ELAC Recommendations on NJDEP Proposed Rule 7:18, Subchapter 11

A subcommittee of the NJDEP-Environmental Laboratory Advisory Committee (ELAC) was established to review and comment on NJDEP Proposed Rule 7:18, Subchapter 11 for New Jersey Quantitation Limits. Previous ELAC subcommittees had developed several recommendations for the New Jersey Department of Environmental Protection, Office of Quality Assurance regarding transmittal of method detection limit (MDL) data from certified laboratories to the Department. The committee had also developed recommendations for the generation and use of MDL data for the development of New Jersey quantitation limits (NJQL).

Key recommendations and criticisms previously provided by the subcommittee were not incorporated into the draft rule. Consequently, the subcommittee has serious concerns about the rule's technical soundness and its impact on the accredited environmental laboratory community and recommends that the Office of Quality Assurance initiate modifications to address the committee's concerns and incorporate its recommendations.

Linking New Jersey accreditation to the ability to produce data that meets NQL criteria is of great concern to the committee. Method Detection Limits (MDLs), which are the basis of NJQLs, are not a measure of laboratory performance but rather a measure of test method variability. The subcommittee's initial understanding was that the NJQL premise was to generate a viable, experimentally determined concentration that could be used as regulatory limits by various programs within NJDEP. Had the subcommittee known that the NJQL would be used as a mandatory accreditation specification, they would have opposed the rule outright.

The method for MDL determination stated within the General Provisions (7:18-5.5.c.10) has been determined to be inadequate by the courts. The committee does not understand the logic for employing an experimental procedure that the USEPA is under court order to change.

Employing a fixed multiplier of the median MDL (7:18-11.3.b.2) to establish an NJQL in the absence of a well-defined explanation is arbitrary. The subcommittee has provided data to OQA in the past that demonstrates that in as many as 30% of the cases a fixed 5X multiplier is not appropriate for establishing a regulatory concentration that can be measured within defined limits of precision and accuracy.

Imposing the NJQL requirements on NELAP accredited laboratories holding secondary accreditation status within the State of New Jersey as a condition of accreditation violates NELAP 2003 Chapter 6 section 6.2.1.d, which states that a secondary AA cannot require additional PT and/or QA requirements." Violation of the NELAC charter would negate interstate reciprocity, which is a cornerstone of the NELAP program.

The subcommittee recommends that the NJQL's link to laboratory accreditation be excluded. Alternatively, the NJQL should be employed exclusively at the program level for use as a data quality objective for any investigative effort. Laboratory participation in assessment or remedial monitoring effort would be based on their ability to report to an NJQL (however defined).

The subcommittee recommends that NJDEP not propose the draft rule for the determination of the NJQLs until a clear and consistent approach to determining MDLs has been proposed and promulgated by USEPA. This would avoid New Jersey's requirements conflicting with the USEPA's.

The subcommittee's specific comments are presented herein:

7:18-1.7(c): The definition of Method Detection Limit should be linked to National approaches for method detection limit determinations such as 40CFR Part 136, Appendix B.1, which is likely to change. The term MDL should also incorporate as yet to be defined equivalent terms that may be incorporated into new USEPA definitions. Allowing other "ways" to determine MDLs promulgates the current MDL confusion and detracts from the manageability of the term. All environmental regulatory agencies should be on the same page with MDL terminology and the methods for determining MDLs.

7:18-5.5(c)11: The requirement to include MDL values in reports should be based on programmatical needs rather than a certification edict. These types of deliverables can only be defined by the program office overseeing the project that determines which information is essential for reporting. Accordingly, this requirement is misplaced and should be stricken from the rule.

7:18-11.2(b)3: The information requested by the Department does not include the *qualitative* verified concentration required by NELAC under Appendix C, Section 3.1 of the 2003 NELAC Standard. Under this requirement, laboratories are required to employ MDLs whose concentration can be verified using an authentic spike. The concentration of the spike is increased until *qualitative* verification is achieved. The concentration of the spike becomes the MDL. Omitting verified values form the collected information creates a NELAC conflict and will result in unrealistic values for the PQL. NELAC laboratories will be placed in the position of having to comply with two conflicting approaches for MDL determination. This type of conflict must not be allowed to exist. As early as 2002, the NJ ELAC recommended an MDL verification step be included in the rule. This recommendation was not addressed by the Department. The data collection approach must be re-engineered to include MDL verification.

