

every detection limit approach has set the criterion for detection at 99 percent confidence (i.e., the lowest level at which a pollutant will be detected with a probability of 99 percent). This criterion results in the probability of a false positive; i.e., that a pollutant will be stated as being present when it is not really present (a Type I error), of one percent.

*Criterion 5:* The quantitation limit approach should identify the concentration that gives a recognizable signal that is consistent with the capabilities of the method when a method is performed by experienced staff in well-operated laboratories. Measurement capabilities among laboratories vary depending on a number of factors, including, but not limited to, instrumentation, training, and experience. Similarly, measurement capabilities among different analytical methods vary depending on a number of factors, including the techniques and instrumentation employed and the clarity of the method itself. Historical approaches to recognizing laboratory capabilities in establishing detection and quantitation limits have varied between two extremes of establishing the limit in a state-of-the-art research laboratory to reflect the lowest possible limit that can be achieved, and establishing the limit based on statistical prediction intervals calculated from a large number of laboratories with varying levels of experience, instrumentation and competence. Generally, use of the former has been employed to serve as a goal or performance standard to be met by other laboratories, whereas use of the latter treats the limit, not as a performance standard that needs to be met by each laboratory, but rather as a characterization of the future performance of the entire universe of laboratory capabilities at the time of method development. Rather than using one of these two extremes, EPA prefers to establish a quantitation limit at a concentration that is achievable with a defined level of confidence in well-operated laboratories.

*Criterion 6:* Detection and quantitation approach should be applicable to the variety of decisions made under the Clean Water Act, and should support State and local obligations to implement measurement requirements that are at least as stringent as those set by the Federal Government. The Clean Water Act requires EPA to conduct, implement, and oversee a variety of data gathering programs. These programs include, but are not limited to, surveys to monitor changes in ambient water quality,

screening studies to identify pollutants of concern, data gathering to support effluent guidelines, environmental assessments to establish water quality standards, and studies to evaluate human health and environmental risks under the Clean Water Act. In addition, EPA should be able to apply detection and quantitation limits to permitting, quality control in analytical laboratories, method promulgation, and other uses of the 40 CFR part 136 methods.

## V. EPA's Findings and Conclusions

As noted previously, EPA considered four sets of detection and quantitation limit approaches advanced by EPA, ASTM International, ACS, and both ISO and IUPAC. Each approach was assessed against the suite of criteria described above for use under the Clean Water Act. The EPA approaches (i.e., the MDL and ML) and the ASTM International approaches (i.e., the IDE and IQE) are supported by clearly defined procedures for implementing the concepts. Neither the ACS nor the ISO/IUPAC approaches are supported by detailed procedures for implementation; this lack of supporting procedures was reflected in the outcome of EPA's overall assessment. Briefly, EPA found that (1) no single pair of detection and quantitation limit concepts perfectly meets EPA's criteria for use under the Clean Water Act, (2) the MDL and ML most closely meet EPA's criteria, and (3) minor revisions and clarifications to the MDL and ML would allow both concepts to fully meet the Agency's needs under the CWA. Details of these revisions and clarifications are described in section VII of this proposed rule. EPA also found that, although the IDE and IQE procedures may be acceptable for establishing detection and quantitation values derived from interlaboratory validation studies, the complexity and subjectivity of the procedures, along with their inability to address individual laboratory performance, make them unsuitable as the primary means of establishing sensitivity under the Clean Water Act. However, EPA believes that the IDE and IQE can be used to establish sensitivity under certain conditions. EPA would be willing to consider and approve under 40 CFR part 136, new test methods that include the IDE and IQE. Details of EPA's findings are provided in the Assessment Document that is available in the docket supporting this proposed rule.

## VI. Peer Review of EPA's Assessment

In August 2002, EPA conducted a peer review of its assessment as presented in a draft Technical Support Document (draft Assessment Document). The peer review was performed in accordance with EPA's peer review policies, which are described in the Science Policy Council Handbook (EPA 100-B-00-001), and performed by two experts in the field of analytical chemistry and two experts in the statistical aspects of analytical data interpretation. Reviewers were provided with a draft copy of EPA's Assessment Document, copies of all data evaluated in the assessment, statistical programs used to analyze the data, and copies of the detection and quantitation approaches evaluated.

In the charge to the peer reviewers, EPA requested a written evaluation of whether the assessment approach described by EPA is valid and of the conceptual soundness of the assessment. Reviewers also were asked to consider and address eight specific questions pertaining to the adequacy of the concepts and procedures, the issues considered, the evaluation criteria developed by EPA, EPA's assessment and conclusions, the data used to perform the assessment, suggested improvements to the procedures discussed, and EPA's consideration of interlaboratory vs. intralaboratory issues. A copy of all materials associated with the peer review, including the peer review charge, the materials provided to the peer reviewers for review, complete copies of the peer reviewers' comments, and detailed EPA responses to each of the comments is provided in the docket supporting this proposed rule.

The comments from the peer reviewers were generally supportive of EPA's assessment and its presentation of the assessment in the draft Assessment Document. The peer reviewers stated that EPA's assessment of detection and quantitation concepts appears valid based on the evaluation criteria and is consistent with the Data Quality Act and EPA's Quality System. The peer reviewers stated further that the detection and quantitation concepts and procedures considered, the issues addressed, and the evaluation criteria developed based on those issues are sufficiently complete and adequate. Although two of the four peer reviewers believe that the use of interlaboratory measurements is important for a general understanding of the laboratory communities' capabilities, they also believe that the MDL and ML are more appropriate to address the issues that