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Situation Assessment Report
on
Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs

U.S. Environmental Protection Agency
Engineering and Analysis Division
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Submitted by
Triangle Associates, Inc.
811 First Avenue Suite 255
Seattle, WA 98104

under subcontract to
SRA International, Inc.
Alexandria, VA

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Introduction

This report describes the findings and recommendations of Triangle Associates, a neutral third party, who conducted a situation assessment concerning issues related to detection and quantitation[1] approaches and uses in Clean Water Act programs. EPA authorized the situation assessment to explore the feasibility and design of a stakeholder process to obtain additional stakeholder input on procedures for the development of detection and quantitation limits and uses of these limits in Clean Water Act programs.

Situation Assessment Process

Triangle Associates conducted the situation assessment through telephone interviews in October and November 2004 with representatives of key stakeholder groups that have an interest in detection and quantitation. Those interviewed included representatives of states, industry, laboratories, environmentalists, standards-setting and testing organizations, and federal agencies, including EPA. EPA sent letters to potential interviewees in advance, explaining the purpose of the situation assessment and encouraging their participation in the interview process. Triangle Associates scheduled the interviews and sent the questions in advance so the interviewees had time to consider their responses. Triangle Associates told the interviewees that the themes from the interviews would be summarized in the report but that no one's name would be identified with specific comments.

Altogether, Alice Shorett and Vicki King of Triangle Associates conducted 28 interviews. In seven cases, the interviews included two or three people, bringing the total number of those interviewed to 37. (See Appendix A for the list of those interviewed.) The telephone interviews ranged in length from 40 minutes to an hour and a half; most lasted about an hour.

During the interviews, Triangle Associates asked interviewees to describe their history with detection and quantitation issues, the key technical and policy questions associated with detection and quantitation, and the technical issues over which there has been disagreement and how the technical issues affect policy. The remainder of the interviews focused on interviewee recommendations for a potential stakeholder process, including its goals, purpose, product, participants, informational needs and other design issues.

This report is based on the results of those interviews.

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[1]Quantitation is the term in common usage among analytical chemists for the act of quantifying or quantification of volume or concentration.

Background

EPA approves test procedures (analytical methods) at 40 CFR Part 136 for monitoring of pollutants in wastewater under the Clean Water Act (CWA). Appendix B to Part 136 contains the *Definition and Procedure for the Determination of the Method Detection Limit* (MDL). The MDL is defined as "the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte." The MDL definition and procedure were promulgated (i.e., published through rulemaking) on October 26, 1984 (49 FR 43430), and have remained unchanged since promulgation. Many of the analytical methods promulgated at 40 CFR Part 136 contain MDLs.

Discharger's laboratories use the MDL procedure to perform measurements of pollutants required to be reported in National Pollutant Discharge Elimination System (NPDES) permits under section 402 of the Clean Water Act (CWA), and for certifications issued by States under section 401 of CWA.

Also on October 26, 1984, EPA codified the minimum level of quantitation (ML) in footnotes to Table 2 in EPA Method 1624 and footnotes to Tables 3 and 4 in Method 1625. In those footnotes, EPA defined the ML as "the minimum concentration at which the analyte must give a recognizable mass spectrum and acceptable calibration point." Subsequently, EPA expanded the definition to "the minimum concentration at which the analytical system must give a recognizable signal and acceptable calibration point for the analyte." (See, e.g., the Glossary at the end of EPA Method 1613 and 1631 promulgated at 40 CFR Part 136, Appendix A).

Details of the ML may be defined differently in different methods, owing to the differing nature of the methods. For example, in Method 1631, the ML is defined as "The lowest level at which the entire analytical system must give a recognizable signal and acceptable calibration point for the analyte. It is equivalent to the concentration of the lowest calibration standard, assuming that all method-specified sample weights, volumes, and cleanup procedures have been employed." In Method 1677, the ML is defined as "The level at which the entire analytical system shall give a recognizable signal and acceptable calibration point, taking into account method specific sample and injection volumes." The ML is the minimum concentration of an analyte that can be measured and reported with a stated degree of confidence. The ML is contained in some of the methods promulgated at 40 CFR Part 136.

In 1999, several industry groups filed suit against EPA (Alliance of Automobile Manufacturers, et al. v. EPA, No. 99-1420, (D.C. Cir.) as a result of EPA revisions of a test used to measure mercury concentrations at low levels, and in October, 2000, the parties reached a settlement agreement that required EPA to assess procedures to determine detection and quantitation limits under EPA's CWA programs by November 1, 2004.

On March 12, 2003, EPA published two notices in the *Federal Register*. One announced the availability of a draft Technical Support Document that described EPA's reassessment of detection and quantitation concepts and procedures (68 FR 11791), and the second proposed revisions to the MDL and ML definitions and procedures (68 FR 11770).

