

1. Revise the definition of the MDL to replace the term "minimum concentration" with the term "estimate of the measured concentration" and replace the phrase "greater than zero" with the phrase "present in a given sample matrix." The revised definition would note the functional analogy of the MDL with the "critical value" described by Currie (1968 and 1995) and the "limit of detection" (LOD) described by the American Chemical Society in 1980 and 1983. The revised definition also would note that the MDL represents the concentration at which the detection decision is made. These proposed revisions are intended to make the definition of the MDL more consistent with the MDL procedure. The proposed revisions reflect peer review comments on EPA's recent assessment of detection and quantitation concepts and procedures.

2. Expand the Scope and Application discussion to recognize that there are a variety of purposes and analytical methods for which the MDL procedure may be employed. The revised text provides examples of four common uses of the MDL procedure (*i.e.*, demonstrating laboratory capability with a particular method; monitoring trends in laboratory performance; characterizing method sensitivity in a particular matrix; and establishing an MDL for a new or revised method for nationwide use). The revised text also clarifies that the procedure may not be applicable to certain test methods such as those used to measure pH or temperature, for example. These revisions are based on questions from stakeholders about the scope and applicability of the MDL procedure.

3. Revise three of the four considerations for estimating the detection limit (see Step 1 of the current MDL procedure and section 4.3 of the proposed revisions), and suggest that the method-specified MDL can be used as the initial estimate when performing an MDL study to verify laboratory performance or to demonstrate that the MDL can be achieved in a specific matrix. The proposed revisions to the original considerations include: (1) Clarifying that, if analysis of blank samples yields an instrument response, the detection limit can be estimated as approximately equal to three times the standard deviation of replicate measurements of the analyte in the blank; (2) replacing "that region of the standard curve where there is a significant change in sensitivity (*i.e.*, a break in the slope of the standard curve)" with "a concentration in the region of constant or effectively-constant standard deviation at low

concentrations;" and (3) replacing "instrumental limitations" with "the lowest concentration that can be detected by analyzing samples containing successively lower concentrations of the analyte."

4. Revise the specifications for establishing the test concentration range according to the intended application of the MDL as follows: (1) If verifying a published MDL, the test concentration should be no more than five times the published MDL; (2) if verifying an MDL to support a regulatory objective or the objective of a study or program, the test concentration should be no more than one third the compliance or target limit; (3) if determining an MDL for a new or revised method, the test concentration should be no more than five times the estimated detection limit; and (4) if performing an iteration, the test concentration should be no more than five times the MDL determined in the most recent iteration. (See Step 3.1 of the current procedure and section 4.3.1 of the proposed revisions.)

5. Delete the calculation of a 95% confidence interval estimate for the MDL. EPA has determined that these calculations are neither routinely performed by laboratories, nor are the results employed by regulatory agencies, including EPA.

6. Revise the discussion of the iterative procedure to require that the iterative procedure be used to verify the reasonableness of the MDL when developing an MDL for a new or revised method or when developing a matrix-specific MDL, but that it remain optional when determining an MDL to verify a method-, matrix-, program-, or study-specific MDL. This change recognizes that the iterative procedure is rarely used to verify laboratory performance, but is considered important during method development. The discussion, as revised, also would provide specific instructions on how to assess the reasonableness of an MDL used to verify laboratory performance. (See Step 7 of the current procedure and section 4.8 of the proposed revision.)

7. Add a new section (section 4.9) to the MDL procedure to address the treatment of suspected outliers. EPA is proposing to add this section in response to frequent questions from stakeholders with regard to outliers in the absence of any affirmative statements in the current MDL procedure. The discussion in this proposed section specifies that suspected outliers be examined for spurious errors that may occur as a result of human error or instrument malfunction, recommends that

correctable errors be corrected before calculation of the MDL, and requires that any corrective actions be documented. The proposed section specifically would provide for invalidation of results from noncorrectable errors and preclude their use in calculating the MDL. The proposed section also describes the use of the Grubbs test for outlying values as a means to screen the results of the replicate samples for possible outliers, and provides an example application of the Grubbs test. Finally, the proposed section would reiterate the requirement that any results generated from more than seven replicates must be used to calculate the MDL unless they are determined to be outliers by the use of an appropriate outlier test. This proposed change addresses the possibility that some laboratories could prepare more than the requisite seven samples and then select only the seven results that yield the most desirable MDL value. Laboratory auditors from various agencies have identified this practice as a problem that can distort the MDL, but it is not specifically prohibited or addressed in the current procedure.

8. Delete the discussion of analysis and use of blanks included in section 4(a) of the current procedure. The current discussion applies to methods in which a blank measurement is required to calculate the measured level of an analyte; it requires separate measurements of blank samples for each MDL sample aliquot analyzed and subtraction of the average result of the blank samples from each respective MDL sample measurement. The proposed deletion of this discussion is in recognition that subtraction of a single (or average) blank sample result from the result for each MDL sample would not change the standard deviation and thus, would have no effect on the resulting MDL. Although EPA believes laboratories would be prudent to analyze blanks for assessing potential contamination, EPA also believes that requiring analysis of blanks or subtraction of blank results during MDL determinations is unnecessarily burdensome.

9. Revise the optional pre-test described in section 4(b) of the current procedure. The current procedure suggests analyzing two aliquots to evaluate the estimated detection limit before proceeding with the full seven-replicate test. Results from these analyses are evaluated to determine if the sample is in the "desirable range for determining the MDL," but no criteria are provided for establishing this desirable range. The proposed revisions