

procedures if revised according to this proposed rule.

IIAG's proposed "full range" validation study is intended to determine precision and bias across the entire working range of an analytical method (*i.e.*, from a blank to the upper end of the working range) and would account for variability between laboratories. IIAG recommends that, unlike the MDL and IIAG's proposed sensitivity test, the "full-range" validation study could be used to characterize bias and precision across the entire working range of the method and results of such a study could be used to establish an interlaboratory method detection level. EPA is requesting comment on the use of data generated through a "full range" validation study to determine a quantitation level, detection level, and corresponding bias and precision criteria that are applicable throughout the entire working range of the method. EPA also is soliciting comment on how IIAG's recommended "full range" validation study would be either more appropriate or less appropriate than EPA's use of interlaboratory validation studies, which are designed in accordance with ASTM Standard D 2777, or other appropriate standards. For example, EPA used the ASTM standard to validate EPA Method 1631 (see Interlaboratory Validation Study of EPA Method 1631).

#### IX. Solicitation of Comments

EPA is hereby requesting public comment on the proposed revisions discussed in section VII of this preamble and on the industry proposal discussed in section VIII. Specifically, EPA is requesting comment on the proposed revisions to the Definition and Procedure for the Determination of the Method Detection Limit at 40 CFR part 136 (Appendix B), to the proposed revision to the definition of "Detection Limit," on whether EPA should add definition of "Minimum Level" at 40 CFR 136.2, and on whether and how the sensitivity test described in the industry proposal could be used in CWA programs. EPA is also requesting public comment on the Assessment Document supporting the proposed revisions discussed in this notice elsewhere in today's **Federal Register** (see Notice of Document Availability and Public Comment Period for the Technical Support Document for the Assessment of Detection and Quantitation Concepts).

Commenters are encouraged to support their views with data or information that would assist EPA in making a final decision on detection

and quantitation procedures for EPA's CWA applications. To ensure that EPA can properly respond to comments, commenters should cite, where possible, the paragraph(s) or section(s) in this proposal to which each comment refers. For further details on submission of comments, please see the **DATES**; **ADDRESSES**; and "How to Submit Comments" sections at the beginning of this preamble.

EPA is particularly requesting comment on the following:

1. EPA is requesting comment on whether to include a definition and procedure for the ML in Appendix B of 40 CFR part 136 (see section VII.D of this preamble). EPA is soliciting comment on whether the proposed addition of an ML definition and procedure in Appendix B is appropriate, or whether either of the alternatives discussed in section VII.D are more appropriate to maintain flexibility in the application of different quantitation approaches.

2. EPA is proposing a recommendation that laboratories periodically demonstrate target analyte recovery at the ML by preparing and analyzing a reference matrix sample spiked at the ML (see section VII.D of this preamble). Specifically, EPA is soliciting comment on whether this recommendation should be made into a mandatory requirement, retained as a recommendation, or replaced by an alternative recommendation for demonstrating recovery at the ML. EPA also is soliciting comments and recommendations regarding procedures for establishing acceptance criteria for ML recovery, and when application of the criteria would be appropriate (*e.g.*, development of new methods, validation of data), if such a requirement were mandatory.

3. EPA is proposing to add a new Step 8 to the MDL procedure to address the identification and treatment of suspected outliers (see Section VII.B.7 of this preamble). This proposed step includes provision for invalidation of results from noncorrectable errors and precludes their use in calculating the MDL. The proposed step also states: "Given the small number of replicates typically used to determine the MDL, it is inappropriate to use a data set that contains more than one statistical outlier." EPA requests comment on (1) the procedures for identifying outliers, (2) the specification that only one outlier may be removed from a data set that is used for MDL determination, and (3) the appropriateness of allowing use of a data set containing six results if an outlier is identified and removed from a data set containing results from the

required minimum of seven replicate samples.

4. EPA is proposing to revise the specifications for establishing the test concentration (spike level) that will be used in the determining the MDL according to the intended application of the MDL (see Section VII.A.4 of this preamble). EPA is soliciting comment on these levels and on the appropriateness of applying these levels according to the intended use of the MDL.

5. EPA is soliciting comment on the sensitivity test and "full-range" validation study described by IIAG and included in the public docket supporting this proposed rule (see Section VII of this preamble). EPA is specifically soliciting comment on those aspects of IIAG's proposed study that relate to detection and quantitation issues.

6. EPA is proposing to delete the Reporting section of the existing MDL procedure. EPA is soliciting comments on whether this change is appropriate.

#### X. Statutory and Executive Order Reviews

##### *A. Executive Order 12866: Regulatory Planning and Review*

Under Executive Order 12866 (58 FR 51735 (October 4, 1993)), the Agency must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Executive Order defines "significant regulatory action" as one that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

- (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.