Many of the 126 comments EPA received in response to the *Federal Register* notices were critical of the assessment and proposed revisions. Rather than proceeding with the revisions, EPA decided to withdraw the proposed rule and contract with a neutral third party to conduct a situation assessment. The purposes of the situation assessment were to obtain additional input on technical and policy issues related to detection and quantitation and to explore the feasibility and design of a stakeholder process. EPA announced this decision in a *Federal Register* notice dated September 15, 2004 (69 FR 55547). EPA selected Triangle Associates, Inc. of Seattle to conduct the situation assessment.

On November 8, 2004, EPA published a notice of document availability in the *Federal Register* with EPA's revised assessment of detection and quantitation concepts and procedures (69 FR 64704) and published a notice withdrawing the March 12, 2003, proposal (69 FR 64708). The withdrawal stated that a vast majority of commenters did not favor the proposed revisions and that EPA planned to work with stakeholders to evaluate one or more of the approaches submitted in comments on the proposal.

Feasibility

As a result of the interviews conducted for the situation assessment, Triangle Associates finds that a stakeholder process to address detection and quantitation issues has a good chance to achieve consensus on revised detection and quantitation approaches and uses in Clean Water Act programs.

Triangle Associates found unanimity across the stakeholder groups on the pressing need to address detection and quantitation. All of those interviewed felt that consensus (or majority support) for revised testing methods would be a significant improvement that would allow the parties to better meet their needs and interests. Triangle also found high interest in a consultative process that would bring the key stakeholder groups together to work collaboratively with EPA to develop revised detection and quantitation methods. In return, the stakeholders are looking to EPA for a similar commitment to collaboration.

There is optimism that a stakeholder process can be successful because participants will not have to “start at zero.” Those interviewed are aware of, and, in some cases, have helped to develop, alternative approaches to those currently in regulation and guidance. These approaches are seen as a good starting point for discussion although some of those interviewed suggest that reaching resolution will not be quick or easy.

For the stakeholder process to be successful, the parties indicate that the group should reach agreement, collaboratively, on the group’s purpose and product at the outset; EPA alone should not determine the outcome. Indeed, it is Triangle’s opinion that the more collaborative the process can be and the greater the commitment there is from EPA to use the consensus results of the process, the more successful the process will be. Success is also contingent on narrowing the focus to selected top priority issues and achieving results within a year or so.

There is recognition across the board that the environmental community perspective has been largely missing from discussions related to detection and quantitation and an acknowledgment that participation of the environmental community is essential to developing acceptable revised detection and quantitation methods. There is also a desire to involve in the process state governments that regulate wastewater through National Pollution Discharge Elimination System (NPDES) permits. Both stakeholder groups expressed interest in participating.

Agreement on the importance of detection and quantitation approaches that have consensus support, the willingness to work collaboratively with EPA and other stakeholder groups to reach this result, the existence of a number of alternative approaches as a starting point for discussion – all suggest that a consultative process has a significant likelihood to succeed.

Based on our professional experience and judgment, Triangle Associates has identified the following conditions for a stakeholder process to be successful:

- EPA commits to review and consider consensus recommendations of the stakeholder process in future revisions of detection and quantitation approaches and uses in Clean Water Act programs.
- EPA has a structured internal team throughout the process that spans the participating units and advises the negotiating team who speaks on behalf of EPA.
- A balance of the interests are at the table.
- Independent technical expertise is available to the stakeholder process.
- EPA provides travel to entities that cannot otherwise participate.
- The scope of the discussion and the resulting product can be accomplished in a year or so.

Categories of Stakeholders

Triangle Associates identified five categories of key stakeholders. We recommend that EPA invite representatives from each of the categories to participate in the stakeholder process:

- State Government
- Industry
- Wastewater Treatment Plants
- Environmental Laboratories
- Environmentalists

In addition to these categories, Triangle Associates recommends that the following parties serve as technical resource to the consultative process:

- Other federal agencies that use EPA methods for detection and quantitation or that have

significant technical expertise on the issues.

- Nationally-recognized experts (academics, researchers) who are effective communicators on technical issues, as needed.

Key Issues and Interests of EPA and Stakeholder Groups

This section identifies, by entity, the key issues and interests that were identified during the interview process by EPA and stakeholder groups. (A summary of key issues across groups follows in the next section.)

US Environmental Protection Agency

EPA is responsible for implementing the Clean Water Act. Section 304(h) of the Clean Water Act requires EPA to "promulgate guidelines establishing test procedures for the analysis of pollutants...." EPA approves and publishes analytical methods at 40 CFR Part 136 to support monitoring and reporting of chemical pollutants under the Clean Water Act.

Based on the interviews, Triangle understands that EPA's key interests relative to detection and quantitation are to develop procedures and approaches that are:

- Scientifically sound
- Practical, implementable, and cost-effective
- Supported by consensus among key stakeholder groups

If the stakeholder process results in a consensus recommendation, Triangle Associates strongly recommends that EPA use the results in developing a new rule concerning the MDL.

