

EPA must consider in support of a permittee's CWA requirements. These commenters concluded that EPA's approach between inter- and intra-laboratory studies is balanced and reasonable. Overall, the peer reviewers supported the continued use of the MDL and ML procedures, almost to the exclusion of the other approaches. The most notable exception was a suggestion that EPA consider abandoning the "traditional" concept of a quantitation limit, such as the ML, and instead consider that any measured result reported with an associated estimate of measurement precision is a quantifiable value. Reviewers stated, however, that use of the ML is practical if EPA desires to establish a quantitation limit.

Although the peer reviewers were generally supportive of the assessment and EPA's current approach to detection and quantitation under the CWA, they had some recommendations for improvement to the Agency's assessment and to the MDL procedure. The reviewers suggested that EPA consider the following: (1) Providing additional references; (2) expanding the discussion of outliers; (3) establishing a repository of reference materials that demonstrate the ability to handle interferences and low level detection; (4) making minor modifications to Evaluation Criterion 4 (i.e., edit to reflect equivalence to an implementation of Currie's critical level); (5) clarifying the MDL confidence interval calculations discussed in Chapter 5 of the Assessment Document; and (6) enhancing the focus on the impact of operational procedures (quality control) in method performance. The Assessment Document available in the docket supporting today proposed rule addresses each of these suggestions.

The peer reviewers also suggested the following improvements to the MDL procedure: (1) Provide clarification to indicate that blank samples can be used to estimate the MDL if those blanks generate a signal; (2) revise the language in Step 1 of the MDL procedure to address certain common misunderstandings (e.g., strengthen the discussion of the selection of the spiking level used for the MDL study); and (3) specify that the spike level used to establish the MDL should not be more than a factor of three times greater than the calculated MDL. The first two suggestions from the peer reviewers regarding improvements to the MDL procedure, have been included in the proposed revision to the MDL procedure. Although EPA agrees with the theoretical arguments related to the last suggestion regarding the spike level,

EPA already tested this suggestion in one of its studies of detection and quantitation concepts and found that it could create laboratory burdens that far exceed the benefits. Specifically, EPA required a spike-to-MDL ratio of three in its multi-technique variability studies (the "Episode 6000 studies"), which are described in the Assessment Document supporting this rule. Two laboratories reported that a large number of iterations would be required (particularly in multiple-analyte methods) in order to achieve a spike-to-MDL ratio of three, and would result in increased laboratory burden and cost. Therefore, this suggestion is not incorporated into the revised MDL procedure in this proposed rule.

Based on peer review comments and comments received over the years from the laboratory community, the Petitioners, and other stakeholders, EPA is proposing revisions to the MDL procedure (see section VII below).

VII. Proposed Revisions to the MDL and ML

This proposal would revise the definition of detection limit for use under the CWA. It also would revise certain aspects of the existing procedure for determining the Method Detection Limit (MDL) in 40 CFR part 136, Appendix B (Definition and Procedure for the Determination of the Method Detection Limit) and modify the discussion to clarify implementation of the procedure. It also requests comment on whether to add a stand-alone definition of quantitation limit and procedure for determining the Minimum Level of Quantitation (ML) in Appendix B.

This proposal incorporates the results of EPA's recent assessment of detection and quantitation concepts and procedures discussed throughout this preamble and in the Assessment Document, and address various stakeholder comments received by EPA since the 1984 promulgation of the MDL (49 FR 43234, October 26, 1984).

The following discussion is divided into five sections: (1) Revisions to the definition of the detection limit are discussed in section VII.A; (2) technical revisions to the MDL procedure are discussed in section VII.B; (3) clarifications and other minor editorial changes to the MDL procedure are discussed in section VII.C; (4) the addition of a definition of quantitation limit and the addition of a procedure to calculate the ML are discussed in section VII.D; (5) section VII.E discusses EPA's continued acceptance of analytical methods from organizations

that do not necessarily use EPA's MDL and ML procedures.

A. Definition of the Detection Limit

Section 136.2(f) currently defines the term "detection limit" to mean "the minimum concentration of an analyte (substance) that can be measured and reported with a 99% confidence that the analyte concentration is greater than zero as determined by the procedure set forth at appendix B of this part." EPA is proposing to revise § 136.2(f) to explicitly equate the term "detection limit" with the "method detection limit" and to reflect the proposed revisions to the MDL procedure at Appendix B as follows: "*Detection limit* means the method detection limit (MDL), as determined by the procedure set forth at Appendix B of this part. The MDL is an estimate of the measured concentration at which there is 99% confidence that a given analyte is present in a given sample matrix." EPA also is proposing to revise the definition of the Method Detection Limit included in Appendix B as follows: "The MDL is an estimate of the measured concentration at which there is 99% confidence that a given analyte is present in a given sample matrix." The MDL is the concentration at which a decision is made regarding whether an analyte is detected by a given analytical method. The MDL is calculated from replicate analyses of a matrix containing the analyte and is functionally analogous to the "critical value" described by Currie (1968, 1995) and the Limit of Detection described by the American Chemical Society (Keith *et al.*, 1980, McDougal *et al.*, 1983).

EPA also is requesting comment on an alternative approach in which the term *limit of detection* would be defined at § 136.2 as "the critical value, which is the concentration at which there is 99% confidence that a given analyte is present in a given sample matrix," and the *method detection limit* would be defined as "the procedure set forth in Appendix B of this part, which can be used to estimate the limit of detection (i.e., critical value)."

B. Technical Revisions to the MDL Procedure

This notice proposes several technical revisions to the MDL procedure at 40 CFR part 136, Appendix B. These revisions are based on EPA's recent assessment of detection and quantitation concepts described in the Assessment Document, as well as comments received from stakeholders, the Petitioners, and the peer reviewers of the assessment. Specifically, the proposed revisions would: