

studies or in additional single-laboratory studies at other facilities. For example, when EPA initially drafted Method 1631 for measurement of mercury, EPA estimated the MDL to be 0.05 ng/L, based on results produced by a contract research laboratory.

Additional single-laboratory studies suggested that the MDL should be raised to 0.2 ng/L to better reflect existing capabilities of the laboratory community. During EPA's interlaboratory study for Method 1631, twelve participant laboratories were asked to conduct MDL studies. Each laboratory obtained an MDL less than 0.2 ng/L, the value published in the promulgated version of Method 1631.

The ML has been used in the 1600-series of EPA chemical methods promulgated for use under the CWA since 1984 as an additional means to characterize method sensitivity, establish the lower end of the calibration range, and serve as a quantitation limit in those methods. Although its use has thus far been limited to the 1600-series methods, the ML concept is applicable to any analytical procedure to which the MDL can be applied under the CWA.

2. Demonstrating Laboratory Performance

The MDL also has been used as a means of demonstrating laboratory capability or performance. For example, a laboratory often publishes results of an MDL study to advertise its ability to detect a pollutant at a low level. Similarly, a laboratory client or a certification program may require that a laboratory demonstrate its ability to achieve a specified MDL using a particular method.

EPA also has used MDLs in approved EPA CWA methods (*i.e.*, promulgated at 40 CFR part 136) to provide a standard for allowing increased flexibility and encouraging advances in technology. Under EPA's CWA Alternate Test Procedures (ATP) program and in EPA's performance-based methods, a laboratory is permitted to modify certain aspects of approved method procedures provided that it is able to achieve an MDL that is less than or equal to one-third the regulatory compliance limit or less than or equal to the MDL specified in the approved method, whichever is greater (see section 9.0 of EPA Method 1631, for example).

3. Use of the MDL and ML in Clean Water Act Programs

Both the MDL and ML have been used as reporting limits for a variety of studies and monitoring efforts under the CWA. For example, EPA often uses the

MDL as a reporting threshold in surveys designed to determine levels of human exposure from consumption of water or fish under the CWA in order to characterize health risks from a variety of pollutants. In recent years, EPA has used the ML as the reporting limit in setting numeric limits for effluent guidelines limitations. EPA recommended in a 1994 draft guidance document that the ML be included in a National Pollutant Discharge Elimination System (NPDES) permit as a footnote to the water quality-based effluent limit (WQBEL) when the WQBEL is below either the MDL or ML of the most sensitive method. (See U.S. EPA Draft National Guidance for the Permitting, Monitoring, and Enforcement of Water Quality-based Effluent Limitations Set Below Analytical Detection/Quantitation Levels, 1994.) This 1994 draft guidance document was very controversial and was never finalized. Because individual States are responsible for implementation and enforcement of NPDES permits, use of the MDL and ML in the NPDES program varies among the States.

4. Concerns Regarding Use of the MDL

Over the years, a number of concerns have been raised about the MDL procedure. Some of these concerns are technical in nature (*e.g.*, selection of appropriate spiking levels and treatment of outliers), while others focus on implementation (*e.g.*, use of the MDL as a regulatory compliance limit). As part of EPA's assessment of detection and quantitation limits, the Agency identified and investigated a number of issues, including concerns that had been presented to the Agency by a variety of sources (*e.g.*, commercial laboratories, permittees, State laboratory and permitting authorities, EPA and other Federal laboratories, and others). Section IV.D of this proposal highlights the most significant issues addressed during the recent assessment. A comprehensive discussion of these issues is provided in the Assessment Document that is available in the docket supporting today's proposed rule and noticed elsewhere in today's **Federal Register** for public comment.

IV. EPA's Assessment of Detection and Quantitation Concepts

EPA first began a comprehensive assessment of detection and quantitation limits in the mid-1990s as concerns about the increased use of water quality-based permitting began to push permit limits for many pollutants below the measurement capabilities of some laboratories for a number of

environmental chemistry methods. One of the key areas of concern centered on the nature of measurement error in the region of detection and quantitation. Because EPA was not aware of studies that included replicate testing across or within the vicinity of this region, EPA focused its early efforts on developing such data, first with a single-laboratory study of measurement error using inductively coupled plasma-mass spectrometry (ICP-MS) techniques, and later with a similar single-laboratory study of measurement error using 10 different analytical techniques commonly used in Clean Water Act monitoring programs.

The October 2000 settlement agreement described in section III.B. of this preamble committed EPA to a fixed timetable and established specific milestones for completing its assessment. The general approach used in the Agency's assessment of detection and quantitation concepts and procedures is summarized below. Additional details concerning the assessment are presented in the Assessment Document that is available in the public docket supporting this proposed rule. EPA is also providing an opportunity for public review and comment on this assessment and the Assessment Document in a separate notice in today's **Federal Register** (see Notice of Document Availability and Public Comment Period on the Technical Support Document for the Assessment of Detection and Quantitation Concepts).

A. Study Plan

In December of 2001, EPA produced a draft Plan for the Assessment of Detection and Quantitation Limits Under Section 304(h) of the Clean Water Act. The December 2001 plan described roles and responsibilities for implementing the plan, provided a background discussion of detection and quantitation limit concepts, and outlined a series of events necessary to support EPA's assessment of detection and quantitation concepts and procedures as required to comply with the terms and schedules set forth in Clause 6 of the settlement agreement.

The draft plan was circulated for review by EPA staff, the Petitioners and Intervenor, and external peer reviewers. The external peer review was performed in accordance with EPA's Science Policy Council Handbook—Peer Review, 2nd Edition (EPA 100-B-00-001, December 2001; the "Peer-review Handbook"). EPA evaluated the comments and recommendations provided by reviewers and, where appropriate, integrated these comments