Burgos, Alexander N

Subject: FW: [External] Fwd: Request for changes to the Environmental Management Commission Regulation 15A NCAC 02L.0101
Attachments: 2022-05-10 ERT LTR.pdf

From: Tyer, Sara <styer@williamsmullen.com>
Sent: Tuesday, May 10, 2022 12:52 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: [External] Fwd: Request for changes to the Environmental Management Commission Regulation 15A NCAC 02L.0101

Mr. Liebman –
Please see below/attached.

Thank you,
Sara

Get Outlook for iOS

From: Tyer, Sara <styer@williamsmullen.com>
Sent: Tuesday, May 10, 2022 12:11 PM
To: rrc.comments@oah.nc.gov <rrc.comments@oah.nc.gov>; brian.liebman@oah.ne.gov <brian.liebman@oah.ne.gov>
Cc: Ware, Ethan <eware@williamsmullen.com>; Talty, Ceanne <jtalty@williamsmullen.com>
Subject: Request for changes to the Environmental Management Commission Regulation 15A NCAC 02L.0101

Please see the attached correspondence which is being sent to you on behalf of Ethan Ware. A copy of the same is being sent via US Certified Mail.

Thank you,

Sara Hopkins Tyer | Paralegal | Williams Mullen
FIRST CITIZENS BANK BUILDING | 1230 MAIN STREET | SUITE 330 | Columbia, SC 29201
T 803.567.4603 | C 803.556.1212 | F 803.567.4601 | styer@williamsmullen.com | www.williamsmullen.com

WILLIAMS MULLEN

Ethan R. Ware
Direct Dial: 803.567.4610
eware@williamsmullen.com

May 10, 2022

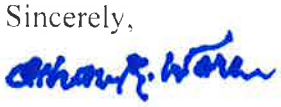
VIA US CERTIFIED MAIL and E-MAIL
Office of Administrative Hearings, Rules Division
1711 New Hope Church Road
Raleigh, NC 27609
rrc.comments@oah.nc.gov
brian.liebman@oah.nc.gov

Re: Request for changes to the Environmental Management Commission Regulation 15A NCAC 02L.0101

Dear Office of Administrative Hearings, Rules Division:

Enclosed please find two copies of public comments we would like to have included in the Administrative Record in response to Request for changes to Environmental Management Commission Regulation 15A NCAC 012L.0101. Please do not hesitate to contact our office if you have any questions or concerns.

Sincerely,



Ethan R. Ware

ERW/ct
Enclosure

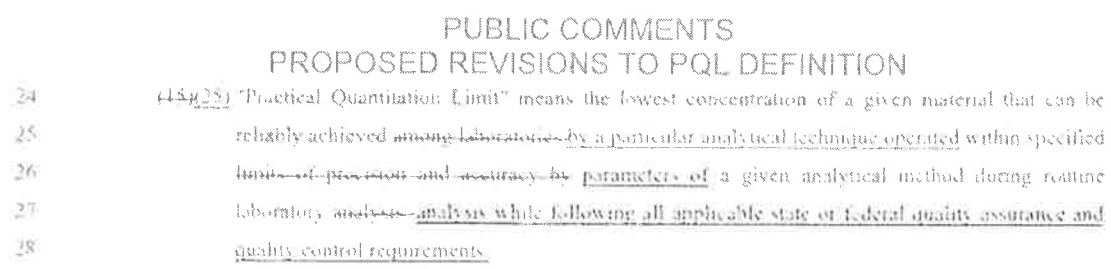
PUBLIC COMMENTS
PROPOSED REVISIONS TO PQL DEFINITION

Williams Mullen of Raleigh, North Carolina, represents mining and manufacturing interests throughout the State of North Carolina, which are subject to water quality standards (WQS) enforced by North Carolina Department of Environmental Quality (DEQ). On behalf of those North Carolina mining and industries, Williams Mullen requests these public comments be included in the Administrative Record in response to Request for Changes to Environmental Management Commission Regulation15A NCAC 02L .0101 ("Draft Rev. WQS"). [N.C.G.S. 150B-21.10 and 150B-21.9.1]. The deadline to submit comments is May 12, 2022.