7:18-11.2(b)3.xx & xxi: The NJ ELAC has consistently asked that these two data elements be excluded from the rule. The Federal Register references incorporated into this rule do not include a requirement for an LCS. Accordingly, it is uncertain what data is required to be reported and where it originates. The Department has not articulated the reasons this data is needed or what its use would be. Because there isn't a defined reason for collecting this data and it's not used for MDL determination, it should be excluded.

7:18-11.3(b)2: A relationship between an MDL and a quantifiable concentration that is a multiple of the MDL has not been defined by the department. Additionally, The NJQL is defined as a concentration that can be reported within a defined level of precision and accuracy. If the defined level of precision and accuracy cannot be mathematically stated for the NJQL, the concept must be redefined. What is the mathematical relationship that establishes the NJQL as a value that meets a mathematically defined level of precision and accuracy? Generation of the NJQL does not guarantee that method calibration criteria can be achieved at that concentration.

The use of a universal arbitrary multiplier (5x) is not an appropriate regulatory procedure. There is no assurance that this multiplier is correct for a wide variety of compounds. The USEPA, which had used PQLs in the past has since abandoned the concept and is currently reviewing whether other measurement procedures are more appropriate for regulatory compliance.

7:18-11.3(c): This specification is arbitrary. Because it is undefined, it cannot possibly be demonstrated that it meets a defined level of precision and accuracy it opens the door for NJQLs that are arbitrary which cannot be experimentally achieved. It further complicates the use of NJQLs as a vehicle for determining laboratory certification for a parameter by imposing an NJQL value that has not proven to meet the criteria set forth within this document. Adopting an alternate NJQL on a program specific basis, while allowing 7:18-11.1.a.3 to remain in Subchapter 11 will negatively impact laboratories that meet the 5X criteria but cannot meet the alternative concentration. By rule, these laboratories would not be accredited by NJDEP. Accordingly, this requirement should also be excluded.

7:18-11.4(a-c): This entire section seems to be misplaced. Rather than make this a certification requirement, it should be part of the site remediation requirements for entity's required to demonstrate compliance with cleanup criteria. Furthermore, obtaining an alternative NJQL because of matrix effects is entirely impractical since the matrix impact is typically unknown until samples are present in the laboratory and being analyzed. Applying for an alternative NJQL for a one time analytical episode cannot be conducted efficiently and will retard remedial progress. This approach is contrary to the remedial process and should be excluded. At a minimum, the burden should be placed on the entity demonstrating compliance rather than the laboratory.

7:18-11.4(e): The requirement to obtain an exemption should be placed on the regulated entity, not the laboratory. This requirement belongs in the specification for remediation not laboratory certification. The program specific regulatory criteria should drive the need to report to a legislated generic quantitation limit or not.

7:18-11.5: The specifications under this section result in a considerable number of laboratories unable to demonstrate NJQL compliance, resulting in wide-ranging negative impact to the laboratory community. Furthermore, it is likely that every accredited laboratory would be disqualified for multiple method parameters, necessitating replicate samples being sent to multiple laboratories to obtain data from an accredited laboratory for all method parameters. This would dramatically increase the costs for sample collection, shipping and analysis by as much as a factor of three. These approaches must be re-evaluated.

7:18-11.5(a)1: This requirement excludes 50% of the laboratory community. If the MDL data generated by all accredited laboratories has an irregular distribution, half of the laboratories, whose performance is virtually indistinguishable from the qualifying half will be excluded and unable to meet this specification. Furthermore, the MDLs have not been verified according to NELA specifications. If unverified MDLs have been employed to generate an NJQL, how will NELAC laboratories nationwide demonstrate compliance?

7:18-11.5(a)2: This specification implies a relationship which does not exist. The department has been unable to demonstrate a mathematical relationship between the MDL and a quantifiable value. The department was given data as early as 2002 which demonstrates that this relationship fails for many organic compounds. It is an incredible leap of faith to think that 5X the MDL is a concentration that can always be included in a calibration and meet method calibration criteria. This factor is arbitrary and this type of approach is unscientific.