

## 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. Emerging contaminant Parameters broadly known as “Per- and Polyfluoroalkyl Substances (PFAS)” and “Organic Fluorine” are not currently listed in Rule 15A NCAC 02H .0804. This precludes laboratories from producing certified regulatory data for these Parameters for North Carolina permits. The aforementioned Parameters must be added to the Rule for permittees to submit this type data in compliance with permits requiring regulatory data to be produced by a certified laboratory.

### 2. Background

A multitude of emerging contaminants broadly known as “Per- and Polyfluoroalkyl Substances (PFAS)” are of great concern for NC regulators and the general public at large. DEQ anticipates that permitted facilities will be required to test for this class of compounds in the near future as a result of NPDES permit conditions and the Environmental Protection Agency’s (EPA) expected publication of an approved test method for PFAS by the end of 2022. NPDES permits section (D)(4) states, in part:

“Laboratories used for sample analysis must be certified by the Division. Permittees should contact the Division’s Laboratory Certification Section (919 733-3908 or <http://portal.ncdenr.org/web/wq/lab/cert>) for information regarding laboratory certifications... Test procedures for the analysis of pollutants shall conform to the EMC regulations (published pursuant to NCGS 143-215.63 et. seq.), the Water and Air Quality Reporting Acts, and to regulations published pursuant to Section 304(g), 33 USC 1314, of the CWA (as amended), and 40 CFR 136; or in the case of sludge use or disposal, approved under 40 CFR 136, unless otherwise specified in 40 CFR 503, unless other test procedures have been specified in this permit [40 CFR 122.41]”.

The publication of EPA method 1633 “Analysis of Per- and Polyfluoroalkyl Substances (PFAS) in Aqueous, Solid, Biosolids, and Tissue Samples by LC-MS/MS” together with the anticipation of regulatory PFAS monitoring requirements will require reporting of certified data for 40 PFAS target analytes. The Parameter known as “PFAS” is not currently codified in Certification rule 02H .0804(d); as such, the NC WW/GW Laboratory Certification Branch does not currently have the authority to certify laboratories for this Parameter. Adding this Parameter to the Certification rule is a necessary precursor to allowing commercial, municipal and industrial laboratories to request certification from the State.

Analysis of “Organic Fluorine” provides an aggregate measurement of chemical substances that contain carbon-fluorine bonds. This analysis is especially useful for understanding the presence and forms of PFAS in wastewater when used in conjunction with methods that target individual PFAS compounds. This analysis may also be useful in confirming the need for remediation of sites where PFAS contaminated is suspected. The NC WW/GW Laboratory Certification Branch does not currently have the authority to certify laboratories for the Parameter known as “Organic Fluorine;” as such, this Parameter must be added to Certification rule 15A NCAC 02H .0804 (d).

### **3. 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).

### **4. Proposed Amendments**

#### **15A NCAC 02H .0804 (d) (17)**

The proposed rule change adds the Organic Fluorine Parameter to the list of certifiable organic Parameters in anticipation of regulatory monitoring requirements.

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

The proposed rule adds the Per- and Polyfluoroalkyl Substances (PFAS) Parameter to the list of certifiable organic Parameters in anticipation of regulatory monitoring requirements for PFAS.

### **5. Impact Summary**

#### **Impact on Regulated Community:**

##### *NPDES Permittees*

The proposed rules do 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 rules will allow facilities to comply

with permits that require PFAS and/or Organic Fluorine monitoring to be performed by a certified laboratory. NPDES permittees include commercial, industrial and municipal entities. Once EPA publishes approved methods for these Parameters, NPDES permittees will have six months to identify a certified laboratory and begin reporting certified data. The adoption of these two Parameters into state rule will allow permittees to avoid issues of noncompliance with their permits related to monitoring for PFAS/Organic Fluorine. If the proposed Parameters are not adopted into state rule in a timely manner – and the EPA publishes approved methods for the Parameters -- permittees would be at risk of being out of compliance with their monitoring requirements. Permittees would still be required to begin 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 in these Parameters, and 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 and are already over the minimum annual fee. Fees for becoming certified and/or adding Parameter Methods once already certified are detailed in rule 15A NCAC 02H .0806. There are currently 215 non-Field laboratories that would be eligible to add methods under the new Parameters. Of these 215 laboratories, 42 laboratories are currently certified for organic Parameters. Laboratories not currently certified would pay an additional \$300.00 application fee and at least the minimum certification fee of \$1,750 for Municipal and Industrial laboratories and \$3,500 for Commercial laboratories. Municipal and Industrial laboratories requesting more than 20 Parameters in an initial application would pay a minimum fee of \$85 multiplied by the number of Parameters. Commercial laboratories requesting more than 41 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 and software needed to perform analyses under these new Parameters is extremely low. The likelihood of Commercial laboratories having or investing in the needed equipment 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.

The technology required for the Adsorbable Organic Fluorine method 1621 is not utilized by any other method within the Certification Branch's current scope. The PFAS method 1633 requires 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 42 laboratories that are certified to perform organic analyses. The 42 currently certified commercial laboratories were polled to gauge their interest in becoming certified

for either PFAS and/or Organic Fluorine. Of those 42 laboratories, 36 provided responses; 11 expressed interest in becoming certified for PFAS and of those 11, 2 expressed interest in also becoming certified for Organic Fluorine. Based on inquiries received by the Certification Branch, we also expect a small number of additional out-of-state laboratories that are not currently certified to request certification for these Parameters. The costs to these additional laboratories would be higher. Table 1 contains a summary of the potential likely maximum costs to commercial laboratories. These costs would largely be incurred in the first year following adoption of the rule.

