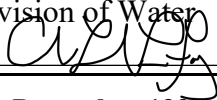


New York State Department of Environmental Conservation, Division of Water

## Division of Water Technical and Operational Guidance Series

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Signature: 

**Title:** Analytical Detectability and Quantitation  
Guidelines for Environmental Parameters

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**\*\*\* NOTICE \*\*\***

This document has been developed to provide Department staff with guidance on how to ensure compliance with the statutory and regulatory requirements, including case law interpretations, and to provide consistent treatment of similar situations. This document may also be used by the public to gain technical guidance and insight regarding how Department staff may analyze an issue and factors in their consideration of particular facts and circumstances. This guidance document is not a fixed rule under the State Administrative Procedures Act subsection 102(2)(a)(I). Furthermore, nothing set forth herein prevents staff from varying from this guidance as the specific facts and circumstances may dictate, provided staff's actions comply with applicable statutory and regulatory requirements. This document does not create any enforceable rights for the benefit of any party.

### I. Summary:

This guidance provides the protocol to ensure environmental tests<sup>1</sup> used in the fulfillment of the New York State Department of Environmental Conservation (NYSDEC) Division of Water (DOW) programs are scientifically valid to accurately quantify and characterize parameters<sup>2</sup> and sufficiently sensitive<sup>3</sup> to support DOW in improving and protecting New York's water resources. Analytical quantitation and detectability of parameters is critical to promote the quality, objectivity, utility, and integrity of environmental data<sup>4</sup> used or funded by DOW.

<sup>1</sup> The term 'environmental tests' refers to analytical methods, analyses, measurements, or test procedures.

<sup>2</sup> The term 'parameters' refers to analytes, constituents, contaminants, specimens, substances, pollutants or elements.

<sup>3</sup> The term 'sufficiently sensitive' is consistent with 40 CFR 122.44(i)(1)(iv).

<sup>4</sup> The term 'environmental data' refers to qualitative or quantitative determinations, results or values.

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## II. Policy:

Pursuant to Section 402<sup>5</sup> of the Clean Water Act (CWA), New York administers the approved State Pollutant Discharge Elimination System (SPDES) program in accordance with the New York State Environmental Conservation Law (ECL) Article 17, Titles 7, 8 and Article 70, as well as 6 NYCRR Parts 621 and 750. Through the SPDES program, DOW administers the programs and procedures required to control discharges to the state's water resources in accordance with the CWA. Additionally, DOW administers the quality system that is required under USEPA Order CIO 2105.0 and 40 C.F.R. Part 35 for quality assurance oversight.

In accordance with these authorities, DOW developed this guidance to ensure environmental testing used to generate environmental data reported to or used in the fulfillment of DOW programs are scientifically valid to accurately quantify and characterize parameters and are sufficiently sensitive to support DOW in improving and protecting New York's water resources.

This guidance sets forth:

- Standardized criteria for environmental testing;
- Standardized criteria for demonstration of competency to generate environmental data. and
- Standardized assessment of measurement uncertainty in environmental testing

## III. Purpose and Background:

The purpose of this guidance is to ensure that environmental tests conducted in support of DOW programs:

- Meet Federal and State requirements;
- Are protective of the State's water resources;
- Are scientifically valid and sufficiently sensitive to accurately quantify concentrations and characterize parameters; and
- Are performed in such manner that demonstrates competency to generate environmental data.

Environmental tests, used for the purposes of either a water quality certificate (CWA § 401) or a SPDES permit for surface water discharge (CWA § 402), must be approved under 40 C.F.R. Part 136. Recognizing the need for scientifically valid and sufficiently sensitive environmental tests, DOW extended the application of 40 C.F.R. Part 136 requirements to all programs, and is now formalizing that application as a matter of policy, for all environmental testing whether required for reporting purposes, conducted, used or funded by DOW.

Additionally, New York State Public Health Law (PHL) § 502 requires environmental laboratory analyses of samples originating from New York State, "for the purposes of public or personal health protection or the protection of the environment or natural resources" be performed by a laboratory certified by the New York State Department of Health's Environmental Laboratory Approval Program (NYSDOH ELAP) for which the Commissioner of Health issues certificates.