PROPOSED DRAFT REV. WQS:

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. DEQ prepared draft rules and solicited input on the proposed actions from internal and external stakeholders in 2021 as part of the most recent 10 years review. Certain changes to Draft Rev. WQS were suggested in response to initial feedback from stakeholders and included in "Request for Changes Pursuant to N.C.G.S. 150B-21.10." See, https://files.nc.gov/ncoah/documents/Rules/RRC/05192022-Environmental-Management-Commission.pdf ("Request for Changes").

The Request for Changes specifically include proposed changes to the scope and definition of practical quantitation limit (PQL) in 15A NCAC 02L .0102 DEFINITIONS. The suggested revisions to PQL are set forth below:



https://files.nc.gov/ncoah/documents/Rules/RRC/05192022-Environmental-Management-Commission.pdf, p. 2 of 3. This is identified as the "Proposed PQL" throughout these comments.

PUBLIC COMMENT: EMA SHOULD DECLINE TO AMEND THE DEFINITION OF PQL AS PROPOSED BY THE REQUEST FOR CHANGES

The Draft Rev. WQS definition of Proposed PQL should be denied because it cedes the State's oversight of WQS to third parties not subject to DEQ review, contradicts existing North Carolina regulatory guidelines governing PQLs, and is so overly broad and vague to be unenforceable.

Groundwater Proposed PQLs

The Division of Water Resources' Classifications, Standards & Rules Review Branch is responsible for the development and maintenance of North Carolina's groundwater WQS. Regulations pertaining to WQS in North Carolina are set out in Title 15A of the North Carolina Administrative Code, Subchapter 2L, Sections .0100, .0200, .0300 and .0400.

For pollutants discharged to waters of the State, DEQ promulgated a WQSs, including WQSs for groundwaters. "Groundwater WQS are the maximum allowable concentrations of contaminants in groundwater which may be tolerated without creating a threat to human health or which would otherwise render the groundwater unsuitable for

use as a drinking water source." https://deq.nc.gov/about/divisions/water-resources/water-sciences/chemistry-laboratory/quality-assurance.

Each analytical procedure for measuring the level of pollutants subject to a WQS has a PQL. The PQL is "the lowest concentration that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions." Id. PQLs are set at some multiple of typical Method Detection Limits (MDLs) for reagent water (generally 3 to 5 times the MDL). Id. "The established PQL for a procedure serves as a reliable and routinely achievable reporting limit for a biological or chemical parameter." Id.

Where the WQS for a substance is less than the PQL in North Carolina, the detection of a substance at or above the PQL constitutes a violation of the WQS. Therefore, the Proposed WQS is a revision to the WQS for those pollutants with WQS less than PQLs.

Comment No. 1: Proposed PQL Cedes State Oversight of WQS

Under established North Carolina law, DEQ evaluates and sets WQS. The Quality Assurance (QA) unit of DEQ, Water Sciences Section (WSS) "is responsible for establishing, implementing and coordinating a comprehensive Quality Assurance/Quality Control (QA/QC) program for environmental sample analyses performed [in North Carolina to meet State standards]." Id. To that end, the policies and procedures for setting PQLs (and thereby WQS) in North Carolina as approved by EPA in 2017 are set out in "Quality Assurance Manual for the North Carolina Division of Water Quality

Laboratory Section" (June 30, 2015) ("QA Manual"). See, https://deq.nc.gov/media/9416/download.

The QA Manual states it is the responsibility of DEQ and WSS to set forth reliable PQL processes and procedures sufficient to protect water quality of the State:

> The Water Sciences Section provides analytical and technical support to the divisions and programs within the Department of Environment and Natural Resources. To ensure that the results produced and reported meet the requirements of the data users and comply with state and federal regulations, a quality management system has been implemented that is clear, effective, well-communicated, and supported at all levels of the Division. The Quality Assurance Manual (QAM) details the quality assurance (QA) program in effect at the DWR laboratories. The primary purpose of this document is to establish and maintain uniform operational and quality control procedures and to ensure data is of a known and documented quality.

QA Manual, Section 3.0, p.8 (emphasis added).