State Government

EPA delegates responsibility for implementing many water programs to state governments. State water quality programs regulate discharges of pollutants to surface and ground waters by writing wastewater discharge permits for sewage treatment plants and industrial discharges. States use risk-based data to set water quality standards. Some states have used detection and quantitation specifications in setting permit limits. They use laboratory results to measure compliance with permits. State environmental laboratory managers also support regulatory and compliance programs by consulting on the "reasonableness" or achievability of permit limits. States certify environmental laboratories; they use MDLs as a checklist or required performance criterion.

States raised concerns that the promulgated methods are versions of technologies that are old. The old technologies do not allow laboratories to "see" as low as the toxicity level of some pollutants (for example, PCBs, PAHs, dioxin). States say they need a compliance determination process for constituents which cannot be "seen" in the laboratories. (Some states are using the MDL as the permit limit for pollutants that are toxic at levels hundreds of times below what can

be detected in a laboratory; the regulated community opposes this approach because they say that data quality at the MDL is "unreliable.")

States also point out that newer technologies have allowed advances in detection and quantitation that result in lower numbers. They say they would like to adopt the lower numbers in permits but the regulated community resists this change.

One state raised the fact that regulatory agencies have focused on the EPA priority pollutant list. In light of the fact that thousands of new chemicals are being produced and introduced into the waterways, with no systematic investigation of their presence or possible effects, it recommends developing screening procedures and encouraging states (with funding) to begin looking in a systematic way for these new chemicals.

States say that EPA has provided guidance on quantitation limits in wastewater but has not standardized an approach. Consequently, there is variability across the country on how quantitation limits are set. States say they are vulnerable to challenges by the regulated community because quantitation is not in statute.

States are also interested in addressing the variability in performance among laboratories that are a result of differences in laboratory equipment and laboratory analyst training and experience.

States believe it is important to pilot test the approach/es developed through the stakeholder process to ensure they work as expected before being finalized. Several states said they want the results of a stakeholder process to be used to revise current regulation; one state said that regulation would be helpful in many circumstances while, in others, guidance would provide more flexibility in implementation.

Based on the interviews, Triangle understands that the key interests of states are in developing detection approaches that

- Are scientifically sound.
- Generate accurate and reliable results in laboratories.
- Will be viable in the vast majority of situations that arise, nationwide.
- Are clearly described, with all the detail, so the procedures are not subject to interpretation.
- Address the variability in results within a laboratory as well as between laboratories.
- Are cost-effective.

Industry

Industry focuses primarily on issues related to quantitation (MLs) because quantitation levels are typically used in writing permits. (The exceptions, as noted above, are permits set by some states at the MDL level for constituents like PCBs and dioxin that are toxic at levels far below what can be detected in laboratories. As noted above, industry opposes permits at the MDL level because of the variability of data quality at the MDL.) Industry points out that water-quality-based permit limits for some constituents are very low (often parts per billion), and it is hard to

measure to that level. The lower the level, the harder it is to measure. Some permits are set so low that almost any detection becomes reportable as a non-compliance. Industry feels it is often penalized for measurement variability rather than actual pollution levels. Since every decrease in permit limits makes treatment and compliance costs rise, this is an important issue for the regulated community.

Industry notes that MDLs were not created to be used as the cornerstone for regulation and compliance, but they have increasingly been used for that purpose. Permits are often written in the context of an MDL achieved by a particular laboratory. If other laboratories cannot achieve that MDL number, it becomes problematic for a permittee to show it is in compliance.

Industry identifies a significant number of problems with the current MDLs and MLs. They say these methods:

- Do not deal with interlaboratory and intralaboratory variability.
- Do not provide guidance on what to report if a laboratory gets different results on different days.
- Are subject to spiking level errors.
- Produce different results depending on the matrix.
- Are ambiguous, which results in different laboratories conducting the MDL differently and producing results that are not consistent across the country.
- Produce precise results but those results may not be accurate.
- Control for false negatives but not for false positives. The current MDL procedure results in unacceptably high numbers of "false positives" ("ghosts" that often disappear in subsequent tests) that can lead to increased requirements and costs for monitoring, fines for failure to comply with permits, and a bad reputation.
- Lack consistency with international consensus standards which industry believes is required by the National Technology Transfer and Advancement Act (Public Law 104-113).
- Lack consistency with other EPA programs (including the Safe Drinking Water Act).

Based on the interviews, Triangle understands that industry's interest is in working with EPA and other key stakeholder groups to develop revised methods to replace what is currently at 40 CFR Part 136 Appendix B. The revised methods should be scientifically-defensible; should address the problems listed above, should be practical to implement, result in accuracy, fairness, and consistency across the county, at a reasonable cost. Industry would like the revised methods to be consistent with international standards and to be usable across all EPA programs.

Wastewater Treatment Plants

Operators of large municipal wastewater treatment plants echo most of industry's criticisms of the current MDL and ML methods, mentioned above.

Some cite an additional concern: they say they have data to indicate that the relationship

between the MDL and ML in EPA guidance does not exist across all analytes. Using a multiple of the MDL to generate the ML either grossly over- or underestimates the ML.