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<sup>5</sup> CWA § 402(b); 33 U.S.C. § 1342(b).

The NYSDOH administers ELAP pursuant to PHL § 502 and regulates laboratories through 10 NYCRR Part 55, Subpart 55-2. This provision is restated in ECL § 3-0119. These laws were promulgated to help ensure that environmental laboratories have the capability to perform specific analyses and to ensure consistency and comparability of environmental tests. This NYSDOH ELAP requirement is independent of the CWA and 40 C.F.R. § 136.1 and applies to samples collected within NYS. DOW must also adhere to the “Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements.” DOW meets this federal requirement by complying with PHL § 502, ECL § 3-0119 and the criteria described in Section *V.2 Competency to Conduct Environmental Tests*.

## IV. Responsibility:

This document originates from DOW’s Bureau of Water Assessment and Management, Standards and Analytical Support Section, with contributions and input from other DOW staff. The DOW Quality Assurance Officer (QAO) or designee (herein referred to collectively as DOW QAO) shall interpret and maintain this guidance.

## V. Procedures:

### V.1 Criteria for Selecting Environmental Tests

The integrity of environmental data relies on proper identification and use of appropriate environmental testing to quantify concentrations and characterize parameters. Therefore, environmental testing will:

- (1) Be approved under 40 C.F.R. Part 136;
- (2) Be selective to accurately quantify the characteristics and concentrations of the monitored parameter;
- (3) Be clear, appropriate, and free from fabrication and falsification;
- (4) Be sufficiently sensitive to meet performance criteria, requirements, or objectives required for the application; SPDES reporting or environmental study/assessment; and
- (5) Have demonstrated applicability of the matrix (water, sediment, biological, etc.) sample, concentration range/scope, and analyte list to be consistent with the target parameter(s).
- (6) Meet guidance described herein when there is:
  - (a) more than one environmental test approved under 40 C.F.R. Part 136 for the analysis of a parameter (V.1.1);
  - (b) no environmental test approved under 40 C.F.R. Part 136 for a parameter (V.1.2);
  - (c) no NYSDOH ELAP issued certificate for a parameter (V.1.3); or
  - (d) a request for an alternate test procedure to a 40 C.F.R. Part 136 method (V.1.4)

V.1.1 When there is more than one environmental test approved under 40 C.F.R. Part 136 for the analysis of a parameter, the environmental test selected will be sufficiently sensitive to meet the performance criteria, requirements, or objectives required for the application.

V.1.2 When there is no environmental test approved under 40 C.F.R. Part 136 for the analysis of a parameter, pursuant to 40 C.F.R. §§ 122.21(e)(3), 122.44(i)(1)(iv), 122.48 and 6 NYCRR §§ 700.3 and 750-2.5(d), the DOW QAO will select an environmental test from NYSDOH ELAP’s list of approved methods for the appropriate field of accreditation (e.g. Drinking Water; Non-

Potable Water). For example, for effluent or ambient water, the DOW QAO will select a method from NYSDOH ELAP's "Non-Potable Water" field of accreditation.

When there are no environmental tests from the appropriate NYSDOH ELAP field of accreditation or when the ELAP approved method(s) do not meet the criteria of V.1(1) through V.1(5), the DOW QAO will select an environmental test following the selection process outlined in V.1.3.

V.1.3 When there are no environmental tests from the appropriate NYSDOH ELAP field of accreditation, or when the ELAP approved method(s) do not meet the criteria of V.1(1) through V.1(5), the DOW QAO will select an environmental test utilizing the following criteria in descending order:

- (1) NYSDOH ELAP approved environmental tests in fields of accreditation other than the sample matrix;
- (2) USEPA recommended environmental tests not found under 40 C.F.R. Part 136;
- (3) Environmental tests recommended in the current version of "*Standard Methods for the Examination of Water and Wastewater*" (Standard Methods);
- (4) Environmental tests recommended or utilized by other states or federal agencies; or
- (5) Environmental tests recommended by a permittee, a lab, or other interested party.