The Proposed PQL undermines this authority and cedes it to unknown third parties, who may draft or develop "analytical and technical" guidelines inconsistent with the DEQ and WSS approach. It does this by replacing the entity responsible for determining PQL; the Proposed PQL would require PQL determinations be made by referring to "a particular analytical technique" and no longer "among laboratories" regulated by DEQ and WSS under the QA Manual. Because these unidentified "techniques" would not be subject to scrutiny by DEQ and WSS, the State loses control of the important analytical and technical quality assurances necessary for a qualified PQL program.

This also jeopardizes DEQ authority to run the WQS program in lieu of EPA. Under Federal law, WQS (for surface waters) must be reviewed and approved by EPA after public review and comment. Sections 301 to 303 Clean Water Act, 33 USC 1301 to 1303.

Since PQLs may be WQSs in certain circumstances, these unidentified PQLs process will require EPA review and approval; EPA granted approval of the existing PQLs process in the QA Manual in 2017. There is no information or way to know if or when EPA would or may approve unidentified "techniques" referenced in the Proposed PQL and whether or not they have been through the required public comment and review. That could result in DEQ enforcing PQLs as WQS, which are not subject to public comment and review or EPA approval.

Comment No. 2: Proposed PQL Contradicts DEQ Guidelines

The QA Manual contradicts the suggested approach in the Proposed PQL regulation. There is no room for shedding laboratory expertise required by the QA Manual in favor of "techniques" in literature and not tested in the North Carolina laboratory setting as required.

The current approach to PQL in North Carolina requires the laboratory evaluate the analyte and determine if the required "precision and accuracy" can be achieved and at what measurement levels consistently "among laboratories". This is important. The QA Manual makes sure this PQL process meets State standards or the laboratory is not certified in the State of North Carolina, regardless of the techniques it uses. This certification process relies on a case by case review of the laboratories, which is no longer necessary or relevant if the PQL is decided based on 'techniques" unknown to the State or the laboratory.

The factors required to be validated by the QA Manual when PQLs set are necessary to produce a valid PQL and thereby a valid WQS when required. Unlike

techniques discussed in various trade journals, the PQL involve evaluation of the reliability of the specific laboratory instruments and technology involved taking into account (1) the method detection limit (MDL) established by EPA methods, (2) the quality and age of the instrument, and (3) the nature of the samples. QA Manual, Section 5.5, p.35. The QA Manual states "PQLs often must be nominally chosen based on best professional judgment using these guidelines." Id. According the QA Manual, the PQLs should equal the "concentration of the lowest non-zero standard in the calibration curve," and this may only be done where evaluation of the equipment using this process is involved. Id.

Moreover, unlike "techniques" from literature, PQLs in North Carolina are to be adjusted for sample size, dilution and percentage moisture—factors that can only be determined by a laboratory on a case by case basis. Id. The PQL could be defined by the sample volume and buret graduations for titrations or by minimum measurement values set by the method for method-defined parameters (e.g., BOD requires a minimum DO depletion of 2.0 mg/L, fecal coliform requires a minimum plate count of 20 cfu, total suspended residue requires a minimum weight gain of 2.5 mg, etc.) all of which are dependent on strict lab-specific procedures being followed. Id. Some EPA methods actually require certain laboratory analytical Standard Operating Procedure (SOP) be demonstrated, and the techniques approach would avoid that protection.

Comment No. 3: Proposed PQL is Internally Inconsistent

The Proposed PQL cannot be adopted as written because it is also internally inconsistent and so overly vague as to be unenforceable. Accordingly, if adopted DEQ would sanction default WQSs with no objective measurements.

First, key terms are undefined, which would make the use of "techniques" unworkable. The term "particular analytical technique" is not explained in a regulation, so PQLs and default WQS would rely on unspecified (and unknown and untested) techniques in any literature, which violates applicable guidelines in North Carolina law that state expressly PQLs are the "lowest concentration that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions." Id.(emphasis added). "Specified parameters" must be followed under the Proposed PQL, but none are included.