Given the problems they see with the current MDL methods, the uncertainties about data quality, and the negative consequences of inaccurate data for regulated entities, wastewater treatment plant laboratories express concern about signing statements that the data are true and accurate.

Based on the interviews, Triangle understands that the interests of municipal wastewater treatment plants are in sound science, good statistics, accurate and reliable results, including assurance and clarity about the quality of the data, and practical procedures that laboratory analysts can understand and implement consistently. They want the revised approaches to become codified in a rule that replaces what is at 40 CFR Part 136 Appendix B.

Environmental Laboratories

Environmental laboratories repeat many of the concerns identified above by states, industry and municipal wastewater treatment plants about data quality and accuracy, false positives and false negatives, uncertainty about reporting results, and variability in the laboratory, both day-to-day and over longer periods of time as samples are processed.

One laboratory expressed skepticism that the MDL procedure, which is purely statistical and mathematical, works even when a laboratory has newer equipment and experienced analysts and noted that they do not have confidence in the data they generate. The laboratory also said that neither their customers nor their staff understand what the numbers mean.

Laboratories also say the procedure is arduous to conduct and expensive.

They raised a concern about the way MDLs are being used from a business perspective, as a marketing tool. The assumption by potential customers is that the lower your MDL, the "better" your laboratory is. In discussions with potential clients, they are told they must be able to achieve a certain MDL – specified in a contract – or they do not get the job.

Another concern about the MDL procedure relates to accreditation. It was pointed out that laboratories have to be able to do the MDL to be accredited. However, if laboratories cannot agree on how to do the procedure, they ask how laboratories across the country can be accredited.

Several laboratories express skepticism that a "one-size-fits-all" approach will work. They believe that more than one approach for detection may be needed for different technologies.

Based on the interviews, Triangle understands that the interests of environmental laboratories are to reach agreement on MDL procedures that produce accurate data, that are practical and clearly described so the analysts can carry them out consistently, that are not too arduous, and that are cost-effective. They say they need to understand and to be able to explain what the numbers mean to their staffs and their customers. They have an interest in consistency across all EPA program areas because it would result in efficiencies for their customers.

Environmentalists

As noted above, the environmental community has been largely absent from national discussions

concerning detection and quantitation methods since the 1970s when a lawsuit by the Natural Resources Defense Council resulted in an expansion of EPA's list of toxic pollutants of concern from 65 chemicals to129 Priority Pollutants. Environmentalists are frequent participants in policy-level discussions concerning water quality, at the grassroots, regional and national levels but they have not generally been participants in technical discussions about detection and quantitation methods and the issues associated with them. However, through interviews with several scientists at environmental organizations and with consultants who have represented environmental organizations in the past, we were able to identify the following issues and concerns from the environmental perspective.

A key concern is the fact that water quality standards for some pollutants (PCBs, PAHs, among others) are many times lower than levels that can be detected in laboratories using MDL procedures and current technology. Since permits are typically set at levels that can be "seen" in the laboratory, environmentalists say it is important – and should be a priority – to provide incentives to improve the capability of equipment to detect pollutants at lower levels and to have laboratories invest in the newer equipment. As more sensitive analytical methods and equipment become available, they say that permit limits should be lowered to reflect the increased capability. They also want to know how revised detection and quantitation methods would be applied in the real world of permit writing and compliance.

Since states typically require permittees to use EPA-approved testing methods, environmentalists would like EPA to take the lead in providing more tools for state and local municipalities to use to test for effects (such as bioassays in organisms or sediment toxicity tests) and to be able to require their wastewater treatment plants to use those tools, especially for detecting bioaccumulatives.

In cases where certain pollutants are toxic at much lower levels than can reliably be detected in a laboratory, they think it makes sense to have permits identify any detection as a violation. They also focus on how to control pollutants that are hazardous below the minimum detection limit.

One spokesperson says that a critical first step in addressing detection and quantitation methods is to find out how states are using detection and quantitation limits in writing permits and the testing that is required of permittees – to provide a context for addressing MDLs and MLs.

Based on the interviews, Triangle understands that the interests of the environmentalists are in having protective standards in place that reflect sound science and the potential health and ecological threats of chemical pollutants and having strong discharge limits in place to let standards be met. They have an interest in the development of more sensitive equipment that can detect at lower levels and in having incentives in place for environmental laboratories to invest in the new equipment. They have an interest in having controls on pollutants to reduce impacts to people and ecological systems.