Preference is given to matrix-specific methods over non-matrix-specific methods; however, non-matrix-specific methods may be selected by the DOW QAO should the non-matrix-specific method's selectivity, sensitivity, and reproducibility be assessed as superior in meeting the needs of the application.

Environmental tests selected under this section will also be evaluated for method capability (V.3).

V.1.4 Alternate/Alternative Test Procedure for Limited Use (ATP-LU) to 40 C.F.R. Part 136

A request for an ATP-LU may be submitted to the DOW QAO when:

- (1) An environmental test is not sufficiently sensitive or selective in detecting and measuring the reported parameter at, or below, the respective water quality standard, criterion, or guidance value;
- (2) requested by a permittee pursuant to 6 NYCRR § 750-1.7(b)(7)(i) and 40 C.F.R. Part 136.5;
- (3) an environmental test is found to be incompatible with project objectives;
- (4) an alternate test procedure improves precision, accuracy, and/or sensitivity; or
- (5) an alternate test procedure improves ease of use or decreases cost, but only if such improvements are accomplished without sacrificing precision, accuracy, or sensitivity.

An ATP-LU will have equal or improved precision, accuracy, sensitivity, and ease of use, as the sufficiently sensitive method for the prescribed application under 40 C.F.R. Part 136.

- (a) For the purposes of either a water quality certificate (CWA § 401) or a SPDES permit for surface water discharge (CWA § 402), ATP-LU requests must meet the conditions prescribed in: 40 C.F.R. § 136.5, 6 NYCRR § 750-2.5(d). The DOW QAO reviews requests following the environmental test selection criteria under section V.1 and evaluation of method capability under section V.3 to make a recommendation for or

against approval to the USEPA Region 2 ATP Coordinator who makes the final determination.

- (b) For all other ATP-LU requests, the DOW QAO will apply the environmental test selection criteria found under section V.1 and evaluate method capability under section V.3 to make a determination whether to approve or deny the request.

In addition, if NYSDOH ELAP issues certificates for the parameter, NYSDOH ELAP must also approve the ATP-LU. Pursuant to the requirements in 10 NYCRR § 55-2.5, any laboratory-developed method, or other method not otherwise approved by NYSDOH ELAP, must be submitted to NYSDOH ELAP for review and approval prior to use. The laboratory must submit data and other information, as required by 10 NYCRR § 55-2.5, supporting the technical merit of the method, and demonstrating that the method's precision and accuracy are equivalent or superior to that of a NYSDOH ELAP-approved method.

## V.2 Competency to Conduct Environmental Tests

To ensure the competency of entities generating environmental data, DOW maintains compliance with Federal and State requirements and the procedures outlined in this guidance. Adherence to PHL § 502 and ECL § 3-0119 is mandatory. However, in the absence of NYSDOH ELAP accreditation for a parameter, demonstration of competency to conduct environmental tests will, where available, be supported by a nationally recognized accreditation programs.

In the absence of nationally recognized accreditation programs, the DOW QAO may request documentation fulfilling the quality principles as expressed in the “*New York State Department of Health Environmental Laboratory Approval Program Certification Manual*” and including but not limited to, the following criteria:

- (1) Staff experience, education, and training to adequately demonstrate technical competency in environmental data collection and/or analysis;
- (2) Possession of, or access to, the proper equipment for completing environmental data collection and/or analysis and be available for inspection by DOW staff;
- (3) Physical facilities to support the operation of completing environmental data collection and/or analysis;
- (4) Standard Operating Procedures that comply with 40 C.F.R. Part 136 test procedures and quality assurance/quality control found within 40 C.F.R. §§ 136.3 and 136.7;
- (5) Results and associated records, including quality control results. Associated records do not need to be submitted to DOW, but are to be recorded and maintained for a minimum of five years and be available for inspection by DOW staff;
- (6) Quality assurance policies and quality control procedures to demonstrate technical competency and generation of technically valid results; and
- (7) A statement of certification affirming that the information submitted is to the best of their knowledge true, accurate, complete, and properly gathered by qualified personnel.

