the form of additional business. The laboratories that have said they would pursue certification have said they would be charging between $400 and $500 per sample, depending on the sample matrix. The total benefit to certified Commercial laboratories will depend on how many permits require monitoring for PFAS and at what sampling frequency. Currently, the handful of NPDES permits with monitoring requirements for PFAS require sampling on a quarterly basis. Although it is expected that there will be an increase in the number of permittees required to monitor for PFAS in the future, there is no way to estimate how many samples certified laboratories would process. As such, the benefit to Commercial laboratories could not be quantified, but it is expected to more than offset their costs for certification.

Impact on the Environment and the Public:

As measured from the baseline conditions, the proposed changes will maintain existing environmental protections at an equivalent or higher level, with a possible benefit increase to the environment as more reliable and comparable data will be submitted in support of the Department's mission of protecting the environment for benefit of its citizens. Having a robust set of reliable and comparable data will better inform decision makers and should result in a better understanding of threats to the environment and human health from PFAS contamination. There may also be other positive benefits to the public as their confidence in the data should be increased by knowing that the data regarding potential recreational surface water and groundwater contamination was produced by a certified laboratory using approved methodologies. While confidence in data is an important benefit to the State, its value could not be quantified.

Impact on State Regulators:

Certification Branch

The impact on the Certification Branch staff will be in terms of time spent to review documentation required for adding a new Parameter Method and auditing the procedures during an inspection. For this Parameter, it is estimated that Certification Branch staff would initially spend approximately ten (10) hours reviewing the documentation required to grant a laboratory certification at a cost of approximately $43 per hour. This amount was based on the average annual salary plus fringe benefits of the Branch's current Chemist I Auditors. Required documentation would include the laboratory's Standard Operating Procedure (SOP), Initial Demonstration of Capability (IDOC), Method Detection Limit (MDL) study and acceptable results on a blind Performance Testing (PT) Sample, if widely available. The time spent and associated cost of staff time may be reduced as auditors become more familiar with method requirements, which could make SOP reviews faster. The 39 currently certified commercial laboratories were polled to gauge their interest in becoming

certified for PFAS. Of those 39 laboratories, 36 provided responses. Of the 36 that responded, only 11 have expressed interest in becoming certified for PFAS. Taking this level of interest into account, if each review for each Parameter Method takes 10 hours, that equates to 110 staff hours at a total staff time cost of $4,730.

Costs to the Certification Branch could be higher if multiple revisions to the SOP are required during that initial review process. However, the laboratories that have responded in the affirmative are highly experienced laboratories in the field of organics analyses. Based on staff experience, their SOPs are not likely to need much revision after our initial review. However, to be conservative, estimates of staff time should be considered a minimum estimate.

It is possible that DEQ will receive requests for certification from laboratories that have not previously been certified in North Carolina. There have already been two inquiries from out-of-state laboratories that do not currently hold NC Certification. The cost to the State in terms of dollars and staff time to certify out-of-state laboratories would be the same as that for in-state laboratories.

Because we expect most interested commercial laboratories to request certification as soon as possible after the Parameter is added to the rule, we expect the bulk of the costs associated with staff time would occur during the first year after adoption of the proposed amendment. This will add to the current workload and stress level of the Certification Branch staff. The Branch has been understaffed for years and does not have the budget to create new positions. The Branch receives no annual appropriations from the General Assembly. Because of inadequate funding to maintain a sufficient staffing level, the Branch struggles to maintain even a seven-to-ten-year inspection cycle, which is far below the three-year inspection cycle that the Branch, Certified laboratories, and outside stakeholder would like to see.

Ongoing costs associated with staff time are also expected to occur in future years related to auditing the procedures for which a laboratory is certified. It is estimated that with the addition of this Parameter to a laboratory's Certified Parameters Listing, that a single Certification Branch staff member would spend two to four hours auditing the Parameter Method during an inspection at a cost of approximately $43/hr. It should be noted, however, that out-of-state laboratories are required to reimburse the State for actual travel and subsistence costs incurred by laboratory certification staff to perform inspections, provide technical assistance or investigate complaints. Out-of-state laboratories shall also be assessed for expenses for an on-site inspection based on the hourly rate of the laboratory certification staff, rounded to the nearest hour and inclusive of preparation time, travel time, and inspection time, stipulated in rule 15A NCAC 02H .0806 (h).