Second, there would be no certainty of what specific technique governs and each technique would be subject to constant change. The advantage of following the current model of requiring PQLs be set by a qualified laboratory procedure, is the State oversees that process pursuant to the QA Manual; lab certification can be vacated if a laboratory does not follow those guidelines. However, the Proposed PQL would allow any industry, community group, or laboratory to rely on a "analytical technique" in setting PQLs and default WQS without any State oversight. Techniques may change or be vacated, which further complicates the analysis, since it would encourage "technique shopping" in order

for the interested party to obtain a desired result. This contradicts the requirement for PQLs and WQSs to be specified and exhibit precision.

Finally, no facility can comply with this new Proposed PQL. It enforces use of "analytical technique[s]...while following all applicable state and federal quality assurance and quality control requirements." This is internally inconsistent in the following ways:

1. DEQ WSS requirements in the QA Manual mandate PQLs be set on a case-by-case basis by evaluation of the laboratory procedures, QA Manual, Section 5.5, p. 35, while the Propose PQL relies on literature (i.e. "analytical techniques") not identified or reviewed by DEQ WSS; and

2. The Proposed PQL does not identify the "specified parameters" within which the technique to be used must operate, which means there is no way to know if the "specified parameters" in the technique are sufficient to meet the QA Manual standards.

REQUESTED ACTION: DENY ADOPTION OF PROPOSED PQL

Based on these comments, it is respectfully requested the EMC deny the Proposed PQL in favor of the existing program established in North Carolina for defined and defensible PQLs and default WQSs.

Submitted this 6th day of May, 2022.

Ethan R. Ware

Ethan R. Ware, Esquire
Williams Mullen
1230 Main Street, Suite 330
Columbia, South Carolina, 29201

PUBLIC COMMENTS
PROPOSED REVISIONS TO PQL DEFINITION

Williams Mullen of Raleigh, North Carolina, represents mining and manufacturing interests throughout the State of North Carolina, which are subject to water quality standards (WQS) enforced by North Carolina Department of Environmental Quality (DEQ). On behalf of those North Carolina mining and industries, Williams Mullen requests these public comments be included in the Administrative Record in response to Request for Changes to Environmental Management Commission Regulation15A NCAC 02L .0101 ("Draft Rev. WQS"). [N.C.G.S. 150B-21.10 and 150B-21.9.1]. The deadline to submit comments is May 12, 2022.

PROPOSED DRAFT REV. WQS:

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. DEQ prepared draft rules and solicited input on the proposed actions from internal and external stakeholders in 2021 as part of the most recent 10 years review. Certain changes to Draft Rev. WQS were suggested in response to initial feedback from stakeholders and included in "Request for Changes Pursuant to N.C.G.S. 150B-21.10." See, https://files.nc.gov/ncoah/documents/Rules/RRC/05192022-Environmental-Management-Commission.pdf ("Request for Changes").

The Request for Changes specifically include proposed changes to the scope and definition of practical quantitation limit (PQL) in 15A NCAC 02L .0102 DEFINITIONS. The suggested revisions to PQL are set forth below:

PUBLIC COMMENTS
PROPOSED REVISIONS TO PQL DEFINITION

(15A 25) "Practical Quantitation Limit" means the lowest concentration of a given material that can be reliably achieved ~~among laboratories~~ by a particular analytical technique operated within specified ~~limits of precision and accuracy by~~ parameters of a given analytical method during routine laboratory ~~analysis~~ analysts while following all applicable state or federal quality assurance and quality control requirements.

https://files.nc.gov/ncoah/documents/Rules/RRC/05192022-Environmental-Management-Commission.pdf, p. 2 of 3. This is identified as the "Proposed PQL" throughout these comments.

PUBLIC COMMENT: EMA SHOULD DECLINE TO AMEND THE DEFINITION OF PQL AS PROPOSED BY THE REQUEST FOR CHANGES

The Draft Rev. WQS definition of Proposed PQL should be denied because it cedes the State's oversight of WQS to third parties not subject to DEQ review, contradicts existing North Carolina regulatory guidelines governing PQLs, and is so overly broad and vague to be unenforceable.

Groundwater Proposed PQLs

The Division of Water Resources' Classifications, Standards & Rules Review Branch is responsible for the development and maintenance of North Carolina's groundwater WQS. Regulations pertaining to WQS in North Carolina are set out in Title 15A of the North Carolina Administrative Code, Subchapter 2L, Sections .0100, .0200, .0300 and .0400.

