ELAC MDL Subcommittee
Recommendations

A subcommittee of the NJDEP-Environmental Laboratory Advisory Committee (ELAC) was established at the request of the Office of Quality Assurance to develop recommendations on mechanisms for importing MDL data from New Jersey Certified laboratories for use in the development of New Jersey Quantitation Limits (NJQL). The subcommittee was chaired by David Speis (Accutest) and included Madhuri Dave (STL-Edison), Sue Durke (The Washington Group), Harvey Klein (Garden State), Linda Tatro (PVWC) and George Sawyer (Casie Protank).

The subcommittee developed several recommendations for the New Jersey Department of Environmental Protection, Office of Quality Assurance regarding transmittal of method detection limit (MDL) from certified laboratories to the Department. The committee also developed recommendations for the generation and use of MDL data for the development of New Jersey quantitation limits (NJQL).

The subcommittee's recommendations are presented herein:

MDL Data Import Mechanisms. The Subcommittee recommends that the department develop data import mechanisms that satisfy the need of laboratory organizations of varying sizes. This would enable each organization to employ import vehicles that are consistent with their level of electronic sophistication. Laboratories with high electronic sophistication would not be burdened by import mechanisms requiring manual data transcription. Smaller organizations would not be burdened by the need to develop sophisticated electronic data tools for importing data.

The Subcommittee endorses the Department's use of the data import mechanisms that use vehicles that are similar to those used in the Private Well Testing Act. This approach clearly addresses the Subcommittees views for accommodating laboratories of different sizes and capabilities without the need to re-invent a data import scheme as detailed in the following points:

- Use existing Department database capabilities, i.e. systems that are in use and accessible to a broad range of Departmental programs.
- Require direct input electronic data deliverables (EDD) using an agency defined format
- Use an Excel type spreadsheet input as an alternative, employing strict data field rules. (Excel capability is the minimum capability requirement for data import)

The Subcommittee requests that the Department consider the following additional recommendations that will simplify MDL development by individual laboratories and Departmental review of imported data:

- Design and develop the database to completion before initiating data collection activities. Suspend data collection until the database is capable of accepting information.
- Define and lock data fields, data dictionary and valid values tables prior to initiating data collection.

- Collect data for reasonable data fields only, have valid reasons for collecting specified data fields.
  - Exclude the replicate data for each MDL study
  - Exclude data that is unrelated to MDLs; LCS spike concentration; LCS recovery; LCS RSD
- Link individual compound data to Department certification codes and each individual laboratory's certified parameters.
- Develop an exclusion list of methods and parameters for which MDL development is not appropriate, e.g., pH, TDS,TSS, TS, Color, Specific Conductivity
- Include a data checker feature that enables on line checking of imported information for accuracy and completeness prior to finalization and submittal to the department. This enables submitting laboratories to correct format errors quickly, prior to Departmental submittal.

MDL Study Guidelines. The Subcommittee also recommends that the Department develop and distribute clear requirements for conducting MDL studies that certified laboratories be required to follow. Following clear specifications promotes data comparability, minimizes interlaboratory variability and increase Departmental usability. The requirements should include the following elements:

- Require all studies to be performed following the specifications of 40 CFR Part 136 Appendix B.
- Require study date to be within the calendar year of data submittal.
- Require laboratories to spike at the concentration of the lowest calibration standard used to generate the calibration curve. Require reporting the concentration of the low calibration standard as a deliverable.
- Limit the initial MDL study data compilation effort to aqueous matrices. Develop method specific guidance for conducting MDL studies in solid matrices. Provide specifications for conducting studies in analyte free matrices.
- Require laboratories to employ an iterative spike procedure to produce MDLs that satisfy the 10X Spike Concentration/MDL Concentration Rule. The broad interpretation of the 10X rule from 40 CFR Part 136 Appendix B is that Spike Concentration/MDL Concentration > 10X for individual compounds have been spiked at an excessively high concentration and should be repeated at a lower concentration.

MDL Data Use and NJQL Development. The Subcommittee further recommends that the Department develop computerized data processing rules for evaluating imported MDLs to filter and exclude non-qualifying MDL data from the data evaluation. Non-qualifying data could bias the database and have a detrimental effect on NJQL development.

NJQL data development must employ a reasonable logic pathway that assures that concentration values generated can be used as a low calibration standard that can meet documented method calibration criteria. NJQL values that are developed without considering a logical process will not establish a link between the generated value and a qualifying calibration standard. The USEPA has gone on record indicating that the method MDL is a precision based value that is not related to sensitivity. Therefore, the NJQL development process must unambiguously demonstrate the relationship between MDL and the low calibration standard.

If an unambiguous link is not established, the result will be the encoding of mandated NJQLs that the laboratory is unable to include in a calibration curve. Accordingly, laboratories will be unable to quantitatively and possibly qualitatively identify the presence of listed parameters at NJQL concentrations. This will create a technical ethics dilemma that laboratories will be unable to resolve that could promote the reporting of fraudulent information.

The Subcommittee recommends that the following elements be considered as essential to the NJQL development process as MDL development sanity checks:

- Institute spike concentration/MDL ratio filtering criteria for all submitted data. For the development of an NJQL that can be used as a calibration standard the use of a 5X rule will be necessary. If MDL studies are performed using aggressive calibration curves that force the low calibration standard to its lowest limit, NJQLs developed using MDLs that exceed the 5X filter will guarantee that the value will not be able to be used for calibration.
- Flag data in the database that does not satisfy the filter requirement and exclude it from the NJQL development process.

Finally, the Subcommittee believes that the Departments needs for lower analytical sensitivity are exclusive of the methods that are mandated for environmental monitoring. The mandated methods have a finite limit for reporting unqualified quantitative identification, which can not be changed with an administrative requirement. These finite limits may not meet the Departments needs. However, they do represent the limitations of the method and the capabilities of the laboratories that use those methods. Without these strict controls in place, laboratories will be unable to produce data that meets NJQL criteria.

The Department may wish to take an alternative approach and re-engineer the definition of the NJQL. Establishing the NJQL at the mean concentration of the data set employing a reasonable spike/MDL ratio filter may accomplish this goal. By requiring calibration starting at a low concentration calibration standard that is a reasonable multiplier of the MDL, i.e. between 5X and 10x, laboratories could qualify qualitatively identified concentrations between the low calibration standard and the NJQL as estimated. This would eliminate the need to calibrate the method at the NJQL, which is key to the argument against the current Department definition of the NJQL. Using this approach, the Department could require laboratories to demonstrate that internal MDLs meet NJQL limits annually.