Key Issues Across All Stakeholder Groups

There was broad agreement among stakeholder groups on the need for revisions to the MDL and ML to address the following issues:

- **Need for common set of terms and concepts:** Across all stakeholder groups interviewees said it was essential to reach agreement at the outset of a stakeholder process on a common set of terms and concepts to be used in the process. This will include a clear statement of what each term means, an explanation of the statistical and analytical assumptions on which concepts are based, and clarity on how they are to be used with respect to detection and quantitation. They see achieving this common set of terms and concepts as a prerequisite to productive dialogue and to evaluating alternative approaches to detection and quantitation that have been proposed.
- **Data quality, reliability, and accuracy:** Interviewees indicate that the ambiguities in the testing procedure to determine the MDL in Appendix B to Part 136 result in inconsistent results. They point out that when multiple laboratories are given the same task to perform, different laboratories carry out the procedure differently, yielding different results. Interviewees point out that the MDL procedure itself produces precise results, not accurate results. They say the problem of data accuracy is greatest when the detection levels of the constituents they are testing are very low. For permittees, the reliability and accuracy of results are key. If test results show they are not in compliance with permits, they can be fined, required to increase monitoring, and marked for increased enforcement scrutiny. Permittees feel they are often fined for the variability of data at the "noise" level, not for actual pollution. They say detection at such low levels has them and the laboratories chasing "ghosts." Often when tests are repeated, the "ghosts disappear." Some interviewees question the validity of the testing procedure itself while others say they do not understand what the numbers mean.
- **Reporting:** Some stakeholders say excluding "non-detects" skews the data. Laboratories point out that they have no guidance on what numbers they should report if they perform the MDL procedure on different days and get different results – which they say can happen as they run samples over days, weeks and months.
- **Variability in MDL results within and between laboratories:** Most of those interviewed pointed to the variability in MDL results within and between laboratories as a major problem. The variability is a result of differences in equipment, analyst training and experience, conditions in the laboratories themselves, ambiguities in the procedure, and the matrix, among other factors. Laboratories with more sophisticated, newer equipment can achieve lower numbers than laboratories with older equipment. This can be a problem for a customer that has to change laboratories and the MDL the new laboratory produces is higher than the MDL achieved by the former laboratory. In such a case, permittees say that compliance and enforcement officials assume the difference is a result of increased pollution rather than a difference in laboratory capabilities.

- **Variability among states in setting MLs:** States say that EPA has provided guidance on a variety of methods for determining quantitation limits but has not standardized the approach. Consequently, there is variability on how quantitation limits are set across the country. States say they are vulnerable to challenges by the regulated community because determining quantitation is not in statute.
- **Permit limits for constituents with toxicity levels that are below equipment detection capabilities:** A key concern is the fact that water quality standards for some pollutants (PCBs, PAHs, among others) are many times lower than levels that can be detected in laboratories using MDL procedures and current technology. States say they need a compliance determination process for constituents which cannot be "seen" in the laboratories. Environmentalists focus on a different aspect of this issue. Since permits are typically set at levels that can be "seen" in the laboratory, environmentalists say it is important – and should be a priority – to provide incentives to improve the capability of equipment to detect pollutants at lower levels and to have laboratories invest in the newer equipment. As more sensitive analytical methods and equipment become available that allow "seeing" pollutants at lower levels, they say that permit limits should be lowered to reflect the increased capability.
- **Reducing permit limits in response to increased equipment capability:** States and environmentalists point out that newer technologies have allowed advances in detection and quantitation that result in lower numbers. They say they would like to adopt the lower numbers in permits but the regulated community is resistant to this change.
- **Updating old methods to match modern technology:** States raised concerns about the fact that the promulgated methods were designed for technologies that are now old. They say there is a need to update the methods to respond to the improved capabilities of modern equipment.
- **Uses of the MDLs and MLs:** As noted above, some of those interviewed point out that the MDL was originally intended to be a simplified statistical procedure to show that laboratories were in good working order, not to be the cornerstone of regulation and compliance, roles which they have subsequently taken on. The regulated community objects to having the MDL put in permits because of the variability of data at the MDL level. Others question the validity of the procedure for generating the ML as a multiple of the MDL; they say the relationship in the formula does not exist across all analytes. Environmentalists say they want to know how revised detection and quantitation methods would be applied in the real world of permit writing and compliance.
- **Accreditation:** Environmental laboratories have to be able to do the MDL to be accredited. However, if laboratories can't agree on how to do the procedure, they ask how laboratories across the country can be accredited.
- **One-size-fits-all versus multiple approaches:** A number of those interviewed are skeptical that a single approach will work. They suggest that more than one approach may be needed for different technologies, perhaps for different analytes. Whatever

approaches are developed, however, must be procedurally clear so they result in consistent results across laboratories nationwide.

- **Practicality and implementability of the current procedures:** Laboratories say the current procedures are hard to understand and to carry out consistently. Looking to the future, they want to be able to put protocols in place that are clear and produce results that are reliable. Interviewees say that procedures for detection and quantitation must be ones that laboratories across the country can carry out in the same way so that they produce consistent results.
- **Cost:** Laboratories across the nation produce MDLs to become certified and to meet their customers' needs. They say that carrying out the current procedure at 40 CFR Part 136 Appendix B is time-consuming, arduous, and costly. They and their customers want testing procedures that produce statistically valid results at reasonable cost.