For pollutants discharged to waters of the State, DEQ promulgated a WQSs, including WQSs for groundwaters. "Groundwater WQS are the maximum allowable concentrations of contaminants in groundwater which may be tolerated without creating a threat to human health or which would otherwise render the groundwater unsuitable for

use as a drinking water source." https://deq.nc.gov/about/divisions/water-resources/water-sciences/chemistry-laboratory/quality-assurance.

Each analytical procedure for measuring the level of pollutants subject to a WQS has a PQL. The PQL is "the lowest concentration that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions." Id. PQLs are set at some multiple of typical Method Detection Limits (MDLs) for reagent water (generally 3 to 5 times the MDL). Id. "The established PQL for a procedure serves as a reliable and routinely achievable reporting limit for a biological or chemical parameter." Id.

Where the WQS for a substance is less than the PQL in North Carolina, the detection of a substance at or above the PQL constitutes a violation of the WQS. Therefore, the Proposed WQS is a revision to the WQS for those pollutants with WQS less than PQLs.

Comment No. 1: Proposed PQL Cedes State Oversight of WQS

Under established North Carolina law, DEQ evaluates and sets WQS. The Quality Assurance (QA) unit of DEQ, Water Sciences Section (WSS) "is responsible for establishing, implementing and coordinating a comprehensive Quality Assurance/Quality Control (QA/QC) program for environmental sample analyses performed [in North Carolina to meet State standards]." Id. To that end, the policies and procedures for setting PQLs (and thereby WQS) in North Carolina as approved by EPA in 2017 are set out in "Quality Assurance Manual for the North Carolina Division of Water Quality

Laboratory Section" (June 30, 2015) ("QA Manual"). See, https://deq.nc.gov/media/9416/download.

The QA Manual states it is the responsibility of DEQ and WSS to set forth reliable PQL processes and procedures sufficient to protect water quality of the State:

> The Water Sciences Section provides analytical and technical support to the divisions and programs within the Department of Environment and Natural Resources. To ensure that the results produced and reported meet the requirements of the data users and comply with state and federal regulations, a quality management system has been implemented that is clear, effective, well-communicated, and supported at all levels of the Division. The Quality Assurance Manual (QAM) details the quality assurance (QA) program in effect at the DWR laboratories. The primary purpose of this document is to establish and maintain uniform operational and quality control procedures and to ensure data is of a known and documented quality.

QA Manual, Section 3.0, p.8 (emphasis added).

The Proposed PQL undermines this authority and cedes it to unknown third parties, who may draft or develop "analytical and technical" guidelines inconsistent with the DEQ and WSS approach. It does this by replacing the entity responsible for determining PQL; the Proposed PQL would require PQL determinations be made by referring to "a particular analytical technique" and no longer "among laboratories" regulated by DEQ and WSS under the QA Manual. Because these unidentified "techniques" would not be subject to scrutiny by DEQ and WSS, the State loses control of the important analytical and technical quality assurances necessary for a qualified PQL program.

This also jeopardizes DEQ authority to run the WQS program in lieu of EPA. Under Federal law, WQS (for surface waters) must be reviewed and approved by EPA after public review and comment. Sections 301 to 303 Clean Water Act, 33 USC 1301 to 1303.

Since PQLs may be WQSs in certain circumstances, these unidentified PQLs process will require EPA review and approval; EPA granted approval of the existing PQLs process in the QA Manual in 2017. There is no information or way to know if or when EPA would or may approve unidentified "techniques" referenced in the Proposed PQL and whether or not they have been through the required public comment and review. That could result in DEQ enforcing PQLs as WQS, which are not subject to public comment and review or EPA approval.

Comment No. 2: Proposed PQL Contradicts DEQ Guidelines

The QA Manual contradicts the suggested approach in the Proposed PQL regulation. There is no room for shedding laboratory expertise required by the QA Manual in favor of "techniques" in literature and not tested in the North Carolina laboratory setting as required.

