

**STATEMENT OF INTEREST**  
**As a Member of the Federal Advisory Committee on Detection and Quantitation**  
**Nan Thomey**  
**President**  
**Environmental Chemistry, Inc.**  
**June 21, 2005**

**Environmental Chemistry, Inc. is a small commercial laboratory providing organic, inorganic, and physical testing services to private industry, government organizations, and engineering and consulting firms.**

- **The detection and quantitation procedures must be based on sound scientific principles.**
- **Detection/quantitation are essential elements used to interpret data to assure that correct decisions can be made based on results of known quality**
- **Long-term variability, method blank levels, and compound identification criteria are essential elements that must be included to improve the quality of data. Consideration must be given to minimize reporting of false positive and false negative results.**
- **Consistency and accuracy of terminology and definitions is essential to the proper interpretation/use of data. Clear, descriptive wording should be provided in addition to statistical equations for ease of understanding by laboratory, regulatory, and public interests**
- **The procedure adopted should be clear, unambiguous, and able to be implemented with minimal training to allow consistent application among analysts and laboratories**
- **Laboratories must be able to demonstrate the on-going validity of procedures using existing quality systems to the extent possible.**
- **The procedure developed should be uniform among all offices/programs within the EPA**
- **It may be necessary to use different procedures based for different analytical technologies, for example, the procedure used for a method performed by titration with a buret could be different than a GC/MS method of analysis**
- **Procedure developed should not provide commercial advantage for one sector over another**



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I have found that although the statistical methods outlined by several groups are quite rigorous, they are not readily understood by laboratory personnel who are not necessarily well versed in statistical theory beyond the basics. This is consistent with the existing technique where we frequently run into differing interpretations. I represent two dramatically different laboratories: a medium sized laboratory in Beaverton, OR and very small ones in Anchorage, AK, Bend, OR, and Spokane, WA. Moreover, I represent the ORELAP Technical Advisory Committee, an ombudsman group that provides an interface between Oregon's NELAC (ORELAP) accreditation people and the laboratory community.

The issues for the different sizes of laboratories are, at the same time, similar and quite different. Small commercial and municipal laboratories operate quite close to the bottom line and do not have the luxury of staff statisticians or extra QA personnel to assist in determining detection and reporting (quantification) limits. The danger is significant that such small laboratories may make unintentional but serious errors. This is of particular concern when the mdl approach is not sufficiently prescriptive and is reliant on a deep conceptual grasp of the statistical issues.

In contrast, larger laboratories conduct many different analyses and continually develop new ones. MDL requirements as presently written are very time consuming and from our initial reads of the combined method this will become a severe inhibition to perfecting methods that use less solvent, time, and generally improve an analysis. This in turn may create needless severe limitations on the technical success of the larger laboratories, potentially unreasonably raising costs and time requirements for needed method development.

Finding an MDL methodology that is both statistically correct and readily applied in the laboratory is my objective. I have found many models all lacking in the latter; especially in a small laboratory where one person may wear many hats and doesn't have time, training, or software to perform complex calculations that ultimately still do no more than estimate the MDL/MRL. Some of the proposed methods have far too many interpretations that can be wrongly applied by laboratory personnel, regulators, and auditors who may not know the intricacies of a given statistical approach. I agree the statistics must be defensible and have long been uncomfortable with some of the unrealistic MDLs observed using the present 136B methodology.

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## ACIL Statement of Interests for the Federal Advisory Committee on Detection and Quantitation

- Generation of quality data

Our primary interest in the work of this committee is the hope that the resulting policies and procedures will allow us to generate higher quality data. The lowest limit of reporting for normal data uses, and certainly for regulatory compliance, should be the quantitation limit. This is because it represents, or should represent, the lowest level at which the accuracy and precision of the data is sufficient to generate a reliable number. If a method quantitation limit is not low enough for the intended use of the data, the first choice should be an alternative method or method modification that will allow for a lower quantitation limit, not use of results between the detection limit and quantitation limit. Quantitation and detection limit procedures must consider factors such as long term variability, method blank levels and compound identification criteria in order to be reliable. In the absence of these requirements both false positives and false negatives may be routinely generated, leading to erroneous decisions.

- Consistency

Procedures for determination of the quantitation limit (and detection limit if needed) must be clear, consistent, technically valid and well documented. They must be adopted consistently by all EPA offices that are engaged in development and publication of analytical methods. To ensure consistency and technical validity, the new procedures for identifying quantitation and detection limits should be applied to current methods and supersede the MDL procedure currently used. EPA should also work to ensure that state regulatory agencies and accrediting organizations such as NELAC adopt the new procedures.

- Ease of Adoption

Within the constraints of technical validity, the new procedures should be as simple and straightforward to implement as possible, in order to ensure quick and complete adoption by testing laboratories.

ACIL is the American Council of Independent Laboratories