Benefits to the Certification Branch will be from the collection of additional Parameter Method fees and possibly increased annual renewal fees for the laboratories that are already over the minimum renewal fee amount due to the number of certified Parameters those laboratories have. Benefits will also come from initial application and certification fees plus the annual renewal fees for laboratories that do not currently hold certification in NC. Based on feedback received by certified and non-certified laboratories, we estimate the total initial benefit to the State in terms of fees collected would be approximately $26,900 ($935 from certified labs + $25,965 from labs seeking certification for the first time), and an ongoing annual benefit in terms of additional renewal fees collected would be $26,000 ($9,750 from each of two out-of-state labs and $6,500 from one in-state lab). The actual benefits to the State will depend on how many laboratories choose to pursue certification for PFAS.

DEQ Permitting Staff

The proposed addition of the Parameter will not require the permitting staff to revise their existing procedures. There are permits that already contain requirements related to PFAS testing, so permitting staff will not be required to make changes to existing permits. In addition, permitting staff have indicated that the proposed rule changes will not influence whether DEQ adds PFAS monitoring requirements to permits in the future.

Having the Certification Branch in a position to offer certification for this Parameter will ensure that DEQ receives certified PFAS data for regulatory purposes. This increases confidence in the quality of the data. While confidence in data is an important benefit to the State, its value could not be quantified. However, it should be noted that if DEQ levies financial penalties based on any future exceedances of standards or discharge limits to permittees based on uncertified data and the data is challenged in court due to not being produced by a certified laboratory, it could cast doubt on the validity of the data and therefore cast doubt on the validity of the penalty.

Having the ability to certify laboratories for this Parameter will also allow DEQ permitting programs to potentially save future staff time on enforcement by reducing the potential for permittees to be out of compliance with permit conditions due to lack of availability of certified laboratories. The adoption of the proposed rule is necessary to avoid putting permittees at risk of noncompliance. Although we expect most, if not all, permittees to achieve compliance with their monitoring requirements in a timely manner after adoption, it is possible that a small percentage do not comply, resulting in the expenditure of DEQ permitting staff time on compliance and enforcement. We expect this to be a rare occurrence; as such, we expect this potential benefit to be minimal.

Summary

The proposed rule amendment does not add additional requirements beyond what already is or will be required in a regulated facility's permit; as such, there should be no costs to permittees from the proposed rule amendment. The benefit to the regulated community would be that there would be laboratories certified to do the analyses and thereby allow permittees to be compliant with permit requirements.

The proposed amendment will create an opportunity for Commercial laboratories to be certified for this Parameter method. Laboratories that choose to become certified would incur modest costs (initial and ongoing) related to seeking certification from the Certification Branch. It is presumed that laboratories that choose to become certified will receive benefits in the form of additional business that would exceed these certification costs.

The cost to the Certification Branch would be in terms of time spent by staff to review the data packets required to grant certification plus future ongoing costs for auditing the new Parameter method. The benefit would be added revenue to the Certification Branch's completely fee-funded budget. There could be benefits to DEQ permitting staff in the form of future time that might otherwise be spent working on notices of violations for permittees that did not have analyses performed by a certified laboratory.

The benefit to the public would be the increased confidence in the State's ability to accurately determine if this contaminant of concern is present and at what levels. The environment would potentially benefit from a certified dataset that allows locations and levels of contamination to be more confidently identified and ultimately remediated.

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

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

(a) Commercial Laboratories shall obtain Certification for Parameter Methods used to generate data that will be reported by the client to the State in accordance with the rules of this Section. Municipal and Industrial Laboratories shall obtain Certification for Parameter Methods used to generate data that will be reported to the State in accordance with the rules of this Section. Commercial Laboratories shall obtain Certification for Field Parameter Methods used to generate data that will be reported by the client to the State in accordance with the rules of this Section. Municipal and Industrial laboratories shall obtain Certification for Field Parameter Methods used to generate data that will be reported to the State in accordance with the rules of this Section.

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

(1) Acidity;
(2) Alkalinity;
(3) Biochemical Oxygen Demand;
(4) Bromide;
(5) Carbonaceous Biochemical Oxygen Demand;
(6) Chemical Oxygen Demand;
(7) Chloride;
(8) Chlorine, Free Available;
(9) Chlorine, Total Residual;
(10) Chlorophyll;
(11) Coliform, Fecal;
(12) Coliform, Total;
(13) Color;
(14) Conductivity/Specific Conductance;
(15) Cyanide;
(16) Dissolved Organic Carbon;
(17) Dissolved Oxygen;
(18) Enterococci;
(19) Escherichia Coliform (E. coli);
(20) Flash Point;
(21) Fluoride;
(22) Hardness, Total;