Table 1: Initial Certification Costs Attributable to PFAS/Organic Fluorine Certification for Commercial Laboratories

	Certified laboratory* *Assumes laboratory will certify for both PFAS and Organic Fluorine	Non-certified laboratory* *Assumes laboratory will certify for both PFAS and Organic Fluorine
Parameter Method Fee	\$85 per Parameter method	\$0  (possible, but unlikely, could be more if requesting certification for 42 or more Parameters)
Application Fee	N/A	\$300
Certification Fee	N/A	\$3,500 (possible, but unlikely, that could be more if requesting a total of 42 or more Parameters)
Estimated # of Laboratories	Eleven (11)	One (1) - It is possible there could be more than one, but to date, only one laboratory has contacted the Certification Branch.
Total estimated # of Parameter Methods for which Labs will seek certification	Thirteen (13)	Two (2)
Total initial cost to interested laboratories	<b>\$1,105</b> (13 Parameter Methods x \$85 fee)	<b>\$3,800</b> (\$300 Application fee + \$3,500 minimum Certification fee x 1 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 these Parameters, we focus on costs to Commercial laboratories. For Commercial laboratories, the minimum annual fee is \$3,500, unless they hold certification for more than 41 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/Organic Fluorine certification. It should be noted that except for laboratories that are certified only for PFAS and Organic Fluorine, the annual costs attributable to certification for PFAS and Organic Fluorine would be between \$0 and \$170.

Table 2: Ongoing/Annual Costs Attributable to PFAS/Organic Fluorine Certification for Certified Commercial Laboratories that Have Expressed Interest

	Laboratories certified only for PFAS and Organic Fluorine	Laboratories already certified for other Parameters in addition to PFAS and Organic Fluorine*
Annual Fee (portion of annual fee that is attributable to PFAS/Organic Fluorine certification)	\$3,500	\$0 for those certified for 41 or fewer Parameters \$85 for those already over the minimum fee and adding one Parameter \$170 for those already over the minimum fee and adding both Parameters *Certified labs pay a minimum annual \$3,500 fee for up to 41 Parameters. These labs are already subject to this minimum fee; as such, the \$3,500 is not attributable to the proposed rule change.
Estimated # of Laboratories (max)	1	3 currently certified for 39 or fewer parameters 8 currently certified for 42 or more Parameters
Maximum additional annual cost to already certified laboratories, assuming they add both Parameters	N/A	<b>\$1,360</b> [(3 labs x \$0) + (8 labs x \$170)]
Maximum annual cost to newly-certified laboratories, assuming they add only these 2 new Parameters	<b>\$3,500</b>	N/A

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 either of these Parameters, 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. Sources at the EPA that were involved with the validation study for the Adsorbable Organic Fluorine method 1621 report that the cost of the major equipment required for startup of Organic Fluorine analysis was approximately \$200,000, not including consumable supplies and standards.

It is presumed that commercial laboratories that choose to become certified for these Parameters 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/or Organic Fluorine 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/Organic Fluorine in the future (as a result of the EPA action to approve the methods), 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 and Organic Fluorine 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 EPA 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 the new Parameter Methods and auditing the procedures during an inspection. For each 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 \$38 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 42 currently certified commercial laboratories were polled to gauge their interest in becoming certified for either PFAS and/or Organic Fluorine. Of those 42 laboratories, 36 provided responses. Of the 36 that responded, only 11 have expressed interest in becoming certified for PFAS, and 2 of those 11 also expressed interest in also becoming certified for Organic Fluorine. Taking this level of interest into account, if each review for each Parameter Method takes 10 hours, that equates to 130 staff hours at a total staff time cost of \$4,940.

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 has already been one inquiry from an out-of-state laboratory that does not currently hold NC Certification. The cost 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 EPA publication of the approved methods, 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. As a consequence 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 is 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 either of these two Parameters 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 \$38/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. The maximum total initial benefit in terms of fees collected would be \$4,905 and the maximum ongoing benefit in terms of additional renewal fees collected would be \$4,860.

### *NPDES Program Staff*

The proposed addition of the two Parameters will not require the NPDES Program to revise their existing procedures. There are NPDES permits that already contain requirements related to PFAS testing that will be triggered once the EPA publishes a method, so NPDES staff will not be required to make changes to existing permits. In addition, NPDES 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 these two Parameters will ensure that DEQ receives certified PFAS and/or Organic Fluorine 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 these Parameters will also allow the NPDES Program 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 NPDES 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 amendments do 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 amendments. The benefit to the regulated community would be that there would be laboratories certified to do the analyses and thereby allow the permittees to be in compliance with the permit requirements .

The proposed amendments will create an opportunity for commercial laboratories to be certified for these two Parameter methods. 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 methods. The benefit would be added revenue to the Certification Branch's completely fee-funded budget. There could be benefits to the NPDES Program 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 where these two contaminants of concern are 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.