

provided the draft Assessment Document to the Petitioners and Intervenor for concurrent review and comment in August 2002. Their comments are also included in the docket for this proposal.

Finally, EPA agreed to invite public comment on the assessment for a period of no less than 120 days and to sign a notice taking final action on the assessment on or before September 30, 2004. Elsewhere in today's **Federal Register**, EPA is publishing a notice of availability of the Assessment Document, titled "Technical Support Document for the Assessment of Detection and Quantitation Concepts," and announcing a 120-day comment period on it.

C. Detection, Quantitation, and Current Controversy

Generally speaking, a detection limit is the lowest concentration or amount of a substance that allows for differentiation between a sample that contains the substance and one that does not. A quantitation limit is the lowest concentration or amount of a substance that can be measured with some stated level of confidence. Establishing such detection and quantitation limits generally involves the application of statistics and chemistry expertise and judgement. The fact that scientific judgement is involved in the detection and quantitation decision is evidenced by the continuing debate on this subject; the number of different terms currently in use by different organizations; the number of concepts and procedures that have been advanced by different organizations to define or determine the detection and quantitation capabilities of analytical test methods; and the fact that there is no general consensus among various government agencies, method developers, or scientific organizations on a single detection and quantitation approach. EPA estimates that more than 50 different terms have been used in published analytical test methods to describe detection and quantitation capabilities of test methods and, in many instances, the same term is used by different organizations to mean different things.

Nearly all of the approaches advanced to date fall into one of two main categories: (1) Those that assume measurement error is constant or effectively constant in the low concentration range and are, therefore, based on the error observed in replicate measurements made at a single low concentration, and (2) those that assume measurement error varies as a function of concentration and are, therefore,

based on the error observed in replicate measurements gathered in the region of detection and quantitation. Examples of the first category (referred to as the "single concentration approach" or "constant error model") include those first advanced by Lloyd Currie (1968) and later adopted in various forms by the American Chemical Society (ACS), the International Organization for Standardization (also known as "ISO"), the International Union of Pure and Applied Chemistry (IUPAC), and EPA. Examples of the latter category (the "variable error model") were adopted in various forms by the U.S. Army Toxic and Hazardous Materials Agency (USATHAMA, now the U.S. Army Environmental Center, or USAEC) and ASTM International. The two categories represent two somewhat different conceptual approaches to the problem of assessing detection and quantitation capabilities. Both approaches require estimates of measurement variability in the low concentration range, but the philosophy behind the first category is based on direct measurement of variability at a fixed concentration in the concentration region most relevant to the problem. The philosophy behind the second category is based on the concept that measurement variability throughout the low end of the measurement range is relevant to the problem of setting detection and quantitation limits. The methodology used in implementing procedures in the second category involves statistical estimation methods that allow data collected throughout the low end of the range to contribute to estimation of measurement variability in detection and quantitation region.

There are also differences in the experimental procedures used to determine detection and quantitation limits. Again, these tend to fall into two categories. The first category of single-laboratory detection limits uses data from an experiment in a single laboratory to estimate detection limits. The second category of multi-laboratory detection limits uses data from experiments from multiple laboratories to estimate detection limits. The rationale for the latter proposal is that actual measurement sensitivity varies among laboratories, regardless of the approach used to estimate the sensitivity of a given method. The Interlaboratory Detection Estimate (IDE) and the Interlaboratory Quantitation Estimate (IQE) adopted by ASTM International is an example of such an approach. Although EPA's MDL procedure does not incorporate specific procedures to account for multiple

laboratory variability, EPA nonetheless has accounted for this variability during method validation as described in Section D.1 below.

D. Historical Use of Detection and Quantitation Limits Under the Clean Water Act

The procedure for estimating the MDL was originally published in 1981 by staff at EPA's environmental research laboratory in Cincinnati, Ohio (Glaser, *et al.*, 1981). The MDL is based on the constant error model described by Currie (1968). EPA promulgated the procedure for determining the MDL for use in CWA programs on October 26, 1984 (49 FR 43234).

The ML was originally proposed on December 5, 1979 (44 FR 69463), in footnotes to Table 2 of EPA Method 624 and to Tables 4 and 5 of EPA Method 625. Between 1980 and 1984, EPA developed Methods 1624 and 1625 and included the ML in similar tables in those two methods. When these four methods were promulgated for use in CWA programs on October 26, 1984 (49 FR 43234), EPA replaced the MLs in Methods 624 and 625 with MDLs, and retained the MLs in Methods 1624 and 1625. Unlike the MDL, there have been changes to the definition of the ML over the years. For example, the term "recognizable signal" has been used instead of "recognizable mass spectra" for non-GC/MS methods.

Since 1984, the MDL and ML have been used in a variety of ways by analytical laboratories, permitting authorities, and regulatory communities. The three most significant uses of the MDL are described below, along with some concerns with those uses.

1. Method Development

The primary purpose of the MDL and ML is to characterize the sensitivity of a particular test method for a particular pollutant. Information about method sensitivity is critical when deciding which method is needed to accomplish a specific measurement objective.

The MDLs published in some EPA methods have been criticized because they are based on the performance of a single laboratory that may not reflect the capabilities of the laboratory community. EPA has responded to this criticism in recent years by gathering MDL information from multiple laboratories. During development of several analytical methods, EPA's Office of Science and Technology addressed the issue by using single laboratory studies to develop an initial estimate of the MDL for each analyte and then verified these MDLs in interlaboratory