Goals and Purpose of the Stakeholder Process

In light of this array of issues and concerns, there was broad agreement across all stakeholder groups that the goals and purpose of the stakeholder process should be to come up with procedures for determining detection and quantitation limits that are scientifically-defensible, acceptable to most or all, easy to carry out, and that are practical and cost efficient. The procedures should produce accurate, consistent, and uniform results. They should become the nationwide standard for how detection and quantitation are determined.

At noted above, there was unanimity across stakeholder groups that an essential first step to achieving the goals and purpose of the stakeholder process is to reach agreement on a common set of terms and concepts so everyone uses the terms and concepts in a consistent way.

There was also broad agreement that once revised approaches have been agreed to, guidelines for interpretation of the results should be provided so there is clarity around what the numbers mean and how they should be used.

Product of the Stakeholder Process

Stakeholder groups generally agreed that the product of the consultative process should be revised detection and quantitation approaches for use in Clean Water Programs that have consensus support among the stakeholder groups. In addition, there should be clarity on the interpretation and acceptable uses of the MDLs and MLs in permitting and compliance.

Most of those interviewed said they want the revised MDL procedures to go through rulemaking and replace the current rule at 40 CFR Part 136 Appendix B. One state was unsure whether the needs of its water quality program would be better served by having revised procedures in regulation or in guidance.

In describing the MDL procedure, stakeholders said they do not want concepts, generalities or a "bible" that is subject to interpretation. They want the procedures to be clear and practical, with all the detail, almost like a cookbook. The result, they say, would lead to uniformity and consistency across all laboratories.

Procedural Issue Related to the Stakeholder Process

If EPA decides to convene a stakeholder process to address detection and quantitation approaches and uses in Clean Water Act programs, stakeholder groups want EPA to be an active participant in the process. This is important because EPA is responsible for issuing detection and quantitation procedures for Clean Water Act programs; it is, therefore, in EPA's interest to help shape revisions to the detection and quantitation approaches (the stakeholder group's expected product). Given this stakeholder preference, Triangle recommends that EPA consider establishing a stakeholder process under the rules of the Federal Advisory Committee Act.

Participation

Triangle Associates recommends that EPA invite five categories of stakeholders to participate in the stakeholder process[2]:

Interested Stakeholders	Affected Stakeholder Roles & Responsibilities	Possible Groups
State Government	• Set water quality standards and permit limits • Test, monitor and enforce compliance • Certify laboratories • Experience working to resolve these issues and geographical diversity	ASIWPCA Invited states
Industry	• Discharge to water bodies • Discharge to wastewater treatment plants • Reflect a range of sizes • Reflect different effluents	Inter-Industry Analytical Group
Wastewater Treatment Plants	• Treat wastewater • Reflect interests of large and small facilities	AMSA WEF
Environmental Laboratories	• Conduct water quality analysis for reporting and compliance	ACIL: Large private Small private

[2]The Society for Testing and Materials (ASTM) was identified as an important participant in a stakeholder process by a number of those interviewed. However, Triangle Associates recommends that ASTM not have an official seat at the table. It is both likely and recommended that individuals associated with ASTM participate in the consultative process as representatives of specific stakeholder groups. Their participation will be particularly valuable in technical discussions of MDL and ML approaches.

Interested Stakeholders	Affected Stakeholder Roles & Responsibilities	Possible Groups
Environmentalists	• Are knowledgeable about water quality testing from a policy perspective • Are knowledgeable about technical issues associated with detection and quantitation approaches	NWF Invited technical consultants and attorneys who represent environmental groups in legal matters

In addition, Triangle recommends that the process have access to two additional categories of parties that would provide technical expertise to the process:

- Other federal agencies that use EPA methods for detection and quantitation or that have significant technical expertise on the issues, including US Department of Defense and US Geological Survey.
- Nationally-recognized experts (academics, researchers, specialists) who are effective communicators on the technical issues.

Representatives of industry, wastewater treatment plants and environmental laboratories have a long history of working on this issue. They expressed interest and willingness to participate in a stakeholder process.

States have been less involved in these issues but they also expressed great interest in participating if they receive assistance with travel costs.

In Triangle's opinion, the biggest challenge will be effective involvement of the environmental community in the process. Many environmental groups are small, grassroots organizations with locally-focused agendas; such organizations have not been engaged in discussions about detection and quantitation. Staff with the appropriate technical backgrounds and organizational budgets adequate to fund environmental community participation in a stakeholder process are very limited in number. In light of these facts, Triangle recommends that the process include individual representatives who have the appropriate backgrounds to provide perspectives from the environmental community.

EPA, as convener of the stakeholder group, will have a seat at the table. It is recommended that EPA coordinate internally among the Office of Water; Office of Enforcement and Compliance Assurance; the Office of Research and Development; the Office of Policy, Economics and Innovation; and the Office of the General Counsel so EPA's representative is able to bring EPA perspectives to the table.