(23) Ignitability;
(24) Surfactants as Methylene Blue Active Surfactants;
(25) Nitrogen, Ammonia;
(26) Nitrogen, Nitrite plus Nitrate;
(27) Nitrogen, Nitrate;
(28) Nitrogen, Nitrite;
(29) Nitrogen, Total Kjeldahl;
(30) Oil and Grease;
(31) Orthophosphate;
(32) Paint Filter Liquids;
(33) pH;
(34) Phenols;
(35) Phosphorus, Total;
(36) Residue, Settleable;
(37) Residue, Total;
(38) Residue, Total Dissolved;
(39) Residue, Total Suspended;
(40) Residue, Volatile;
(41) Salinity;
(42) Salmonella;
(43) Silica;
(44) Sulfate;
(45) Sulfide;
(46) Sulfite;
(47) Temperature;
(48) Total Organic Carbon;
(49) Turbidity;
(50) Vector Attraction Reduction: Option 1;
(51) Vector Attraction Reduction: Option 2;
(52) Vector Attraction Reduction: Option 3;
(53) Vector Attraction Reduction: Option 4;
(54) Vector Attraction Reduction: Option 5;
(55) Vector Attraction Reduction: Option 6;
(56) Vector Attraction Reduction: Option 7;
(57) Vector Attraction Reduction: Option 8; and
(58) Vector Attraction Reduction: Option 12.

(c) Metals: Each of the metals listed in this Paragraph shall be considered a certifiable Parameter. One or more Parameter Methods shall be listed with a laboratory's certified Parameters. Analytical methods shall be determined from the sources listed in Rule .0805(a)(1) of this Section. Certifiable metals are as follows:

(1) Aluminum;
(2) Antimony;
(3) Arsenic;
(4) Barium;
(5) Beryllium;
(6) Boron;
(7) Cadmium;
(8) Calcium;
(9) Chromium, Hexavalent (Chromium VI);
(10) Chromium, Total;
(11) Chromium, Trivalent (Chromium III);
(12) Cobalt;
(13) Copper;
(14) Hardness, Total (Calcium + Magnesium);
(15) Iron;
(16) Lead;
(17) Lithium;
(18) Magnesium;
(19) Manganese;
(20) Mercury;
(21) Molybdenum;
(22) Nickel;
(23) Potassium;
(24) Phosphorus;
(25) Selenium;
(26) Silica;
(27) Silver;
(28) Sodium;
(29) Strontium;
(30) Thallium;
(31) Tin;
(32) Titanium;
(33) Vanadium; and
(34) Zinc.

(d) Organics: Each of the organic Parameters listed in this Paragraph shall be considered a certifiable Parameter. One or more Parameter Methods shall be listed with a laboratory's certified Parameters. Analytical methods shall be determined from the sources listed in Rule .0805(a)(1) of this Section. Certifiable organic Parameters are as follows:

(1) 1,2-Dibromoethane (EDB); 1,2-Dibromo-3-chloro-propane (DBCP); 1,2,3-Trichloropropane (TCP);
(2) Acetonitrile;
(3) Acrolein, Acrylonitrile;
(4) Adsorbable Organic Halides;
(5) Base/Neutral and Acid Organics;
(6) Benzidines;
(7) Chlorinated Acid Herbicides;
(8) Chlorinated Hydrocarbons;
(9) Chlorinated Phenolics;
(10) Explosives;
(11) Extractable Petroleum Hydrocarbons;
(12) Haloethers;
(13) N-Methylcarbamates;
(14) Nitroaromatics and Isophorone;
(15) Nitrosamines;
(16) Nonhalogenated Volatile Organics;
(17) Organochlorine Pesticides;
(18) Organophosphorus Pesticides;
(19) Per- and polyfluoroalkyl substances (PFAS);
~~(19)~~ (20) Phenols;
~~(20)~~ (21) Phthalate Esters;
~~(21)~~ (22) Polychlorinated Biphenyls;
~~(22)~~ (23) Polynuclear Aromatic Hydrocarbons;
~~(23)~~ (24) Purgeable Aromatics;
~~(24)~~ (25) Purgeable Halocarbons;
~~(25)~~ (26) Purgeable Organics;
~~(26)~~ (27) Total Organic Halides;
~~(27)~~ (28) Total Petroleum Hydrocarbons – Diesel Range Organics;
~~(28)~~ (29) Total Petroleum Hydrocarbons – Gasoline Range Organics; and
~~(29)~~ (30) Volatile Petroleum Hydrocarbons.

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(10);
Eff. February 1, 1976;

Amended Eff. November 2, 1992; December 1, 1984;
Temporary Amendment Eff. October 1, 2001;
Amended Eff. August 1, 2002;
Readopted Eff. July 1, 2019.
Amended Eff. XXXXXXXX.