

Comments on Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Analysis and Sampling Procedures

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The NELAC Institute (TNI) is a 501(c)(3) non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community.

TNI manages the National Environmental Laboratory Accreditation Program (NELAP). Currently, 15 state agencies are recognized by TNI as Accreditation Bodies. TNI's Accreditation Bodies are responsible for ensuring the competency of environmental testing laboratories, including those analyzing waste water under the National Pollutant Discharge Elimination System (NPDES) program. Over 2000 laboratories are accredited under NELAP.

TNI also manages a Consensus Standards Development Program. TNI is accredited by the American National Standards Institute as a voluntary consensus standards organization and fully conforms to all requirements in OMB circular A-119.

TNI generally supports the proposed actions published in this proposed rule and is providing comments in only three areas.

1. Citation of NELAC standard

The preamble to the proposed rule stated:

For methods that have insufficient QA/QC requirements, analysts could refer to and follow the QC published in several public sources. Examples of these sources include the instructions in an equivalent approved EPA method or standards published by the National Environmental Laboratory Accreditation Conference (cf. Chapter 5 of the compendium published in 2003.)

The National Environmental Laboratory Accreditation Conference ceased operation in 2007 and the document referenced is now obsolete. TNI suggests the language be revised to read:

For methods that have insufficient QA/QC requirements, analysts could refer to and follow the QC published in several public sources. Examples of these sources include the instructions in an equivalent approved EPA method or standards published by The NELAC Institute (cf. Volume 1: *Management and Technical Requirements for Laboratories Performing Environmental Analyses*.)

2. Method Modifications

TNI is a strong proponent of the performance approach and fully supports the proposed language in 136.6 relative to method modifications.

3. New Quality Assurance and Quality Control Language

TNI commends the Agency on proposing minimum quality control (QC) analyses. TNI has long supported such minimum requirements as essential for improving data quality. However, TNI believes the proposed language at Part 136.7 lacks sufficient detail and as written, will present many problems, both for laboratories and laboratory auditors. TNI has a consensus standard, *Management and Technical Requirements for Laboratories Performing Environmental Analyses*, that represents the best professional practice in the industry, contains sufficient detail for laboratories and laboratory auditors to clearly understand what is required, and defers to QC requirements in mandated methods where such QC requirements exist. Thus, the QC requirements published in methods developed by EPA, ASTM or Standard Methods would apply where such QC requirements exist. Where such requirements do not exist, the TNI standard specifies the minimum requirements. The TNI standard is a consensus standard focused on environmental analyses that “contains the essential elements required to establish a quality system that produces data of known and documented quality.” No other such consensus standard exists and thus under the National Technology Transfer and Advancement Act, TNI believes the Agency should consider using the TNI standard as TNI’s standard is not “inconsistent with applicable law or otherwise impracticable.”

The paragraphs below address each of the 12 proposed mandated requirements.

(1) Demonstration of Capability (DOC)

TNI supports the concept of a Demonstration of Capability (DOC). However, as written, the language is vague. Is this something the laboratory performs one time or annually? Does it apply to the method or to the analyst? What specific procedures are required for a DOC? TNI’s standard contains extensive language concerning DOCs, and requires both an initial DOC and an on-going annual demonstration to demonstrate continued proficiency for each analyst. In addition, TNI outlines a method validation process that must be used to demonstrate the competence of the laboratory. The TNI standard has detailed instructions for what activities should be performed and has appropriate activities for asbestos, chemistry, microbiology, radiochemistry and toxicity laboratories.

(2) Method Detection Limit (MDL)

The proposed language at 136.7 implies that laboratories would have to perform MDL studies for all methods, including methods for parameters such as temperature, pH, BOD, and presence/absence tests for microbiological organisms and effluent toxicity tests. MDL studies are not appropriate for such parameters. Further, if NPDES permitted laboratories are not required to report to the MDL (and many are not) why would the laboratory need to demonstrate this capability? The TNI standard uses the internationally accepted definitions of Limit of Detection (LOD) and Limit of Quantitation (LOQ). Under the TNI standard, if laboratories report data to the LOD, they must perform an LOD study, and more importantly, must verify that the LOD is appropriate. All laboratories must establish an LOQ and verify acceptable precision and accuracy at that concentration. The TNI standard has an exclusion for methods

for parameters such as pH or temperature, where LOD/LOQ studies are inappropriate. The TNI standard also addresses the unique situations for other scientific disciplines such as radiochemistry and whole effluent toxicity.

(3) Laboratory reagent blank (LRB), also referred to as method blank

TNI supports requirements for method blanks to be a minimum QC requirement. However, the proposed language does not describe the frequency of such analyses, what constitutes an acceptable blank result, and what corrective actions should be performed by the laboratory if unacceptable results are observed. Furthermore, the concept of an LRB may not be applicable to tests such as pH or temperature. The TNI standard contains extensive detailed language describing these activities.

