Roger Claff
American Petroleum Institute

My personal interest and the interest of my organization is that a consensus method for establishing detection and quantitation limits associated with water quality measurements be found, and that the procedures of this method ensure that detection and quantitation limits derived by them are scientifically sound and provide accurate descriptors of both data quality and analytical method performance. The need for rigorously derived and properly interpreted detection and quantitation limits is particularly important when conducting ambient water quality monitoring with regulatory or compliance implications, or when monitoring effluents to determine compliance with water quality based permit limits set at or near the quantitation capabilities of the analytical instrument or method.
In such circumstances all parties have a basic interest in ensuring that the environment is properly protected through, first and foremost, a fair and accurate assessment of compliance status, and this can only be achieved when the quantitation capabilities of the analysis are accurately and unambiguously established. Beyond this regulatory compliance issue, application of a scientifically sound and universally accepted procedure for determining detection and quantitation limits provides for more certain assessments of data quality and laboratory method performance, and also improves data comparability among laboratories.

Finally, my organization and I have an interest in ensuring that this consensus method is prac"tical, cost-effective, and can be readily implemented by all stakeholders to this process -industry, laboratories, state agencies, environmental groups, and EPA. The method should be consistent with, and tailored to, these organizations' intended uses of the data.

Interest Sheet

David J. Piller
Exelon Generation Company

Develop through collaborative process scientifically sound methods of determining the sensitivity and accuracy of analytical methods used in environmental decision-making. These decisions affect the ability of NPDES permit holder to analyze and ensure samples for compliance with local, state and federal statues.

Exelon is pleased to be part of the collaborative process to develop the guidelines

We **would** expect:

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that consistent standard definitions and terminologies be used across environmental programs established by local, state and federal agencies. These definitions would apply to all analytical laboratories in providing dependable results during the analytical process.

that scientifically sound techniques be selected to estimate sensitivity and accuracy based on acceptable principles so that the estimate is perfonned the way in which it was
intended.

that sensitivity of a method is selected to distinguish a: signal from background noise and accuracy is composed of precision and bias where precision is the ability to repeat or reproduce the same measured value and bias is the degree to which a measured value differs from the true value.

NPDES pennittees depend on the speed, accuracy, and cost-effectiveness of the laboratories that provide us with the analytical data to demonstrate compliance; we in industry are also sensitive to the need for the detection and quantitation procedures to be practical, both for the regulatory authorities and for the laboratory community.

It is important to understand all aspects of the chemical measurement process so that all components of variability and bias can be taken into account. That the estimate values should include the entire analytical method from sample preparation through the instrumental measurement. It also means that the estimate must be based on routine laboratory operating conditions, similar to the sample that is being measured. This includes, run sequence, sample handling, calibration frequency and time dependent variables. When the decisions are or could be based on measurements made by multiple labs then inter-laboratory variability must also be included in the estimate.

Finally, in the interest of fairness consistency and certainty, detection and quantitation procedures that are scientifically sound, should be incorporated in all programs administered by the EP A. The NPDES program and drinking water program, for example, should strive to use consistent, scientifically sound methods for determining detection and quantitation levels. To the extent practicable, the procedures should also be'consistent with international and industry consensus standards.

Interest Statement

Larry LaFleur
National Council for Air and Stream Improvement, Inc.

It is in the interest of all parties concerned that environmental regulations be based on a sound technical basis. This is particularly true for the concepts of detection and quantitation related to their use in demonstrating regulatory compliance and in taking other water quality measurements with significant regulatory implications. A solid technical foundation for these concepts is critical to assuring public confidence in both industry and the regulatory authorities. A situation where poor science leads to contention only undermines that confidence.

Along similar lines, industry is interested in having certainty in the regulatory compliance process and in other processes with regulatory implications. This manifests in several ways. First, we need reliable analytical procedures that can produce accurate and precise measurements so we can make the process control decisions we need to assure compliance and then to demonstrate that compliance. Then, we need regulatory compliance levels that protect the environment but can also be reliably determined. Compliance levels based on concentrations where competent laboratories who correctly execute the analytical procedures cannot come to a reasonable level of agreement on the concentration present can only lead to potentially irresolvable debate. Also, unrealistic or unreliable measures of the capabilities of analytical methodologies result in unrealistic regulatory compliance

expectations.

We understand that complete mathematical certainty (with respect to defining detection and/or quantitation) is both unachievable, unrealistic and in many instances unnecessary. Thus, we are interested in striking a reasonable balance between that mathematical perfection and practicality. We would hope that this process can result in procedures or definition for estimating detection and quantitation that are consistent with or appropriate to the intended uses of the detection or Quantification levels.

My F ACDQ Interests

John H. Phillips
The Ford Motor Company

Both my personal interests and the interests of my constituency are;

To have a consistent, scientifically sound means of estimating the sensitivity and accuracy of analytical test results used in environmental decision making.

Consistent -This means that the same definitions and terminologies are used from lab to lab, state to state and program office to program office. This would allow everyone to be able to communicate clearly, reduce confusion and improve efficiencies. This does not mean that the same criteria must be used for every regulatory purpose only that the same terms and definitions be used so that we can understand each other.

Scientifically Sound -This means that the techniques selected to estimate sensitivity and accuracy should be based on accepted scientific principles so that the estimate performs the way in which it was intended. For example if one characteristic of the estimate is to be set at a 1 % false positive error rate then the estimate should perform to that standard in actual practice.

Estimating -It is not practical (or it is impossible) to measure the entire population, therefore we must rely on a reasonable estimate which has the appropriate level of trade off between representation and implementation cost. Statistical theory is great for establishing the principles, understanding our DQOs and measuring how close we are to the DQOs, but practicality must be included to make the final solution
feasible.

Sensitivity -Sensitivity is the ability of a method to distinguish a signal from background noise. Two measures of sensitivity are commonly made usingintemational terminology, Critical Level (Lc), where an acceptable false positive error rate is set and the Limit of Detection (LD), where an acceptable false negative error rate is set.

Accuracy -Accuracy is composed of two components precision and bias. Precision is the ability to repeat or reproduce the same measured value. Bias is the degree to which a measured value differs from the true value. The international terminology would be the Limit of Quantification (LQ), where both acceptable precision and bias is achieved for a measurement.

Analytical Test Results -It is important to understand all aspects of the chemical measurement process so that all components of variability and bias can be taken into accounts. This means that the estimate should include the entire method from sample preparation through the instrumental measurement. It also means that the estimate

must be based on routine laboratory operating conditions, just like the sample which is being measured. This includes, run sequence, sample handling, calibration frequency and time dependent variables. When the decisions are or could be based on measurements made by multiple labs then inter-laboratory variability must also be included in the estimate.

Environmental Decision Making -We must carefully look at purpose for which the measurement data is being used. Depending upon use and intended purpose the DQOs will vary as might the estimate variables (false positive error rate, false negative error rate, precision and bias), being used to generate our estimates. For some environmental decisions, such as regulatory compliance accuracy may be the dominate factor, therefore only the quantification estimate may be applicable.