Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs

FDIC Seidman Center, Rooms 203 & 205
3501 Fairfax Drive, Arlington, VA
Thursday – Friday, September 29-30, 2005

Final Meeting #2 Summary

Decisions at Meeting #2

- Approved, by consensus, the summary of the June 21-22 committee meeting.
- Adopted, by consensus, working draft definitions of terms for use in the committee process with the understanding that the definitions would be refined as work progresses and decisions are made.
- Developed and approved, by consensus, draft criteria to evaluate a final package of recommendations; the draft criteria will be finalized at a future committee meeting.
- Created a Policy Work Group to: 1) identify and define uses of detection and quantitation; 2) identify the existing situation for each use category and data quality objectives for each type of use and user; and 3) pose policy issues that emerged in carrying out their assignments.
- Tasked the Technical Work Group with: 1) proposing an approach or approaches for conducting a pilot test, including possible purposes and objectives of the pilot test; and 2) identifying existing data sources and their possible uses in a pilot test. The group was asked to expand the definitions of the characteristics in the evaluation matrix and to add to the glossary of terms, as necessary.

DAY 1 – Thursday, September 29, 2005, 9:00 AM – 5:00 PM

Richard Reding, EPA Designated Federal Officer, opened the meeting at 9:00 a.m., welcomed participants, and turned the meeting over to Alice Shorett, facilitator.

Ms. Shorett introduced the facilitation team and initiated a round of introductions of advisory committee members. She noted that a tremendous amount of work had been completed since the committee's first meeting in June. She emphasized that the advisory committee's purpose was to focus on the policy implications of detection and quantitation and asked for the committee's help in keeping the discussions on that level. She asked that committee members use the microphones and identify themselves for the benefit of observers listening to the meeting on teleconference lines.

Welcome from EPA
Mary Smith, Engineering and Analysis Division Director and EPA designee on the committee, thanked committee members and other members of the Technical Work Group for their hard work since the June 21-22 committee meeting. She reported that her Division had undertaken outreach within EPA and was working to keep internal communication open on detection and quantitation.

With respect to pilot testing, Ms. Smith reported that her office had received funding to pilot test several different approaches. While the pilot testing concept would be discussed further in this meeting, she said that EPA envisioned a scope of work that would enable pilot testing several procedures at once. This would allow the committee to address some policy issues simultaneous with pilot testing a handful of procedures. She also announced that Michael Shapiro, EPA's Deputy Assistant Administrator for the Office of Water, would join the meeting on Friday afternoon.

Agenda Overview
Ms. Shorett briefly reviewed the agenda for both days, including a few minor scheduling adjustments, and identified the purpose and relevant materials in committee member packets for each part of the agenda. In the facilitators' calls with caucuses leading up to the meeting, she noted that many committee members had identified the "uses" of detection and quantitation as a key policy issue and said that "uses" would be discussed the following morning. Several committee members spoke up to agree and suggested that a policy-level discussion of uses would also help shape pilot testing.

Discussion and Approval of Meeting #1 Summary
Ms. Shorett asked committee members for comments on the draft summary. There were no comments and the committee voted to approve the summary, by consensus.

Action: The committee approved, by consensus, the Meeting #1 summary, as drafted.

Common Base of Information
Referring to a handout in members' packets, Ms. Shorett briefly reviewed the informational needs committee members had identified at their June meeting. She indicated that all of the informational requests from that meeting would be responded to during the course of this meeting. Three would be addressed through reports from the state caucus, the environmental caucus and one by an EPA presentation. The remaining would be addressed through Technical Work Group products prepared for the meeting.

State Caucus Report of its Survey on State Uses of Detection and Quantitation
Ms. Shorett called on Dave Akers of Colorado to present the state caucus' report of the survey of states it had conducted since the committee's June meeting. (The state caucus provided the survey results in both hard copy and a PowerPoint presentation. The latter can be found on the EPA website at http://epa.gov/waterscience/methods/det/.) Noting that 31 states had responded to the survey, Mr. Akers briefly reviewed the responses to each part of the survey. He concluded with the following observations:

- Across the states, many approaches are used for detection and quantitation.
- A high percentage of states use the Method Detection Limit (MDL).
- There appears to be no "right way" to use the values and some states have fairly complex decision matrices for setting requirements.
- Many states use both detection and quantitation levels in some way.

In the discussions that ensued, the following comments, questions and responses were offered:

Question: Did you get an indication of what states that do not use 40 CFR use instead?
Response (Dave Akers): Some narrative comments from states that are included in the back of the handout respond to this question.

Question: In what sense is the determination of detection and quantitation limits required? For accreditation? For regulation?
Response (Dave Akers): It was difficult to extrapolate the difference between the two.

Question: In your question about testing for certain pollutants in wastewater and ambient monitoring, were you asking about compliance measurements or specific ambient monitoring?
Response (Dave Akers): We cannot back the percentages out to determine how much is related to ambient monitoring and how much is related to compliance measurements.
Response (Tim Fitzpatrick): In the Technical Work Group, we talked about a Detection Limit other than the critical level. In this context, we left that open. In 40 CFR, it is probably closer to the critical level than the detection limit that will be discussed later.

Question: Did the survey ask states if they only accredit for safe drinking water?
Response (Bob Avery): The survey asked only about NPDES (National Pollutant Discharge Elimination System) permitting programs. To my knowledge, states are required to follow 40 CFR.
Comment: I believe that about 30 states have their own Clean Water Act accreditation programs.
Comment: It would be nice to know the number of states and which states have accreditation programs.

Question: Did your survey cover pretreatment or did it address only regulations for direct discharging?
Response (Dave Akers): Our survey did not explicitly cover pretreatment. We were mainly trying to get at NPDES permitting.
Response (Tim Fitzpatrick): I did not fill out the survey for Florida, and I do not know if the pretreatment program had a chance to respond to this survey.
Comment: Since pretreatment is regulated, it would seem to be an important piece of information and it would be good to have some data from that program.
Comment: I want to echo the comment about pretreatment data. From the environmental perspective it would be important to know what the sources for some of these pollutants are.
Response (Bob Avery): The questions we developed and sent out came originally from this group. For the purpose of this initial survey, we decided to keep it fairly

simple and address the committee's questions. We always have the opportunity to go back to respondents and ask additional questions.

Response (Tom Mugan): In Wisconsin, I can talk with the pretreatment coordinator in the state. It would be difficult to survey all of the POTWs (publicly-owned treatment works) or control authorities in the state. While many of them refer to the state requirements, many others have their own procedures since they really regulate the contributors. It would be much more difficult to get that information.

Comment: It might be a question that could be more appropriately addressed to the public utilities, to get their input on their uses.

Comment (Tom Mugan): With respect to uses, when we did the state survey, we tried to get into some use issues like what levels (detection or quantitation or other) are used for determining a limit or for enforcement. The responses to the survey showed differences among the states in what level they use for different uses. There was a perceived need from the survey results to minimize false positives.

Response: In Virginia, Hampton Roads would defer to the state.

Response (Chris Hornback): We could do a sampling of our members (Public Utilities) to find out what approaches public utilities are taking. I suspect many are deferring to the NPDES.

Comment: I would agree that there is not a state-to-state approach to getting data on pretreatment. It is a difficult but an important question to answer.

Question: From an overview perspective, did you get a sense of the understanding of different definitions from respondents on the state surveys?

Response (Bob Avery): A respondent from Michigan filled out the questionnaire and had me review it to make sure he had understood the questions. He thought the laboratory was reporting out a quantitation limit instead of a detection limit for non-detects. Once that was clarified, he had to go back and re-answer the questionnaire.

Comment: I request that we post the state survey on the website if it is not already there.

Action: Ms. Shorett asked if the National Association of Clean Water Agencies (NACWA) might survey its members regarding pre-treatment approaches and uses to get responses to report at the December committee meeting. Chris Hornback, Director of Regulatory Affairs at NACWA, said he thought such a survey would be appropriate and asked the committee for input on the questions to ask. The state caucus members said that they will continue to reach out to the 19 states not represented in the survey and report back to the committee in December with a more complete set of results to the survey.

EPA Caucus Report of Federal Agency Uses of Detection and Quantitation

Mary Smith of EPA spoke briefly about water programs at EPA, focusing on NPDES permits and drinking water. Using a PowerPoint slide, she illustrated the differences

between these two programs in four areas: detection, quantitation, compliance mechanisms, and compliance and detection/quantitation.

	Ambient Water	**Drinking Water**
Detection	MDL	MDL
Quantitation	ML = 3.16 x MDL	PQL (Practical Quantitation Level) = 5-10 x MDL
Compliance Mechanisms	Permits -national Effluent Limit (EL), based on available method -Water Quality Based Effluent Limits (WQBEL)	MCL (Maximum Contaminant Level)
Compliance and D/Q	EL or WQBEL need not be > MDL/ML	MCL > PQL

The information, she said, was intended to contribute to the discussion of uses. She said that she would work with other EPA programs in advance of the committee's December meeting to show how those programs use detection and quantitation. She asked for committee input on specific questions related to uses that she should ask when talking to the other EPA programs.

Question: Is it possible to prepare a list of specific references to 40 CFR that appear in regulations where it is hard-wired that those procedures must be used? I know that EPA has effluent guidelines that specify use of 40 CFR. It would be helpful to see what other federal programs use 40 CFR Appendix B and for what purpose. It would only be relevant if a specific guideline references a specific procedure, because that represents a floating limit (a limit that can change based on actual results, rather than a set limit that laboratory results have to meet).

Response (Mary Smith): My guess is that it is not a floating limit but is based on a specific number. I can go back and get some examples to see if there are some guidelines that might get into this issue and provide them.

Comment: [To EPA] In terms of questions to ask other EPA programs, it would be useful to know which one of these six numbers *are* being used for these various uses and, then, which ones *should* be used for these various uses.

Question: Is the Reliable Detection Limit (RDL) used under the Clean Water Act?

Response: No

Comment: In California, you are required to report the RDL.

Comment: This is a term that is important to include in the glossary.

Response (Tim Fitzpatrick): The RDL I am referring to is the Required Detection Limit

Action: Prior to the December meeting, Mary Smith committed to expand the table beyond Office of Water programs to include other federal programs. She said that she would (1) identify the detection or quantitation concept they use; (2) outline the compliance programs (e.g., pesticides have a registration program); (3) identify whether there is a different reporting limit than the compliance limit; and (4) provide examples of effluent guidelines. Committee members also requested a report of all references to 40 CFR Part 136 that appear in regulation or guidance.

Environmental Caucus Report of Its Informal Survey

Ms. Shorett then called on Michael Murray of the environmental caucus to present background information and the results of an informal survey the caucus had conducted following the June committee meeting. He identified the following themes from the 14 responses they had received (For other points from his report, please see the environmental caucus PowerPoint presentation on the EPA website.):

- A majority was at least somewhat familiar with issues, and approximately one-half had detection or quantitation limit issues arise in their work.
- Current detection and quantitation limits are not necessarily protective of the environment, in particular for persistent, bioaccumulative, toxic chemicals.
- Development and implementation of detection and quantitation limits need to be consistent with requirements of the Clean Water Act.
- Current approaches to determining detection and quantitation limits are flawed, with varying ability of labs to measure and report values near the detection or quantitation limit.

Comment (Mary Smith): When approving analytical methods for chemicals of concern, EPA is looking into new methods that would improve detection capabilities. EPA looks at emerging methods as frequently as possible. If there are suggestions of methods that need to be validated, we would be glad to discuss those. Putting methods into 40 CFR takes some time given the process that is required – validation, proposed rule, and final rule.

Ms. Shorett then asked the other caucuses to report on their outreach and input from constituents.

Industry

John Phillips noted that industry had been engaged in this issue for many years and was anxious to make progress. However, he said, his constituents felt that the committee could not make any decisions without first discussing the uses and reaching agreement on definitions.

Environmental Laboratories

Richard Burrows said he had nothing to report at this time on behalf of the environmental laboratories.

Public Utilities

David Kimbrough reported that the most recent meeting of the California Laboratory Accreditation Work Group, which represents people associated with labs throughout the state, had focused on this topic from a policy perspective. He said that in California, the state sets the minimum level and detection leveland requires labs to perform to those levels. The group briefly discussed whether requiring labs to perform to a specified level was preferable to having each lab perform to its capabilities.

Chris Hornback said that his constituents were concerned about putting the cart before the horse, or in other words, addressing technical issues and pilot testing approaches before thorough discussion and decisions on policy issues. He said that policy – uses and needs – should drive technical issues, not the reverse. He noted that the National Association of Clean Water Agencies had a number of groups it could contact related to pretreatment uses of detection and quantitation or for other policy-related questions.

Panel Presentation and Discussion of Draft Definitions of Terms

Ms. Shorett called on Bob Wheeler, facilitator of the Technical Work Group, to introduce a panel presentation on draft definitions of terms. Mr. Wheeler thanked all the Technical Work Group members for their hard work over several months. He noted that the Technical Work Group alone had held nine two-hour teleconference calls since the June committee meeting. In addition, the Technical Work Group had formed four subgroups which had also held separate teleconference calls.

He recalled one of the assignments that the committee had given to the Technical Work Group in June: to define the critical level (L_C), the detection level (L_D) and the quantitation level (L_Q), and to define detection and quantitation, reporting limits, uncertainty, and false positives and false negatives. He then listed the materials in committee member packets that the Technical Work Group had developed in response to this assignment, including:

- "Definition Options for Detection and Quantitation for the Technical Work Group, Definition Sub-Group";
- "Issues to Consider when Defining Detection and Quantitation" (also known as a "white paper"); and
- A Glossary of Terms.

With respect to the draft "Definitions Options," Mr. Wheeler said that the document was intended for review and discussion at this meeting. He said that the Technical Work Group had a hard time agreeing on a single definition because the group recognized that picking a specific definition would, in essence, predetermine the procedure or procedures that might ultimately be selected. Since the selection of one or more procedures is primarily a policy decision, the Technical Work Group felt it was more appropriate to bring a number of definition options to the committee for its consideration.

He said that the Technical Work Group hoped the committee would adopt the definitions as a "working draft" to allow the process to go forward. He said that the committee might decide to narrow the number of definitions, but the committee did not need to agree on one definition at this meeting.

He introduced the members of the panel:

- Steve Bonde, Laboratories
- Tim Fitzpatrick, States
- John Phillips, Industry
- Jim Pletl, Public Utilities
- Richard Rediske, Environmental Community
- Brad Venner, EPA

Mr. Wheeler asked panel member to address the following four questions.

1. Why was drafting definitions (for critical level, detection level and quantitation level) such a difficult assignment?
2. Which definitions does your caucus propose and why?
3. What are your suggestions for where we go with definitions from here?
4. What is your perspective on the white paper and how do you feel the advisory committee can use that document?

John Phillips, Industry

1. Reason for difficulty

Mr. Phillips said defining these terms was difficult for several reasons. The Technical Work Group started with a long list of published definitions, several pages long. The definitions represent both concepts and philosophies and many of them are hard for a layperson to understand. Some of the definitions were incomplete procedurally, that is, they did not or were not easily implemented. In short, it was a difficult assignment because the definitions define concepts and philosophies and they also impact the implementation or the procedural requirements or restrictions that are needed when coming up with that parameter.

2. Preferred definitions of L_C, L_D, and L_Q

Mr. Phillips said that industry, in general, preferred definitions that presented the conceptual, technical or statistical concept and left the details to the procedure. Industry also, generally, preferred definitions that were simple and relatively easy to understand. Given that orientation, Mr. Phillips indicated that industry preferred layperson's definition #1 for critical value and layperson's definition #2 for detection limit. For statistical definitions, industry preferred #2 for critical value, #2 for the detection limit and #1 for quantitation limit.

3. Recommended next steps on definitions

The industry caucus encouraged the committee, at a minimum, to reach consensus on layperson's definitions so the committee could use the terms in its discussions. It

would also be desirable, Mr. Phillips said, to reach consensus on the statistical definitions, but, if not, the committee could use what it had as a framework for going forward.

4. Perspectives on the "white paper"

The industry caucus recommended that the white paper be used primarily as a quick reference or "crib sheet." For more in-depth information, Mr. Phillips recommended Dr. Robert Gibbons and David Coleman's book, Statistical Methods for Detection and Quantification of Environmental Contamination.

Questions/Responses

Question: Could you explain why industry prefers definition #2 for the critical level over #1?

Response (John Phillips): Definition #2 presents the concept we are trying to achieve; we assume the procedure will have the detail. Definition #1 makes no allowance for non-zero blanks. There is no recovery bias adjustment in it and it doesn't apply to censored methods. While they could be added, the additions would make the definition too long.

Brad Venner, EPA

1. Reason for difficulty

Mr. Venner indicated that his views did not reflect the main body of the thinking within the Definitions Subgroup and said that he would be presenting a minority report. From his perspective, the Technical Work Group was dealing with foundational issues – both in the statistical community and in the analytical community – about how to look at detection limits. The statistical framework for thinking about detection limits really colors how one thinks about detection limits. He said that one of the main difficulties to consider in detection limits was controlled (versus random) calibration, which complicated the statistics.

2. Preferred definitions for L_C, L_D, and L_Q

He said that EPA did not favor any of the layperson's definitions. For the statistical definition of critical level (L_C), he said that EPA would prefer a modification of the existing EPA definition, as follows (modification in italics type): it is the minimum concentration of an analyte that can be measured and reported *such that the lower 99% confidence limit on the result is greater than zero.* EPA recommended the modified MDL definition because:

- It is compatible with the existing MDL definition but the modification clarifies the intent of the MDL definition.
- It makes the MDL definition equivalent to the IUPAC critical value.
- It is compatible with the current Office of Groundwater and Drinking Water approach.
- It has conceptual advantages in terms of what is being done when talking about detection.

For detection level, he said that EPA did not have a strong preference. When talking about detection limits, he said, emphasis could first be placed on making a detection decision or, second, trying to quantify what the uncertainty around an observed result was. Placing the emphasis on a confidence limit rather than on a detection decision clarifies that this was the main thing EPA would like to do.

Using a graph, Mr. Venner described the approach that focused on finding an observed result and reporting a confidence limit around that result, which becomes the primary task of the analytical chemist. An advantage of the confidence limit approach, he said, is that when an analyte result is recorded, plus the confidence limit, there is information there for both the regulated community, which is concerned about false positives, and also for the regulatory community, which is more concerned about false negatives. Another advantage is that the proposed definition is compatible with those used by Groundwater and Drinking Water programs at EPA.

3. Recommended next steps on definitions
He had no specific comments on this question.

4. Perspectives on the "white paper"
Mr. Venner said that the white paper does a good job of discussing a lot of issues in a general way. He recommended the technical assessment that EPA prepared for a proposed rule (Revised Assessment Document, October 2004) for more detailed discussion. He also recommended the Gibbons and Coleman book as a good reference.

Questions/Responses

Comment: The statistical and analytical worlds are different and this can sometimes lead to ideas that are problematic when interpreting statistical results. In the real world, when you look at concentrations of a chemical rather than a response, the results are always equal to or greater than zero. It gets to the issue of statistics vs. the real practice of analyzing for chemicals in any matrix. If you have true detects, your mean is always going to be greater than zero.

Response (Brad Venner): When you're an analyst, you will actually get a negative result when it's below the mean. These are observed results, not true results. The way those results are interpreted is that anything below zero is thought of as basically having no analyte concentration or a mean result of a negative value and perhaps an upper confidence limit that is just slightly positive. Labs do not like to report a negative value which is one reason why the analytical community has focused on detection decisions and does not report results that are less than zero. The problem with that censoring approach is that it does lose some information.

Comment: I like phrasing it as true results vs. measured. In a sense, measured is even a bit loose because we're not really measuring a negative concentration. It's just an artifact in the process.

Comment: I think it's really good that your definition and all of the layperson definitions use the term result rather than concentration. Use of the term concentration, which could refer to a result or a true concentration, could be the

source of endless confusion in the MDL so it's good that we are getting away from that. The problem I have with the definition is that it is fixed upon distinguishing something from zero whereas what we actually need to do in the lab is distinguish something from what we see in a method blank. If your definition used mean of the method blank instead of zero, I would be happy with it.

Response (Brad Venner): I would agree that the method blank should be corrected for in an analytical result. This issue is discussed in the white paper and I think it's a very important thing to consider. My preference would be to deal with that in the method at a procedural level rather than in the definition.

Comment: If [Mr. Venner] thinks we should be correcting for the method blanks, he has a lot of people at EPA to persuade. Currently, we are not allowed to do that for virtually all methods. Given the situation on the ground, I think our definition has to allow for that.

Comment: When correcting for the method blank, there is an assumption that your blank is a constant value over the course of a day or an analytical blank. That's not necessarily true. You have to be very careful when applying concepts like that.

Response (Brad Venner): Statistically speaking that's not a major issue, but in practice, I agree, it is.

Tim Fitzpatrick, States

1. Reason for difficulty

Mr. Fitzpatrick said there are different perspectives reflected in the procedures and published papers. For example, the committee just discussed the issue of a reference point. Is it a zero? Is it a pure average signal minus the blank concentration? Some of the methods also imply different procedural techniques. One of the problems with defining these layperson's terms is that it does imply a focus on one or more types of procedural methods for determining detection limits.

2. Preferred definitions for L_C, L_D, and L_Q

Critical value (L_C): Because Mr. Fitzpatrick had not participated in the Definitions Subgroup and had not spoken to all members of the state caucus, he said he would give his own opinions. He thought that #2 or #4 of the layperson's definitions might be most appropriate for Lc. He said he had a problem with defining zero as the absolute reference point given the practical implications of reaching agreement with EPA to change all the methods and allow blank correction, and the difficulty of non-constant blank and other practical issues in the laboratory. Perhaps defining some other point for detection limit, such as the mean blank concentration, might be a better reference point, although that might prove difficult in some of the so-called censored methods to be talked about later. He said he personally favored #2 of the statistical definitions.

Detection Limit (L_D): He favored #3 or #4 of the layperson's definitions because they did not include the word "detection" (which is being defined) in the definition and

because they address the issue of false negative rates in defining L_D (detection). For the statistical definition, he favored #3.

Quantitation Limit (L_Q): He said #1 seemed the simplest, especially since it linked the quantitation limit to its intended purpose, which is often important in analytical work.

3. Recommended next steps on definitions

Mr. Fitzpatrick said he thought the first step was to define what is meant by the underlying concepts and maybe link that to uses as discussed earlier. He noted that most of the procedures were derived from the concepts and suggested tabling further discussion of these definitions until the committee is closer to making recommendations on linking these procedures to their intended uses and stating what is meant for the use of these procedures.

4. Perspectives on the "white paper"

It is a general overview document and gives a layperson's overview of the procedures. He echoed Mr. Venner's recommendation of the Revised Assessment Document because the document provides a lot of background detail that should be kept in mind when looking at the white paper.

Steve Bonde, Labs

1. Reason for difficulty

He had no specific comments on this question.

2. Preferred definitions for L_C, L_D, and L_Q

Critical Value (L_C): Mr. Bonde said that labs preferred #1 of the layperson's definitions because it was clear and understandable. He said that labs would be in agreement regarding the use if they were able to use the method blank or lab blank rather than zero.

Detection Limit (L_D): He said the caucus preferred #1 and #2 of the layperson's definitions. For the statistical definition, he said that the laboratory caucus preferred #2 because of its simplicity.

Quantitation Limit (L_Q): Mr. Bonde said the laboratory caucus liked #1.

3. Recommended next steps on definitions

He had no specific comments on this question.

4. Perspectives on the "white paper"

The laboratory caucus agreed that it is a good layperson's overview.

Questions/Responses:

Question: Did you consider a modification of EPA's definition in 40 CFR, such as Mr. Venner mentioned, but referencing it to a blank as a definition of L_C rather than the ones given here?

Response (Steve Bonde): Yes. That would be the laboratory caucus' preference. I would also like to note one thing that came up as I looked at the glossary of terms: whether it is predictive (*a priori*) or observation-based (*a posteriori*).

Jim Pletl, Public Utilities

Mr. Pletl prefaced his remarks by noting that his caucus had not had time to discuss and reach consensus on the definitions. He said his caucus felt strongly that it was very important to establish the uses before taking the next step on definitions.

1. Reason for difficulty (Ken Osborn, Technical Work Group member, by telephone)

Mr. Osborn said the Technical Work Group's difficulties in coming up with definitions had to do with the almost schizophrenic use of the detection limit terms. Whether or not one discriminates from the blank or discriminates from zero is a smaller issue. Ultimately, Mr. Osborn said, there is going to have to be some resolution to the disjointed use of data generated by environmental laboratories for client purposes, where the data set could be used in a larger context. Until that is resolved in some way, he said he thought that issues would continue to come up with appropriate definitions.

2. Preferred definitions for L_C, L_D, and L_Q

Mr. Pletl said that the public utilities caucus did not develop preferences among the definitions because it felt that the uses needed to be defined before taking a next step on definitions.

3. Recommended next steps on definitions

Mr. Pletl said that the public utilities caucus believed that setting the uses would tell the committee what the definitions should be. He said that he, personally, would not be surprised if there were multiple definitions, depending upon uses.

4. Perspectives on the "white paper"

Mr. Pletl thought that the white paper did a good job of identifying the issues that had come up for the Technical Work Group.

Questions/Responses

Question: Intuitively, it seems that we should be able to come up with definitions and even approaches independent of uses. Please give me some examples to show how or why there would be different uses that would drive different definitions of some of these terms.

Response (Jim Pletl): It is quite possible that, depending upon your use, the issue of blank correction and how blank correction is going to play into decision making may or may not be a critical issue. Another issue the Technical Work Group discussed was sample matrix. Are we concerned more about detecting and quantifying results relative to a reagent grade blank, or are we more concerned about what happens in relation to a real world sample – in a matrix? You may be interested in what happens in a reagent blank when you are trying to assess the

performance of a lab. If you are trying to determine compliance with a permit limit, you may be more concerned about how you quantify or detect relative to that matrix.

Comment: I think the implications of a finding (regulatory, compliance or financial) can be kept separate from getting information on true concentrations of an analyte.

Comment: What the committee is trying to do is build a tool that will be useful, but to choose which tool, you have to know what it is going to be used for. Even within the realm of statistics, do you use tolerance interval vs. confidence interval vs. prediction interval? They are neither right nor wrong; they simply do different things depending on what you want to do. A significant issue, for example, could be an effect of a calibration curve where the least squares of calibration give you a positive intercept. There are also interferences caused by matrix effects, which produce negative results irrespective of calibration or even blank effects. Depending on what you want the reporting limits to do, you will choose a different one.

Comment: I know that you get negative results, but the negative results are again interferences or something else that is in the system that really is there. It is not indicating a negative concentration of the analyte of interest so I think we just need to be clear. That is again where we have to be thinking about the actual, purely analytical issues, the matter out there that we are measuring in the context of these statistical issues. Analytical chemistry and statistics are two worlds and we're bringing them closer together. We need to think about what is important in each and make sure that our results are meaningful.

Comment: An example of why the definitions might vary with the data quality objectives comes from my lab when we were trying to identify background contamination in a lake. My laboratory worked out a reporting limit and when numbers below that reporting limit went in, the laboratory corrected for that, but we also reported the original data to the state. Uncensored data is needed to evaluate what was really there. Eventually our laboratory found the source of the problem, which was a chemist who was wearing a shaving cream or an aftershave lotion that was giving off minute amounts of a compound during the extraction process. Once the laboratory discovered that, the problem disappeared. However, had the laboratory corrected for that, it is possible we might not have found the problem because the spikes were irregular. The laboratory needed to retain that data to solve the problem. There were obviously two different needs for those data as they were generated. One was to provide the data set judged against the background that gave an effective detection limit that was much higher than it would have been otherwise and two, was the data set that ultimately allowed the laboratory to find out what the source was and to correct for it. And that's where we are today.

Comment: We may have consensus that we are talking about several different points. When you look at a continuum in concentration, there is a point where there is nothing, the zero point. Because it is really difficult to measure that, we establish an L_C when we are talking about false positive error rate, an L_D when we are talking about false negative error rate, and L_Q where we are talking about where

we can quantify. We do not have to come to formal agreement on exactly what conditions we are going to use to establish these points but I think we at least have consensus that there are these three distinctive points and we need to take them into consideration in making decisions.

Richard Rediske, Environmental Community

1. Reason for difficulty

Mr. Rediske said coming up with the definitions was hard because there is a need to balance between something specific vs. general. Where does one draw the line?

2. Preferred definitions for L_C, L_D, and L_Q

Mr. Rediske said it was important to have a one-sentence definition. He said the environmental caucus liked the basic, layperson's definitions. The details should go into the procedure.

Critical Value (L_C): Mr. Rediske said the environmental caucus preferred #1 of the layperson's definitions and #2 of the statistical definitions because they were simple.

Detection level (L_D): He said the caucus preferred either #1 or #2 of the layperson's definitions and #2 of the statistical definitions. He said it was important to start defining terms with respect to alpha and beta, type 1 or type 2 errors.

3. Recommended next steps on definitions

He had no specific comments on this question.

4. Perspectives on the "white paper"

It is a good basis to build on. It gets at the heart of some of the conflicts that the committee is trying to resolve. The work that has been done is really good and he said the environmental caucus really appreciated the level of effort everybody put in.

Questions/Comments

Comment: We are using terms like RDL, PQL that are not included in the Glossary of Terms but they should be included. If there is a hierarchy that always holds true, equal to or greater than, it would be helpful to include that so we can remember which one is above the other. This would be particularly useful for those in the outside world who will have to use what we come up with. Consistency would also be helpful. For example, the glossary provides quantification as the "use." It would be helpful to indicate that the terms quantitation and quantification are interchangeable.

*Comment***:** With regard to the glossary, it would be nice to include a reference to those definitions that have been used for many years, in particular, by the research community. If any of the definitions have been taken from specific sources, such as Currie or IUPAC, it would be helpful to note that. On the quantitation definitions, #3 and 4 seem to be independent of L_D. In the white paper, Figure 2 needs to be clarified.

Response (John Phillips): The Technical Work Group developed a document that includes all of the definitions that exist in publications.

Comment: I think we can agree with the relative positioning or levels for L_C, L_D, and L_Q, that they will always be in that sequence. What we cannot do is predict with any degree of certainty where an MDL or ML will fall on that continuum. I think it is clear that the MDL will always be lower than the ML.

Question: In the example from the Episode 6000 data, where the MDL and ML fell below or above L_D or L_Q, was that not technology-related? That is part of the problem we have with the MDL where you have seven replicates but a very low standard deviation. Was this a case where the signal method was not appropriate for the various technologies we have?

Response (John Phillips): Yes. There were a lot of different spike concentrations that were derived and they selected one for the MDL. It shows that there may be some problems with the methodologies with respect to applying the MDL to them.

Comment: I think we may need to take a closer look at the analytical method to see if it fits the technology and the variability that we are getting when we are testing the various spike concentrations. We need to make sure that whatever is developed in the future matches the technology available.

Comment: The issue of low measurement and low variability is good. The whole blank issue is critical, particularly in metals. Getting the blank low has really driven improvements in measurement.

Comment: We always make an assumption that all methods are equal but they are not. They change over time, which is one of the reasons you get signals like this. It is not because of the instrument or the technology in general but because instrument conditions change.

Comment: When we look at lower concentrations, it is that much more likely that you are going to have an issue with a blank. Since the blank is not considered at all in the MDL determination, it is that much more likely that you are going to calculate an MDL that is below the level that all of your blanks are at.
If we are going to add other terms to the glossary, we should attempt to state which of our three fundamental levels we think they relate to. The MDL, for example, is an attempt to approximate L_C. The ML is an attempt to approximate L_Q. I believe California's RDL is an attempt to approximate L_D.

Comment: From my perspective, the issue of having low blanks that may be measurable and with low variability is good. That says we're able to measure at lower levels. Getting the blank low has really driven a lot of the improvements in measurement as well as new instrumentation. I think a goal of any technique is to get the blank and the variability down low.

Response (Mary Smith): Definitions are important. To a certain extent, there are two versions of the MDL running around. One is in 40 CFR Appendix B. If you are a lab creating your own MDL, that is what you use. It is based on seven values and might be created on one day with the same operator, etc. When EPA creates an MDL that is put into a Part 136 method, it is a little different. EPA uses a minimum of six labs and probably has 7-14 values coming out of each lab for a particular pollutant. We then pool all of the data and come up with an MDL.

You need to keep that in mind because it does reflect on the uses. In the chart I used earlier, I was talking about the MDL that EPA creates, using more than one lab to create that value.

Comment: It may be helpful to distinguish between the promulgated MDL versus a single-lab MDL.

Mr. Wheeler then asked committee members to work together in their caucuses over lunch to review the definitions. He asked that they consider whether there was consensus on any definition, if the list could be narrowed, or if it should remain unchanged. He said that the facilitation team would tally the preferences from the morning's discussions over lunch for the committee's review when it reconvened. He emphasized that the committee was not being asked to make a final decision.

A member suggested that it might be useful to the committee to discuss the MDL/ML issues paper, because some of the issues under discussion were imbedded in that document.

After the committee reconvened from lunch break, Mr. Wheeler asked Larry LaFleur to present the highlights of the paper "Concerns with the EPA Method Detection Limit (MDL) and the EPA Minimum Level (ML)," produced by the Technical Work Group. Mr. LaFleur reported that the subgroup had reviewed the 136 comments in the docket regarding the proposed changes to the MDL and ML and had categorized the concerns but had not attempted to evaluate them technically or for their relevance.

When Mary Smith asked if the committee wanted to evaluate the MDL/ML comments, opinions differed. One member questioned the purpose of doing so while another thought it could be worthwhile to capture those concerns. A third said that some of the comments applied to many current EPA methods, not just the MDL and ML. The committee decided not to undertake an evaluation of the comments at this time.

Committee Decision on Working Draft Definitions of Detection and Quantitation

Mr. Wheeler reviewed the facilitators' tally of caucus preferences for the layperson's and statistical definitions from the morning's caucus reports. The committee reviewed the marked-up document "Revised Definition Options for Detection and Quantitation" (Attachment A).

In developing a group of working definitions for the committee's use as it continues to do its work, the following definitions will be carried forward. It was understood that the working definitions can be re-visited as the committee continues its deliberations. Therefore, the committee voted, by consensus, to carry the following definitions forward.

L_C Detection – Layperson's Definitions

1. Critical Value (L_C) – The minimum result which can be reliably discriminated from a blank[1] (for example, with a 99% confidence level).

[1] The committee acknowledged that the use of "blank" versus "zero" needs further discussion.

2. Critical Value (L_C) – The lowest result that can be distinguished from the blank (see footnote) at a chose level, a, of statistical confidence.

L_D Detection – Layperson's Definitions

1. Detection Limit (L_D) – The lowest true concentration that will almost always be detected.[2]
2. Detection Limit (L_D) – The minimum detectable value is [the] smallest amount or concentration of a particular substance in a sample that can be reliably detected by a specific measurement process.
3. Detection Limit (L_D) – The minimum true concentration that will return a result above the critical value given a specific measurement process and confidence level.

L_C Detection – Statistical Definitions

1. Critical Value (L_C) – Smallest measured amount or concentration of analyte in a sample that gives rise to a Type I error tolerance of alpha under the null hypothesis that the true amount or concentration of analyte in the sample is equal to that of a blank. (The alternative hypothesis is that the true amount or concentration of analyte is greater than that of a blank.)
2. Critical Value (L_C) – The minimum observed result such that the lower 100 (1-a) % confidence limit on the result is greater than zero.
3. Critical Value (L_C) – The minimum observed result such that the lower 100 (1-a) % confidence limit on the result is greater than the mean of the method blanks.

L_D Detection – Statistical Definitions

1. Detection Limit (L_D) – Once L_C is established, L_D is the smallest concentration or amount of analyte at which the tolerance for Type II error is equal to beta.
2. Detection Limit (L_D) – The lowest true concentration such that the frequency that the result is greater than L_C will be 100% (1-ß).

L_Q Quantitation Definitions

1. Quantitation Limit (L_Q) – The smallest detectable concentration of analyte greater than the detection limit where the required[3] accuracy (precision and bias) is achieved for the intended purpose.

Panel Presentation and Discussion of Detection and Quantitation Procedures Matrix

Mr. Wheeler asked members to turn their attention to the other Technical Work Group assignments by referencing the following materials in their packets, as prepared by members of the Technical Work Group:

- Matrix of procedures and characteristics;
- Description of the characteristics; and
- Footnotes to the matrix.

[2] The committee wants the term "detected" to be modified.
[3] EPA requested additional conversation around the use of the word "required" in the definition.

He explained that the purpose of this panel was to present to the committee draft definitions of the characteristics that the committee had identified at the June meeting. He said that the panel would also report on the Technical Work Group's input on the procedures, including procedures that the Technical Work Group recommend not be included in the matrix. He noted that the panel would briefly discuss the evaluation of specific procedures in the matrix that individual Technical Work Group members had done. (The Group as a whole had not had time to evaluate and normalize the procedures.) Presenters, with the procedures they evaluated, were as follows:

- Richard Reding: Method Detection Limit (MDL), Minimum Level (ML)
- Tim Fitzpatrick: Water Research Centre, International Organization for Standardization/International Union of Pure and Applied Chemistry (ISO/IUPAC)
- Larry LaFleur: Consensus Group Procedure, American Society of Testing Methods Interlaboratory Detection Estimate/Interlaboratory Quantitation Estimate (IDE/IQE)
- Richard Burrows: American Council of Independent Laboratories (ACIL) Procedure, Long-Term MDL (LTMDL)
- Jim Pletl: Osborn Lab Quality Assurance, Office of Surface Water Quantitation Limit (OSW QL)
- Steve Wendelken: Hubaux-Vos, Lowest Concentration Minimum Reporting Level (LCMRL)

Mr. Wheeler added that Richard Rediske was on the panel to give the Environmental Community's perspective, but that he was not speaking about a specific procedure.

Mr. Wheeler explained that, after hearing the panel presentation, the committee would work in caucuses to review the characteristics and measures to respond to the following questions related to the characteristics:

- Are any missing?
- Can any be combined or eliminated or are they about right?
- What characteristics should be the focus of the pilot test?

With respect to the procedures, he asked the caucuses to consider the following questions:

- Is the list about right?
- Should any procedure that has been removed be returned to the list?
- Is the list about right to go into pilot testing?
- What are the uses of the procedure from your caucus' perspective?

In the presentations of procedures, each presenter identified the features of the selected procedure and compared and contrasted it with the MDL and ML.

Caucus Reports

When the committee reconvened in plenary, the following points were made:

Caucus	Characteristics	Procedures	Other Comments
Industry	Does the procedure include verification of L_C, L_D, and L_Q? Characteristics should be modified when matrix is normalized. Uses should be identified and correlated for each procedure with the characteristics.	Before we undertake a pilot study, we need to make sure that EPA's request to have a complete, written procedure is met.	The Technical Work Group should be tasked with determining which procedures have written protocols and to normalize the responses in the current matrix to make the matrix more useful.
Environmental Community	The following need to be addressed: false positives/negatives, bias, reflecting routine performance, prescriptive/descriptive.	This caucus did not address combining the procedures. It felt the committee was not at a point to discuss pilot testing except to say that pilot testing needs to be synchronized with data quality objectives.	
Environmental Laboratories	No serious characteristics are missing from the spreadsheet; none should be combined or eliminated. Most important characteristics are false positives and negatives and censored/uncensored methods, as well as costs	A well-defined pilot should be able to evaluate several procedures at once. This caucus suggested grouping the procedures into two or three study designs. For example, one design could include MDL, ACIL, LTMDL, Consensus, Osborn procedures, and another could lump Hubaux-Vos and IDE.	A policy working group should be created to look at many of the policy issues that bridge technical questions.
Public Utilities	It would be helpful to know whether or not a	This caucus was not ready to remove or add	The goals and objectives of pilot

Caucus	Characteristics	Procedures	Other Comments
	procedure specified lab performance and whether those specifications were met. Some of the characteristics could be combined or dropped, to make the matrix less complex. Most important characteristics: ongoing performance, measurement quality objectives, actual values for false positives and negatives, method blanks, interlab quality limits, and matrices	any procedures to the list or to move to pilot testing. It said that the Technical Work Group needed to reach consensus on the matrix.	testing should be a policy discussion.
States	Characteristics should be looked at based on the uses. Characteristics of lower priority include: defensibility and prescriptive/descriptive aspect.	Remove IUPAC, Water Research Centre and [EPA] Office of Solid Waste procedures because there are no written protocols for them. Some procedures might need modification or additional work to be ready for pilot testing. States asked how this would be handled.	
EPA	EPA wanted clarification of characteristics, not to drop any. Bias is either interference or calibration error. Removing false negatives is important, but more thought is needed as to how that	Remove OSW, WRC and ISO/IUPAC (because it is similar to ACIL). The remaining procedures could be combined into two groups to pilot test.	Clarification is needed on the objectives for doing pilot testing. Key EPA objectives include bias, precision, data quality objectives, uncertainty, and

Caucus	Characteristics	Procedures	Other Comments
	would be tested. The Technical Work Group should focus on characteristics that are critical to pilot testing and set others aside for later.		test method validation. EPA needs a clearly-written procedure, feedback on ease of use and a feel for the relative cost of the procedure.

Public Comment
Ms. Shorett reviewed the ground rules for offering public comments and invited commenters to speak in the order they had signed up.

Peter Ciarleglio, URS Corporation
He said that he was grateful for the opportunity to observe the committee and was impressed with all the detail and the seriousness with which members are pursuing this issue. He said that, intuitively, he liked what the public utilities caucus had presented on the need to identify uses. He said that the MDL would be all right if it were never used for anything. In the past, it was only used to monitor the performance of the laboratory procedures. Even the labs would not use it in their reports. Instead, they would use some convenient value that was higher than the detection limit but lower than any regulatory limit they knew of. He said that he currently reviews a lot of lab data. Frequently, labs are asked to report down to the MDL, and somebody is using the data for something. Sometimes, it is not an appropriate use. With regard to the concepts of L_C and L_Q, he said that L_Q is really more important than the MDL because of its relationship to compliance issues. He said he thought that it was inappropriate to apply something like a critical level, whether it was run well or run poorly because it is not as applicable to a compliance purpose as the quantitation limit. The problem, he said, is that quantitation limits are much more ambiguously defined than the MDL. There are a lot of things that result: it can be the lowest standard or some multiple – sometimes it is an approximate multiple. He said that he did not agree, and most labs do not use, EPA's current definition of the ML as being a multiple of the MDL because the MDL is already a flawed number. It really needs to be based upon precision criteria at that concentration rather than on a multiple of the MDL.

Shen-yi Yang, EPA Office of Solid Waste (OSW)
Ms. Shen-yi thanked the committee for the opportunity to observe the meeting. She offered comments to clarify the OSW Program. She said she heard Mr. Pletl present the OSW procedure, or the lower level quantitation limit that the office uses. Her hope is that the committee and all the Technical Work Group members had a chance to review the OSW position paper she provided to Mr. Reding. In that position paper, OSW clarified how the program is set up and the mission it is trying to accomplish. The OSW method development really is set up to achieve the OSW mission. The OSW mission is to have a means available for establishing remediation and land disposal restrictions, as well as being able to list and de-list hazardous waste. OSW deals with a lot of complex

matrices. However, different facilities use different raw materials and different processes to treat their waste. So, even with waste categorized as F006, the matrices can be very different. Also, OSW considers multiple pathways (e.g., ingestion, inhalation) and multiple media (e.g., ground water, air, surface water, soil). That is why it is really difficult for OSW. When the office develops a method, it promulgates a level like a method detection limit or quantitation limit. The OSW methods are based on performance, so when a method is developed, OSW always conducts an initial definition of proficiency by multiple laboratories. OSW has method validation studies based on the matrix being studied each time. For example, right now OSW is studying perchlorate. Richard Burrows was a part of that study. She said OSW studied four matrices: soil, sludge, water and wastewater. There were 26 laboratories that participated. In the method, OSW lists performance criteria, all the QA/QC requirements, and performance acceptance criteria. Normally, OSW will depend on the statistical result to derive percent recovery. The office does not have set acceptance criteria, because it really depends on the analyte being studied and on the matrix. OSW methods are based on risk and on how the data will be used. The threshold level where decisions are made is based on risk, not on technologies. In OSW methods, the scope and applicability are clarified. When the project starts, the team has to get together to develop a project quality assurance plan and a sample analysis plan. In the plan, OSW specifies the level they have to report. When OSW provides the plan to the laboratories, they will select the appropriate method for their use, based on OSW data quality objectives. The program can use and can generate useful data. The Office of Water and OSW are set up differently. OSW is really based on the performance and on risk.

Question: Is there documentation other than what we have received so far on the approach that we could consider?
Response: We are thinking about how to phrase it. We are giving the laboratories great flexibility to justify their numbers. We want to make sure the data can be used for our risk decision.

Question: Did we receive the document that Shen-yi referred to in our packets?
Response (Alice Shorett and Richard Reding): It is not in your packet. The Technical Work Group received it and looked at it and we have a copy of it here, I believe. It is a two-page concept paper right now. When the Technical Work Group looked at it, a number of members mentioned they used this approach in their analyses when they did samples for Superfund or RCRA, but there was no detailed procedure or recipe to go through.

Sharon Drop, SAIC

Ms. Drop said that SAIC, the company for whom she works is mainly a government contractor. She is currently working with Shen-yi in the Office of Solid Waste. To add to Shen-yi's comments, Ms. Drop said that the nature of the approach that OSW is taking is aimed more at verifying that the laboratory can actually measure at the level needed for whatever their action level is – that their client is trying to meet. It is currently under development. SAIC and OSW have not developed a formalized, written procedure yet, but that is something they are working on.

Ms. Drop added her own comment expressing her appreciation for all the work that everybody in the room has done so far. The level of interest from industry and the laboratory community in trying to come to convergence and consistency in approaches to quantitation and detection is impressive. With that in mind, and in reading through the definitions that were being discussed today, she wondered if the group had considered the ASTM definitions. There is currently an ASTM standard out of the D-19 Water Committee that is developing a number of definitions related to chemical analysis that include definitions for detection and quantitation. The wording that is being considered might be consistent, but it is important that the group give some consideration to those ASTM definitions as the committee develops its own, especially because the 40 CFR table specifies the use of ASTM analytical methods. It would be good to have some consistency between ASTM and the Office of Water as far as their definitions for detection and quantitation.

Comment (John Phillips): I don't think we looked at ASTM definitions other than the IDE/IQE definitions. I am not aware of others. We did talk to some D-19 committee members and asked them for terminology, but we did not get any for detection and quantitation. Is this a new work product?

Response: It is a new standard that they are working on. Perhaps that is why you were not aware of it.

Wrap-Up

Alice Shorett briefly reviewed the agenda for Day 2 and asked committee members to read two documents in their packets for Day 2 of the meeting: policy issues and draft evaluation criteria. She thanked the committee for a productive first day of the meeting and asked members to go to the Flat Top Grill for a group dinner.

Richard Reding adjourned the meeting at 5:20 p.m.

DAY 2 – Friday, September 30, 2005, 8:00 AM – 4:00 PM

Richard Reding opened the meeting at 8:00 a.m.

Alice Shorett, facilitator, led a round of introductions and briefly reviewed the agenda, noting that it would feature a discussion of policy issues related to the uses of detection and quantitation. As requested at the first meeting, she presented a chart that identified key milestones in the process design, by meeting. (Please see the Triangle Associates PowerPoint presentation on the EPA website.)

Policy Issues and Proposed Process to Address Them

Ms. Shorett then turned to a handout in members' packets that was the facilitators' recommendation for how to organize and address the list of key policy issues the committee had brainstormed during the first meeting. After review, the committee added rulemaking to the list.

List of Uses of Detection and Quantitation

Ms. Shorett called on Larry LaFleur to review the list of uses that the industry caucus had prepared. Mr. LaFleur explained that industry had drafted the list of uses and substituted that list for procedures in the matrix. He encouraged the committee to pull out as many uses as possible and then see where some could be combined. He then reviewed and explained each of the following items in the list of uses: QA/QC Laboratory Performance, Method Promulgation, Effluent Guideline Development BAT Averaging, Effluent Guideline Development Variability Factors, Permit Applications, Compliance Monitoring, Ambient Monitoring, and Non-Regulatory Operational Monitoring – an industry-specific requirement for compliance.

In the discussions that ensued the following points were made:

- From an industry standpoint, there is a non-regulatory component of process design. For labs, there are performance-based quality control and method development requirements.
- From a laboratory standpoint, one must think separately about initial demonstration and capability and on-going lab performance. It is not clear that a performance-based method needs to be done separately, because what needs to be done is similar to what EPA needs.
- For a laboratory, method development, method validation, and method promulgation are all different. One of the products is a guideline document on how to use quantitation and detection and guidance documents on alternate test procedure (ATP).
- The environmental community noted that data quality objectives are important as are setting permit limits and ambient water quality limits, and determining compliance.
- From a measurement quality objective perspective, it was noted that there is no difference between them in terms of Clean Water Act compliance. The real question is where L_C and L_Q are. In the end, different measurement quality objectives are not going to be needed.
- It was noted that the data used for TMDLs and 303(d) listings are often different. In that sense, regulatory special studies (e.g., TMDL, toxicity studies) and other studies could be added to the list of uses.
- It was noted that there might be different reporting requirements or thresholds for some of the uses.
- It was also noted that data reporting by the labs is very important. If labs are not reporting data in the manner that the regulatory agency can use, it causes problems. Setting effluent limits is different than determining the need for limits in permits.
- It was suggested that compliance monitoring and compliance determination should be included in the list of uses.
- Proper uses are really the key to the success of this in terms of an outcome. When procedures are not used properly, problems result.
- Rather than focusing on false negatives and false positives, it was suggested the committee should focus on true negatives and true positives and how data is used.
- Measurement quality objectives should be a key component of the discussion.

Action: After considerable discussion, the committee agreed to form a Policy Work Group that would develop a product on the uses of detection and quantitation for discussion at the December meeting.

Establishment of a Policy Work Group
It was agreed that the Policy Work Group would include the following members:

- Environmental Community: Mike Murray and Barry Sulkin
- Environmental Laboratories: Cary Jackson and Nan Thomey
- EPA: Mary Smith
- Industry: Roger Claff and Larry LaFleur
- Public Utilities: Chris Hornback and David Kimbrough
- States: Dave Akers and Tom Mugan

The committee's charge to the Policy Work Group was to first describe, expand upon or "lump" the categories of uses and then define them. The categories of uses identified during the meeting included:

- QA/QC Laboratory Performance
- Method Promulgation
- Method Validation
- Effluent Guideline Development BAT Averaging
- Effluent Guideline Development Variability
- Permit Applications
- Compliance Monitoring
- Ambient Monitoring
- Non-Regulatory Operational Monitoring
- Regulatory and Other Studies
- Local Limits for Pretreatment

The Policy Work Group was also asked to identify the existing situation of uses of detection and quantitation for each use category (at what points, by whom); identify the data quality objectives for each type of use and user; and pose the policy issues presented by the information above.

Draft Evaluation Criteria
Ms. Shorett asked members to turn to a handout in their packets entitled "Preliminary Draft Evaluation Criteria" that the facilitation team had prepared based on a list the committee had brainstormed at the first committee meeting. She then described the process for the committee to make progress toward developing final evaluation criteria. Committee members, working in their caucuses, were to review and, if appropriate, to revise the criteria identified in the document for their caucus, and then were to identify the criteria they thought should be used to evaluate a final package of detection and quantitation methodologies.

Caucuses met and then reported out on their review of the document. The report from caucuses is included as Attachment B. In summary, all caucuses reported that they all saw commonalities of interest and that they were comfortable with the criteria that "must be met" in a final package of committee recommendations that other caucuses had identified. In addition to the caucus reports on the draft criteria, the following points were made.

Environmental Community perspectives on uses

- Permit limits must be driven by water quality standards and resource protection, not by lab capabilities.
- Detects between L_D and L_Q cannot be zero. It is improper to treat them as zero.
- Water quality standards are intended to protect water bodies.
- Information reported to the regulatory agencies does not capture important values: recovery and bias.
- Different states have different policies for what should happen when water quality standards are below lab capabilities. Some states allow dischargers to report zero when they have an effluent limit between detection and quantitation or below detection and quantitation. If a lab detects a pollutant, it should be required to report the concentration of the discharge at the detection limit. If the effluent limit is below that, it creates a situation for enforcement that is ambiguous. When there is uncertainty, a regulatory or policy response is required. It is incumbent on the states to say this is what we know and do not know. A limit must address these holes.

Public Utilities' key policy issues

- Guidance on how data are reported relative to L_C, L_D, L_Q, especially levels below quantitation, needs to be in a final package.
- What are appropriate uses of data below quantitation?

Discussion of Revised Draft Evaluation Criteria

Ms. Shorett presented the draft evaluation criteria that had been revised based on input from the caucuses. The revised draft evaluation criteria that must be met, as discussed during discussion and report-out from caucuses, were as follows:

- Address both detection and quantitation procedures.
- Balance, cost and rigor.
- Provide clear, consistent, technically-valid procedures to replace existing procedure in 40 CFR part 136 appendix B.
- Provide guidance document (e.g., SW846 – method 5035A).
- Provide confidence in detection and quantitation procedures at low enough levels to protect human health and the environment.
- Address false positives and negatives.
- Must be flexible enough to address matrices (e.g., sample interference, reflect routine lab operation).
- A procedure that reflects routine laboratory operation.
- Provide explicit definitions for a detection limit and a quantitation limit.

- Detection:
  - Must address false positives and false negatives (may be different for different applications).
  - Reflective of routine performance.
  - Define procedures for addressing matrix effects.
- Quantitation suitable for regulatory compliance:
  - Explicit measurement quality objectives including precision and bias and accounting for interlab variability.
  - Appropriate quality control procedures.
  - Reflective of routine performance.
- Procedures that determine in an unambiguous and legally-defensible manner compliance with the Clean Water Act.
- Detection and quantitation procedures must be consistent for different regulatory uses.
- 40 CFR promulgated procedures that clearly define measurement quality objectives for different uses-may realize that they are all the same.
- Procedures allow assessment of ability to meet the measurement quality objectives on an ongoing, batch-by-batch basis.
- Calibration check at the quantitation limit with predetermined recovery rates.
- Method blank with maximum acceptable concentration as a percentage of the quantitation limit.
- Be a complete, tested, understandable, written procedure and promulgated at 40 CFR part 136 appendix B.
- Include a statement of uncertainty level around detection and quantitation levels.
- Include a procedure for validation and a procedure for laboratories.
- Meets various use needs.

Action: The committee approved, by consensus, to keep the revised draft evaluation criteria in their current state until the December committee meeting when the committee will determine the final criteria it will use to evaluate a procedure or set of procedures.

Discussion of Pilot Testing

Mr. Wheeler, facilitator, explained that the concept of pilot testing had first been raised during the fall 2004 Situation Assessment and noted that the Technical Work Group had briefly discussed several aspects of pilot testing: study design, timing, and budget. He then introduced Richard Reding of EPA who reviewed with the committee possible steps and an approximate timeline (about a year) for pilot testing (see the Triangle Associates PowerPoint on the EPA website). He indicated that a possible next step was to task the Technical Work Group with developing a study design.

Following discussion of a pilot testing design, the Technical Work Group was given the following charge:

1. Expand the glossary of terms.
2. Refine the matrix characteristics based on the committee's discussion.

3. Recommend procedures to include in pilot testing and procedures not to go into pilot testing; identify procedures that need to be modified.
4. Develop concepts of a draft pilot study design:
   - Propose purposes or objectives of a pilot study, recognizing that the committee will make the final decision based on policy considerations.
   - Look at existing data that might be useful in a pilot study and suggest how such data could be used.

Action: The committee asked the Technical Work Group to develop pilot testing concepts for committee discussion at the December meeting.

The facilitators asked the caucuses, over lunch, to discuss the report they wanted to present to Michael Shapiro and to the other committee members after the lunch break.

Caucus Reports and Policy Dialogue with Michael Shapiro
When the committee reconvened from a break for lunch, Ms. Shorett introduced Michael Shapiro, the Deputy Assistant Administrator for the Office of Water, who had joined the meeting. She invited members to use this opportunity to give him status reports from each of the caucuses and to engage him on the issues.

Mr. Shapiro said that his staff had kept him posted on the committee's work. He thanked committee members for the tremendous amount of productive work that they, and the Technical Work Group, had done.

He noted that he also co-chairs the Forum on Environmental Measurements (an EPA-wide group that is trying to achieve better coordination and quality on methods across the agency) and said that the Forum on Environmental Measurements was watching the work of the committee very closely because its recommendations could serve as a model and were likely to set precedent for the rest of the agency.

He assured members that this process had the full attention of the top leadership in the Office of Water. He said he was there mainly to hear from committee members, to get a sense of the progress that has been made, the issues that are coming up, and to find out how committee members see moving forward.

Ms. Shorett then invited the members, reporting by caucus, to introduce their members and give a status report.