For environmental tests made *in-situ*, in addition to the above criteria (1-7), the DOW QAO may request documentation fulfilling the following criteria to demonstrate competency to generate environmental data:

- (a) For Analyze Immediate On-Site (AIOS) parameters, entities must adhere to “*NYSDOH ELAP Certification Manual Field Analyses/Analyze Immediate Parameters, Item number 249, March 28, 2012*”;
- (b) For parameters other than AIOS, in which NYSDOH ELAP issues a certification, **and for** a CWA compliance reporting purpose pursuant to CWA §§ 401 or 402 or groundwater discharge permits, entities will hold NELAC<sup>6</sup> Field Sampling and Measurement Organization (FSMO) accreditation. Entities need not hold FSMO accreditation for process control monitoring;

The DOW QAO may, at their discretion, direct the analysis of parameters to a designated laboratory with known competency when it is critical for the protection of human health.

The DOW QAO may, at their discretion, direct that laboratories performing analysis for a field of study be certified by a DOW designated accreditation body.

### V.3 Evaluation of Method Capability

New methods, non-standard methods and laboratory designed methods will be evaluated by the DOW QAO to confirm that the methods are appropriate for their intended use. This evaluation of method capability will follow the quality principles as expressed in “*Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA*” and including but not limited to, the following:

- (1) have demonstrated applicability in terms of both the matrix (water, sediment, biological, etc.) sampled and concentration range to be consistent with the target parameter;
- (2) be sufficiently sensitive to accurately describe the characteristics and concentrations of monitored parameters at or below water quality criteria, permit limits or study objectives;
- (3) be compatible with project performance criteria, requirements and/or objectives;
- (4) be traceable, transparent, reproducible, unbiased, validated and documented;
- (5) identify the proper sample preservation and sample volume necessary for the analysis;
- (6) have documented error rates;
- (7) have documented susceptibility to experimental conditions (such as temperature, acidity, reaction time) and be appropriate for the parameter of concern taking into consideration the data objectives;
- (8) have a scale of operation (quantity of sample necessary to perform the analysis) that is practical for sample collection, handling, and analysis;
- (9) maintain heterogeneity of any subsample of the field sample required for analysis; and
- (10) completion of analysis in a time frame comparable to similar USEPA approved or NYSDOH ELAP listed methods.

### V.4 Measurement Uncertainty

In addition to identifying what environmental tests are to be used and determining the competency to perform environmental testing, it is equally important to identify the limits of measurement uncertainty associated with the result. All environmental testing has a level of uncertainty and it is the responsibility of the analyzing authority to apply quality control measures to minimize and quantify that uncertainty.

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<sup>6</sup> National Environmental Laboratory Accreditation Program

For the purposes of this guidance, detection and quantitation limits are restricted to the application of the Method Detection Limit (MDL), the Minimum Level (ML), and the Practical Quantitation Limit (PQL).

Detection and Quantitation: Variables such as instrumentation, calibration supplies, sample volume, and matrix interference may influence analytical results. Therefore, it is not unusual to have different reporting levels associated with an environmental test. This makes it essential that environmental information include metadata qualifying the collection and analysis of environmental samples.

The DOW QAO advises DOW staff on appropriate analytical detection and quantitation limits. In determining appropriate analytical detection and quantitation limits, the DOW QAO evaluates references including, but not limited to, scientific peer reviewed documents, NYSDOH ELAP, the National Environmental Method Index (NEMI), Standard methods, 40 C.F.R. Part 136, and DOW selected analytical methodologies or performance metrics.

## VI. Related References

National Guidance for the Permitting, Monitoring, and Enforcement of Water Quality-Based Effluent Limitations Set Below Analytical Detection/Quantitative Levels, USEPA March 22, 1994

National Environmental Laboratory Accreditation Conference 2003, USEPA 600/R-04/003

Title 40 of the Code of Federal Regulations Part 136 Guidelines Establishing Test Procedures for the Analysis of Pollutants (August 2017)

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA, USEPA/260R-02-008, October 2002

Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements, USEPA, December 12, 2012

New York State Department of Health Environmental Laboratory Approval Program Certification Manual March 28, 2012

The NELAC Institute, General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations (FSMO-V1- 2014)

## VII. Attachment A – Glossary of Terms

1. Competency: The demonstrated ability to apply knowledge and skills.
2. Environmental Data: The qualitative or quantitative determinations, results or values reported from an environmental collection activity or test of the biological, chemical,



radiochemical or physical characteristics in the environment (e.g. wastewater, stormwater, ground and surface waters and their related ecosystems). “Environmental Data” may also include assessments of the performance of environmental technologies. Also known as Environmental Measurement Data.