The current approach to PQL in North Carolina requires the laboratory evaluate the analyte and determine if the required "precision and accuracy" can be achieved and at what measurement levels consistently "among laboratories". This is important. The QA Manual makes sure this PQL process meets State standards or the laboratory is not certified in the State of North Carolina, regardless of the techniques it uses. This certification process relies on a case by case review of the laboratories, which is no longer necessary or relevant if the PQL is decided based on 'techniques" unknown to the State or the laboratory.

The factors required to be validated by the QA Manual when PQLs set are necessary to produce a valid PQL and thereby a valid WQS when required. Unlike

techniques discussed in various trade journals, the PQL involve evaluation of the reliability of the specific laboratory instruments and technology involved taking into account (1) the method detection limit (MDL) established by EPA methods, (2) the quality and age of the instrument, and (3) the nature of the samples. QA Manual, Section 5.5, p.35. The QA Manual states "PQLs often must be nominally chosen based on best professional judgment using these guidelines." Id. According the QA Manual, the PQLs should equal the "concentration of the lowest non-zero standard in the calibration curve," and this may only be done where evaluation of the equipment using this process is involved. Id.

Moreover, unlike "techniques" from literature, PQLs in North Carolina are to be adjusted for sample size, dilution and percentage moisture—factors that can only be determined by a laboratory on a case by case basis. Id. The PQL could be defined by the sample volume and buret graduations for titrations or by minimum measurement values set by the method for method-defined parameters (e.g., BOD requires a minimum DO depletion of 2.0 mg/L, fecal coliform requires a minimum plate count of 20 cfu, total suspended residue requires a minimum weight gain of 2.5 mg, etc.) all of which are dependent on strict lab-specific procedures being followed. Id. Some EPA methods actually require certain laboratory analytical Standard Operating Procedure (SOP) be demonstrated, and the techniques approach would avoid that protection.

Comment No. 3: Proposed PQL is Internally Inconsistent

The Proposed PQL cannot be adopted as written because it is also internally inconsistent and so overly vague as to be unenforceable. Accordingly, if adopted DEQ would sanction default WQSs with no objective measurements.

First, key terms are undefined, which would make the use of "techniques" unworkable. The term "particular analytical technique" is not explained in a regulation, so PQLs and default WQS would rely on unspecified (and unknown and untested) techniques in any literature, which violates applicable guidelines in North Carolina law that state expressly PQLs are the "lowest concentration that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions." Id.(emphasis added). "Specified parameters" must be followed under the Proposed PQL, but none are included.

Second, there would be no certainty of what specific technique governs and each technique would be subject to constant change. The advantage of following the current model of requiring PQLs be set by a qualified laboratory procedure, is the State oversees that process pursuant to the QA Manual; lab certification can be vacated if a laboratory does not follow those guidelines. However, the Proposed PQL would allow any industry, community group, or laboratory to rely on a "analytical technique" in setting PQLs and default WQS without any State oversight. Techniques may change or be vacated, which further complicates the analysis, since it would encourage "technique shopping" in order

for the interested party to obtain a desired result. This contradicts the requirement for PQLs and WQSs to be specified and exhibit precision.

Finally, no facility can comply with this new Proposed PQL. It enforces use of "analytical technique[s]...while following all applicable state and federal quality assurance and quality control requirements." This is internally inconsistent in the following ways:

1. DEQ WSS requirements in the QA Manual mandate PQLs be set on a case-by-case basis by evaluation of the laboratory procedures, QA Manual, Section 5.5, p. 35, while the Propose PQL relies on literature (i.e. "analytical techniques") not identified or reviewed by DEQ WSS; and

2. The Proposed PQL does not identify the "specified parameters" within which the technique to be used must operate, which means there is no way to know if the "specified parameters" in the technique are sufficient to meet the QA Manual standards.

REQUESTED ACTION: DENY ADOPTION OF PROPOSED PQL

Based on these comments, it is respectfully requested the EMC deny the Proposed PQL in favor of the existing program established in North Carolina for defined and defensible PQLs and default WQSs.

Submitted this 6th day of May, 2022.

Ethan R. Ware, Esquire
Williams Mullen
1230 Main Street, Suite 330
Columbia, South Carolina, 29201