Process Design Recommendation

Based on the interviews and our professional judgment, Triangle makes the following process recommendations.

Scope of Work
The scope of work of the stakeholder group would be to reach agreement on:

- A common set of terms and concepts
- One or more specific approaches and procedures for detection and quantitation for use in Clean Water Act programs (not all EPA programs)
- Interpretation and uses of the numbers that result from the testing procedures

Federal Advisory Committee
To initiate the stakeholder process, Triangle recommends that EPA consider establishing a formal advisory committee in accordance with the Federal Advisory Committee Act (FACA). As required under FACA, all plenary meetings of the stakeholder group would be announced in the Federal Register and open to the public.

Design
Triangle Associates recommends that the stakeholder group process consist of plenary and technical work group sessions. Plenary sessions would focus on policy issues, provide direction and assign tasks to a technical work group, review draft technical work group products, and reach agreements. Plenary sessions are expected to be in-person meetings.

Between plenary sessions one or more technical work groups are recommended to carry out tasks assigned at plenary sessions, develop draft products, and report their findings to plenary sessions for review, further direction, and approval. Technical work groups would reflect a balance of the interests participating in the stakeholder process. It is expected that the work of these groups would be accomplished primarily through conference calls.

Facilitation
A process facilitator would manage the overall stakeholder process as well as the plenary sessions. A technical facilitator would facilitate technical work groups to develop draft products for review and consideration at plenary sessions.

Recommended Work Flow
Triangle recommends that in the initial plenary session, the committee reach agreement on a set of organizational protocols, define the problem to be resolved, identify informational needs, and confirm a schedule of meetings (plenary and technical). In light of the problem statement, the group would reach agreement on the goals, purpose, and product of the stakeholder group.

Members would articulate the interests they bring to the table relative to the problem to be addressed. They would also hear a brief history of detection and quantitation approaches and their uses to provide a context for their work.

At this meeting, the committee would be expected to initiate work on a set of topics and issues that would continue throughout the process. Work would be accomplished both in plenary session (approximately four to five sessions, one to two days in length) as well as through the work of a technical work group between plenary sessions. The number of technical work group meetings and conference calls would depend on the assignments from the plenary sessions. Their work is expected to focus on the following:

- A set of common definitions and concepts for use in the stakeholder process
- Evaluation criteria for screening alternative approaches
- Evaluating proposed methods for detection and quantitation
- Interpretation and uses of the MDL and ML (detection and quantitation) numbers in the permitting process

Once the committee has reviewed the alternatives, it would select detection and/or quantitation procedures to pilot test, to see if the results match expectations. The group will provide direction on what analytes will be used for the pilot testing, which laboratories will conduct the tests, and a schedule for carrying out the tests. The group will also agree on what they expect the results of the pilot testing to show and clarify how the numbers generated through the pilot tests should be used in reporting and compliance.

After the pilot tests have been conducted, the technical work group would review and analyze the results relative to the evaluation criteria and prepare a report of findings to present at the next plenary committee meeting. At this meeting, the plenary committee would be expected to:

- Review the technical work group's assessment and evaluation of the procedures that were pilot tested and
- Reach consensus on revised approaches and procedures for detection and quantitation.

The group would also be expected to make a recommendation on how quantitation should be determined – whether it should be linked to the MDL or not – and whether the procedure for quantitation should be in a rule or in guidance.

If the stakeholder process results in a consensus recommendation on revised approaches and procedures for detection, Triangle recommends that EPA use the results in subsequent rulemaking to amend 40 CFR Part 136 Appendix B for detection.

Protocols

At its initial meeting, Triangle Associates recommends that the stakeholder plenary committee develop procedural ground rules to govern its discussions. The proposed ground rules would cover the following:

- Expectations of Committee members
- Composition of the Committee, including access to technical resources; use of a work group to carry out specific tasks and prepare draft products for Committee review and consideration
- Decision-making (definition of consensus)
- Responding to media contacts
- Public input at Committee meetings
- Summaries of Committee and work group meetings and their distribution
- Schedule of meetings and planned completion date
- Roles and responsibilities of the facilitators

Conclusion

Triangle Associates, as neutral third party situation assessor, finds that convening a stakeholder group to address detection and quantitation procedures for use in Clean Water Act programs is feasible and appropriate. Provided EPA is as collaborative in its approach to this process as possible and that the conditions of success identified above on page 6 are met, Triangle Associates believes that the group has a good chance of successfully reaching consensus on revised testing methods and procedures for detection and quantitation approaches and uses in Clean Water Act programs.