(4) Laboratory fortified blank (LFB), also referred to as a spiked blank, or laboratory control sample (LCS)

TNI supports requirements for LCS analyses to be a minimum QC requirement. However, the proposed language does not describe the frequency of such analyses, what constitutes an acceptable result, and what corrective actions should be performed by the laboratory if unacceptable results are observed. While the LCS is applicable to most chemical tests, the concept is not applicable to some microbiological or toxicity tests. The TNI standard contains extensive detailed language describing these activities.

(5) Matrix spike, matrix spike duplicate, or laboratory fortified blank duplicate (LFB/D) for suspected difficult matrices

TNI supports requirements for such activities as matrix spike and matrix spike duplicates for suspected difficult matrices, however, like the LCS, it is not widely applicable to other types of tests. The TNI standard contains language describing these activities including frequency and acceptability.

(6) Internal standards, surrogate standards (for organic analysis) or tracers (for radiochemistry)

TNI supports requirements for such activities as internal standards and surrogates to be essential QC requirements when specified by method. However, the proposed language does not describe the frequency of such analyses, what constitutes an acceptable result, and what corrective actions should be performed by the laboratory if unacceptable results are observed. The TNI standard contains requirements for surrogates.

(7) Calibration (initial and continuing), initial and continuing performance (ICP) solution also referred to as initial calibration verification (ICV) and continuing calibration verification (CCV)

TNI supports requirements for calibration and calibration verification as minimum QC requirements. However, the proposed language does not describe the frequency of such analyses, what constitutes an acceptable result, and what corrective actions should be performed by the laboratory if unacceptable results are observed. The proposed language does not address the differences in calibration requirements for analytical instruments (those that generate a result) and support equipment (e.g., balances, ovens, water baths). The TNI standard contains extensive detailed language describing these activities.

(8) Control charts (or other trend analyses of quality control results)

TNI supports requirements for evaluating QC results to determine the validity of the resulting data.

(9) Corrective action (root cause analyses)

TNI supports the requirements for corrective action. The TNI standard goes even further and discusses requirements for the monitoring of the implementation of the corrective action to ensure that the actions taken are effective. TNI also requires preventative actions and provides details concerning the process.

(10) QC acceptance criteria

TNI agrees that QC acceptance criteria are important. The TNI standard allows established acceptance criteria such as method or laboratory derived limits.

(11) Definitions of a batch (preparation and analytical)

As written, a laboratory could define a batch as all samples analyzed over a one year period and perform the required QC checks once per year. TNI has established both sample preparation and analytical batch requirements.

(12) Minimum frequency for conducting QC checks

TNI agrees that the minimum QC checks must be performed at some frequency. The proposed language does not define the frequency, and thus a laboratory could decide the frequency was once per year, or a laboratory auditor could decide to require a laboratory to perform an MDL study daily. The TNI standard has clearly defined frequencies for QC checks. Some are daily, some are with each batch, and some are annually, as appropriate for the specific QC check.

Other QC Requirements

The 12 items proposed to be added while all essential, do not represent the full extent of activities that laboratories should be required to perform in order to demonstrate that their results are technically valid. The requirements in TNI's standard, which are based on the internationally accepted standard ISO/IEC 17025, *General Requirements for the Competence of Testing and Calibration Laboratories*, contain many more elements addressing issues such as:

- Personnel,
- Accommodation and Environmental Conditions,
- Method Selection and Method Validation,
- Measurement Traceability,
- Collection of Samples,
- Handling Samples, and
- Reporting the Results.

Based on the discussion above, the proposed language does not provide sufficient detail, nor are the quality control measures applicable to all types of monitoring performed under the Clean Water Act and seem to have been written primarily for chemical analyses. Additionally, some of the requirements, as written, would require NPDES auditors to require QC measures that are inconsistent with the requirements under the standard adopted by the National Environmental Laboratory Accreditation Program, and are, in some cases, impossible to perform.

While TNI applauds the agency's recognition of essential quality controls to document the quality of the generated data, these measures should be written with enough specificity to allow reasonable requirements for each test type. An undertaking such as this would be tantamount to a "Certification Manual for Wastewater Laboratories". In lieu of such a document; TNI strongly encourages the use of the consensus-based TNI Standards.

TNI suggests the Agency replace the current proposed Section 136.7 with the following:

Regardless of the publisher, edition or source of an analytical method approved for CWA compliance monitoring, analysts must use suitable QA/QC procedures whether EPA or other method publishers have specified these procedures in a specific part 136 method, or referenced these procedures by other means. Consequently, EPA expects that an analyst using consensus body methods for reporting under the CWA will also comply with the quality assurance and quality control requirements listed in the appropriate sections in the consensus body compendium. EPA's approval of use of these voluntary consensus standard body methods contemplated that any analysis using such methods would also meet the quality assurance and quality control requirements prescribed for the particular method. Thus, not following the applicable and appropriate quality assurance and quality control requirements of the respective method means that the analysis would not comply with the requirements in EPA's NPDES regulations to monitor in accordance with the procedures of part 136 for analysis of pollutants.

For methods that have insufficient QA/QC requirements, analysts should refer to and ensure that the essential quality control requirements published in consensus standards such as those published by The NELAC Institute (cf. Volume 1: *Management and Technical Requirements for Laboratories Performing Environmental Analyses*) have been met.