

August 15, 2003

Mr. G. Tracy Mehan, III
Assistant Administrator, Office of Water
U.S. Environmental Protection Agency
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Washington, DC 20460

**National Consensus on Detection and Quantitation Levels
EPA's Rulemaking on MDL and ML Procedures
RIN 2040 - AO53 (68 Fed. Reg. 11,770 (March 12, 2003))**

Dear Mr. Mehan:

The undersigned companies and organizations represent a broad cross-section of interests from the municipal, industrial, scientific, and laboratory communities. We are concerned about the direction EPA's Office of Water appears to be taking in its March 2003 proposed rule on the MDL (method detection limit) and ML (minimum level of quantitation). Protection of human health and the environment to a large degree depends on the ability to measure accurately the presence or absence of contaminants of concern. The current MDL/ML approach routinely gives erroneous estimates of the sensitivity of laboratory measurements, and the proposed revisions are no improvement. Moreover, the ML is used as a compliance level when water quality-based effluent limitations are below the capabilities of current analytical methods. Setting a suitable compliance limit is important because limits set below what can be reliably measured can result in penalties for supposed "violations" that are really the result of analytical variability or "noise." This can be harmful to human health and the environment because resources that would be spent on real problems are instead spent on phantom ones.

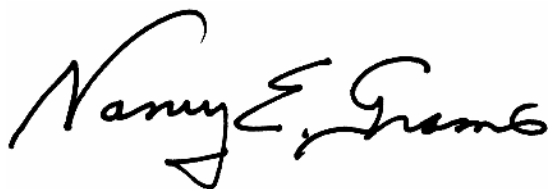
We the undersigned desire scientifically sound approaches for determining detection and quantitation levels for water analytical methods. These determinations, while embedded with numerous technical issues, are a matter of great importance and raise critical issues for the NPDES permitting program. We agree that the EPA Office of Water's proposed MDL and ML procedures do not provide a scientifically acceptable basis for establishing detection and quantitation levels, nor do they provide a sound basis for ascertaining compliance with NPDES permit limits set below levels of quantitation. We have achieved consensus on the attached principles, which we believe do provide a technically sound basis for establishing detection and quantitation levels. We ask that EPA consider and adopt these principles in the development of a final, agency-wide approach to addressing detection and quantitation levels. Some of the organizations signing on to this letter may provide separate comments detailing their views regarding specific elements of the attached consensus principles.

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Many of the undersigned companies and organizations have worked with the Agency for years on exploring the numerous difficult policy and technical questions inherent in the MDL/ML issue. We believe there are now available fully implementable procedures for determining detection and quantitation levels that reflect the attached principles, are based on sound science, and are a significant improvement over the proposed MDL and ML procedures.

The undersigned parties are ready to work with EPA to develop those procedures and are confident that we can arrive at procedures that will have broad-based support among our organizations and other key stakeholders. We will contact your staff after they have had an opportunity to review the attached principles and the detailed comments on the March 2003 proposed rule that are being submitted separately.

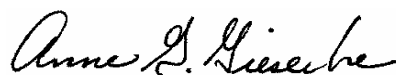
Yours very truly,




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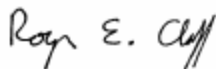
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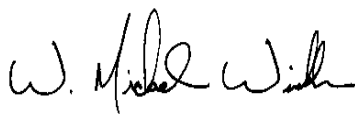
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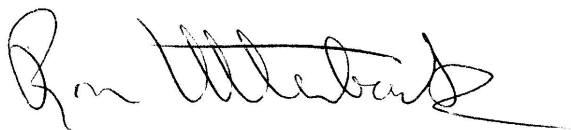
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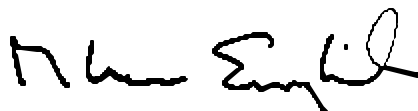
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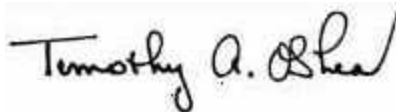
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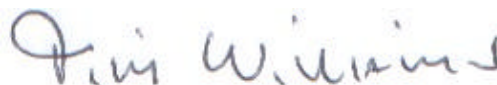
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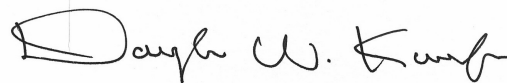
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Managing Director, Government & Public
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Attachment

Consensus Principles on Detection and Quantitation Levels

1. The MDL/ML proposal at 68 Fed. Reg. 11,770 (March 12, 2003) is unacceptable because it does not take into account the following principles.
2. The “evaluation criteria” used by EPA’s Office of Water in its Assessment Document (*Technical Support Document for the Assessment of Detection and Quantitation Approaches*, EPA-821-R-03-005 (February 2003)) were written inappropriately to favor the MDL and ML over alternative detection and quantitation levels. The Office of Water has not yet conducted an unbiased evaluation of the alternative proposals against appropriate evaluation criteria and must do so.
3. The detection level and quantitation level must be based on sound scientific principles. Low-cost and/or simple approaches must not be selected if inaccurate compliance determinations or unmeasurable permit limits may result.
 - a. The definition of “quantitation” must account for both precision and bias.
 - b. Detection limit procedures must take into account the variability and bias of method blank results.
 - c. For consistency with international standards, EPA must adopt the definitions of L_C (critical value), L_D (detection limit), and L_Q (quantification limit) of IUPAC (International Union of Pure and Applied Chemistry) that are being adopted by international standards organizations (*e.g.*, the International Organization for Standardization (ISO)).
 - d. The L_C , L_D , and L_Q are three distinct points, each of which has unique criteria that must be satisfied.
 - e. False positives (Type I errors), false negatives (Type II errors), and precision must all be addressed by detection concepts and reporting of analytical results for regulatory purposes.
 - f. Precision, bias, and qualitative identification (where appropriate) must all be addressed by the definition and concepts of quantitation and by the reporting of analytical results for regulatory purposes.
 - g. Detection limit procedures must include procedures for ongoing demonstration of sensitivity, preferably incorporated into the routine analytical quality control as a check against false negatives.
4. EPA’s Office of Water has not considered all the different uses of the MDL and ML in the Clean Water Act program (as a start-up test for a single laboratory, as a figure of merit to characterize an analytical method, as a permit compliance level, etc.) and has not evaluated the appropriateness of the MDL or ML for each of these uses.

- a. Because of the differing technical demands of different regulatory and laboratory quality assurance uses of detection and quantitation levels, an ML used for regulatory purposes cannot be determined solely as a multiple of the MDL.
- 5. The definitions of and procedures for determining detection and quantitation levels must take into account that quantitation levels are used as regulatory compliance levels in NPDES permits.
 - a. Detection and quantitation levels must take into account routine variability within a laboratory over time.
 - b. Any detection or quantitation level that is used as a regulatory compliance level must account for *interlaboratory* variability.
 - c. EPA should specify consensus standard procedures for establishing significant figures and for rounding data.
 - d. There is no appropriate regulatory use for single measurements that fall between the detection level and the quantitation level because by definition quantitation is uncertain in that range.
 - e. In its procedures for establishing detection and quantitation levels, EPA must develop guidance on how to account for the effects of various matrices.
- 6. EPA must strive for consistency across all EPA offices (the Office of Water, Office of Research and Development, Office of Ground Water and Drinking Water, and Office of Solid Waste and Emergency Response) in defining and applying detection and quantitation levels.