Appendix A: List of Interviewees

Dave Akers, Section Manager, Water Quality Protection
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver CO 80246-1530

Bob Avery, Manager, Laboratory Services
Michigan Department of Environmental Quality
3350 North M.L.King Boulevard
Lansing MI 48906

Gary Beers, Permits Unit
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver CO 80246-1530

Dr. Gerald Bowes
Staff Toxicologist and Chief, Standards Development Center
State Water Resources Control Board
1001 I Street
Sacramento CA 95812

Richard Burrows
Severn Trent Laboratories
4955 Yarrow Street
Arvada CO 80002

James Christman
Utility Water Act Group
Hunton and Williams
951 East Byrd Street
Richmond VA 23219

Roger Claff
American Petroleum Institute
1220 L Street NW, 9th Floor
Washington DC 20005-4070

Gary Dechant (Consultant)
Analytical Quality Associates, Inc.
521 ½ Shanne Street
Grand Junction CO 81504

Dr. Andy Eaton, Lab Director
AWWA Representative to the Joint Editorial Board
Standard Methods for the Examination of Water and Wastewater
Laboratory Director
MWH Labs
750 Royal Oaks Drive, Suite 100
Monrovia CA 91016

Zonetta English, Former ELAB Chair
Metropolitan Sewer District
4522 Algonquin Parkway
Louisville KY 40217

Albert Ettinger
Environmental Law and Policy Center
35 East Wacker Drive #1300
Chicago IL 60601

William T. Foreman, Ph.D., Research Chemist
Methods Research and Development Program
U.S. Geological Survey
National Water Quality Laboratory
MS-407, Bldg. 95, Entrance E3
Denver CO 80225-0046

Geoffrey Grubbs, Office of Water
Director, Office of Science and Technology
US EPA Headquarters
1200 Pennsylvania Avenue, NW, 4301T
Washington DC 20460

Jack Hall
American Society for Testing and Materials - International

Bldg. K1006
2012 Highway 58, Suite 1000
Oak Ridge TN 37830

Jim Hanlon, Office of Water
Director, Wastewater Management
US EPA Headquarters
1200 Pennsylvania Avenue, N.W., 4201M
Washington, DC 20460

Christopher Hornback, Director, Regulatory Affairs
Association of Metropolitan Sewage Agencies
1816 Jefferson Place, NW
Washington DC 20036-2505

Patty Lee, Laboratory Manager
Hampton Roads Sanitation District
PO Box 5911
Virginia Beach VA 23471

Larry LeFleur
Environmental Group, American Chemical Society
National Council for Air and Stream Improvement
PO Box 458
Corvallis OR 97339

Dr. Joe Lowry
USEPA National Enforcement Investigations Center
Denver Federal Center
Building 25 Door E-3,
Denver CO 80225

Tom Maloney, Chief of Quality Assurance
U.S. Geological Survey
National Water Quality Laboratory
MS-407, Bldg 95, Entrance E3
Denver CO 80225-0046

Beth McGee
Chesapeake Bay Foundation
Philip Merrill Environmental Center
6 Herndon Avenue
Annapolis MD 21403

Greg Mohrman, Director, National Water Quality Laboratory
U.S. Geological Survey
National Water Quality Laboratory
MS-407, Bldg 95, Entrance E3
Denver CO 80225-0046

Mike Murray
National Wildlife Federation
Great Lakes Natural Resource Center
213 West Liberty Street, Suite 200
Ann Arbor MI 48104

Ken Osborne, Quality Assurance Officer
East Bay Municipal Utility District
375 11th Street
Oakland CA 94623

John H. Phillips
Ford Motor Company and Alliance of Auto Manufacturers
EQO
3 Parklane Blvd, PTW Suite 950
Dearborn MI 48126

Mark Pifher, Director, Water Quality Control Division
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver CO 80246-1530

Jim Pletl, Environmental Scientist
Hampton Roads Sanitation District
PO Box 5911
Virginia Beach VA 23471

Bill Ray, Quality Assurance Program Manager
State Water Resources Control Board
1001 I Street
Sacramento CA 95812

Steve Saiz, Environmental Scientist

State Water Resources Control Board
1001 I Street
Sacramento CA 95812

Jennifer Samson
Clean Ocean Action
P.O. Box 505
Sandy Hook NJ 07732

Jerry Schwartz
Senior Director, Water Quality Programs
American Forest & Paper Association
1111 19th Street, NW, Suite 800
Washington DC 20036

Mike Shapiro, Office of Water
Deputy Assistant Administrator
US EPA Headquarters
1200 Pennsylvania Avenue, N.W., 4101M
Washington, DC 20460

Mary Smith, Office of Water
Director, Engineering and Analysis Division
US EPA Headquarters
1200 Pennsylvania Avenue, N.W., 4303T
Washington, DC 20460

Barry Sulkin
Tennessee Public Employees for Environmental Responsibility (TN PEER)
4443 Pecan Valley Road
Nashville TN 37218

Nan Thomey
Environmental Chemistry, Inc.
2525 West Bellford, Suite 175
Houston TX 77054

Brad Venner

USEPA National Enforcement Investigations Center
Denver Federal Center
Building 25 Door E-3,
Denver CO 80225

Bill Yancey
BP Chemicals Senior Regulatory Consultant
150 West Warrenville Road Bldg. 605
Mail Code 5A
Naperville IL 60563