3. Environmental Test(ing): Analytical methods, analyses, measurements, or test procedures used to produce quantitative and/or qualitative data representing the biological, chemical, radiochemical, or physical factors or characteristics of a parameter derived from a data collection activity, investigation, examination measurement, observation, calculation, or test.
4. In-situ: The location of the sample measurement is taken in the waterbody, influent, effluent, or discharge being monitored. No sample is collected. For example, using a meter or probe.
6. Method Detection Limit (MDL): The minimum concentration of a substance that can be reported with 99% confidence that the measurement is distinguishable from the method blank (absence of analyte). Although many environmental tests have published MDLs, a laboratory’s MDL may differ from the published value as the MDL takes into consideration the matrix, instrument used to make the measurement, the analyst, the effects of sample handling and preparation and dilutions. Therefore, an MDL is not a set or fixed value. The MDL is defined by USEPA as “the minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results.” 40 C.F.R. § 136.2(f). Determination of the MDL must follow the procedure set forth by USEPA in 40 C.F.R. Part 136 – Appendix B (July 1, 2018). Also known as a Detection Limit (DL).
7. Minimum Level (ML): The lowest level at which the entire analytical system gives a reliable signal that can identify and quantify an analyte. Generally, equivalent to the concentration of the lowest calibration standard, assuming that all procedure-specified sample weights, volumes, and cleanup procedures have been employed. The ML is an acceptable calculated limit greater than the MDL where the required accuracy for reliable measurements are achieved.
8. New York State Department of Health Environmental Laboratory Approval Program (ELAP): Established in 1984 to ensure the accuracy and reliability of environmental laboratory analyses; administers PHL § 502 and regulates laboratories through 10 NYCRR Part 55, Subpart 55-2.
9. New York State Environmental Conservation Law (ECL) § 3-0119: States that “Any laboratory tests or sample analysis required pursuant to article seventeen... of [the Environmental Conservation Law] for which the commissioner of health issues certificates of approval pursuant to section five hundred two of the public health law shall be conducted by a laboratory which has been issued a certificate of approval.”
10. New York State Public Health Law (PHL) § 502(4): States that “No state agency, authority, county, city, including the city of New York, town, village, water district, sewer district or

other political subdivision of the state shall contract with any laboratory for laboratory examinations for which the commissioner issues certificates of approval pursuant to subdivision three of [Public Health Law Section § 502], unless such laboratory has been issued such certificate.”

11. Parameter: The physical, chemical, biological or radiological measurable factors/properties that may affect water quality. Also known as: analytes, constituents, contaminants, specimens, substances, pollutants, or elements.
12. Practical Quantitation Limit (PQL): The minimum concentration an analyte can be identified and quantified at a level greater than the MDL with the precision and bias (accuracy) that provides reliable measurements. It is a mathematically calculated limit greater than the ML that has been determined either by multiplying the standard deviation of the replicates used in determining the MDL by 10 or more often as 3-5 times the MDL depending on analyte characteristics.
13. Reporting Limit (RL): Established by the environmental testing laboratory through calibration of the analytical instrument per defined analytical protocols. The value is defined by the laboratory and is generally between the MDL and the PQL. Also known as Laboratory Reporting Limit.
14. Sufficiently Sensitive: Consistent with 40 C.F.R. § 122.44(i)(1)(iv), an analytical or test method for which: (1) the method minimum level (ML) is at or below the level of the applicable water quality criterion for the measured parameter; (2) the method ML is above the applicable water quality criterion, but the amount of the parameter is high enough that the method detects and quantifies the level of the parameter; or, (3) the method has the lowest ML of the analytical methods approved under 40 C.F.R. Part 136 or required by DOW.