States
Dave Akers, Colorado Department of Public Health and Environment introduced his colleagues: Bob Avery (Michigan), Tim Fitzpatrick (Florida) and Tom Mugan, (Wisconsin). He then reported on the survey the state caucus had conducted after the first meeting. Based on the survey results, he said, it is clear that states are using both detection and quantitation in any number of decision-making processes, assessing ambient waters, determining permit limits, determining compliance with permit limits, and they are doing that in a number of different ways.

Mr. Akers said the survey results highlighted for his caucus the challenge of getting all of the states more engaged in this process. He said that the committee's discussions of the survey results on Day 1 had revealed a need to go back and develop some deeper understanding of what the states are doing. Beyond that, he said, to achieve state buy-in on the product of this committee, his caucus realized it would have to engage the states in a good dialogue on the issues so that there could be, hopefully, something nearing consensus. He said his caucus would do some further polling.

Mr. Akers said that the process so far had been really collaborative, with people willing to step forward and put issues on the table. There is an incredible array of knowledge assembled on the Technical Work Group. Their level of expertise and dedication has set the committee up to be very well informed on the technical issues. As discussions this morning revealed, most committee members are mindful that there is a lot of work yet to go. Mr. Akers said they were happy to be here and that they feel like this process is going to result in beneficial change.

Questions/Responses

Question (Mike Shapiro): Out of curiosity, what kind of comments or questions have you heard from your colleagues in the states?

Response (Bob Avery): When we first sent the survey out, there was a period of deafening silence. When the survey went out again, this time to the NPDES managers, we got a few questions, mainly asking for clarification. Overall we heard from 31 states. We're going to continue to try to reach the states who did not respond to make this a complete survey.

Question (Mike Shapiro): When you asked the states whether they use detection limits or quantitation limits, was the question asking if they, for example, set the effluent limit in an NPDES permit at the detection limit? Or were you asking if they had to certify the detection limit for the method they were using if it was below the standard you are testing against or something like that?

Response (Bob Avery): We didn't ask how they set the permit limit. This is clearly one of our policy issues, and we're probably going to need to go back out to the states on that.

<u>Environmental Community Caucus</u>

Michael Murray, National Wildlife Federation, Great Lakes Office in Ann Arbor, Michigan introduced his colleagues: Barry Sulkin (Environmental Consultant), Richard Rediske (Grand Valley State University), and Rob Moore (Environmental Advocates of New York).

Mr. Murray said there are some policy-level ideas that are important. One is providing confidence in detection and quantitation procedures at low enough levels to protect human health and the environment. Others are being consistent with requirements of the Clean Water Act; giving equal attention to false positives and negatives; addressing matrices; sample of interference issues; addressing recovery and bias; and procedures that ideally reflect laboratory operations. Another is the issue of what is practical to

implement. Other issues that are important are cost vs. rigor and practicality vs. rigor, which might be slightly different issues but are still important.

He said the environmental caucus is interested in seeing procedures that are really almost a philosophy, that encourage continuing development of more sensitive methods, including analytical techniques as well as methods for determining detection and quantitation levels. During the morning discussion, the caucus members came up with a few other issues of interest to them, including that permit limits be driven by water quality standards rather than existing technical capabilities. If the standards are low and need to be more stringent, there is a need to drive improvements in the technical capabilities.

Mr. Murray said the environmental caucus is very interested in the issue and implications of samples that come back as detected but not quantified below the quantitation limit. The caucus is very interested in seeing some kind of action being required in such scenarios.

The environmental caucus also conducted an informal survey of environmental interests around the country, contacting a few watershed group list serves and people in environmental groups. The caucus members asked about their familiarity with the issue; if detection and quantitation had come up in their work and, if so, in what ways; issues they wanted the environmental representatives to bring to the committee table; and names of scientists and engineers who are not aware of this process but who could provide useful input into the process.

Mr. Murray said that in the responses to date, the majority were at least somewhat aware of the issues. About half said that detection and quantitation had come up in their work. Some said they felt there were problems with the current approaches to determining the detection and quantitation levels. A number said that they felt the current limits were not necessarily protective of the environment or human health. They pointed out that bioaccumulatives and toxic chemicals need to have limits that are consistent with requirements of the Clean Water Act.

A theme that was raised a few times is the intersection of the methodologies for detection and quantitation with sampling or analytical methodologies and the importance of seeing and working with that intersection. Several pointed to situations where there are few local laboratories that have capabilities to measure particular pollutants at sufficiently low levels and wondered whether or not permittees could be required to seek out those laboratories that can measure at lower levels. Other issues of concern were summarizing monitoring data when there are a number of non-detects or non-quantified values; revisiting the need to improve both analytical methods as well as detection and quantitation methods; and the implications for dischargers and permitting agencies of values that are below the quantitation level but above the detection level. A couple of responses focused on the value of having more federal funds available as well as having industry bear a greater burden to develop more sensitive detection and quantitation methods.

Comment (Michael Shapiro): I heard several themes in your comments. One is the need to pursue and provide incentives for better methods, in terms of their precision, sensitivity and availability, so that we are not constrained in making environmental decisions by the unavailability of methods to achieve our goals. The second relates to what happens when results come back that are between the detection limit and the quantitation limit in different situations.

Response (Mike Murray): In Michigan PCBs are an issue we keep coming back to. The water quality criterion in the Great Lakes is much, much lower than the official minimum level in 40 CFR. It is not the case that we are between detection and quantitation. This is a case where there is clearly a need for improvement in analytical methodology. As we have found, we cannot get too far into this discussion of detection and quantitation level procedures without thinking about the pollutants and analytical techniques. Ideally, we are going to have a procedure or procedures that are as widely applicable as possible.

Comment: We do not want to end up making things worse. Using PCBs as an example, what if, when we run pollutants through these procedures for determining detection limits and quantitation limits, we find a procedure does not perform as well as we had thought. We are very concerned that there might be a long lag time before a new method comes on board that people can use to monitor the lower levels that protect the environment. I think we want to keep moving forward to close up this big loophole but we also want to protect the environment at the same time.

Industry Caucus

Larry LaFleur with the National Council for Air and Stream Improvement introduced his colleagues: Dave Piller (Exelon Power), John Phillips (Ford Motor Company representing the Alliance of Automobile Manufacturers), and Roger Claff (American Petroleum Institute).

Mr. LaFleur said these first meetings have been foundation building and getting everyone on the same page in terms of goals, understanding, objectives, even a common vocabulary, which will certainly provide a great foundation for moving forward. The industry caucus particularly appreciates the fact that the committee has delved into some of the more substantive discussions of uses of detection and quantitation in different programs and different applications. He said that for the industry caucus, legally-defensible and unambiguous procedures for assuring compliance are critical and the caucus thinks that the discussion of those uses and the characteristics associated with those uses is really what should drive the process of selecting which of these procedures for calculating detection limits are preferred. He said the caucus members were grateful that the committee is getting into those discussions and that they look forward to continuing them.

Mr. LaFleur said it is also interesting to note the degree of commonality of interests. The environmental community's list is similar to industry's list. There are many shared values and shared interests. Resolving them is the task that the committee has to look

forward to. Mr. LaFleur also expressed his appreciation to EPA for their flexibility in considering different approaches for ways the pilot study might be used to aid the advisory committee in its deliberation process.

Public Utilities Caucus

Chris Hornback, Director of Regulatory Affairs at the National Association of Clean Water Agencies introduced his colleagues: Zonetta English (Louisville-Jefferson County Metropolitan Sewer District), Jim Pletl (Hampton Road Sanitation District), and David Kimbrough (Castaic Lake Water Agency, representing the California Association of Water Agencies).

Mr. Hornback said the public utilities caucus is grateful to be part of this process. He agreed with the words collaborative, commonalities, and common interests that others had used in describing the process to-date. It has been surprising to see how much commonality there is among the committee's interests on these issues. The public utilities perspective is much like that of industry. The primary criterion for a procedure is that it determines in an unambiguous and legally-defensible manner compliance with the Clean Water Act. To be successful, he said, the committee has to accomplish two major objectives. The first is to select potentially new or different detection and quantitation procedures that meet a certain set of criteria. The second is to have clear guidelines on the uses of these key measurements.

Mr. Hornback said the public utilities are interested in discussing how L_C, L_D and L_Q should be used throughout different Clean Water Act programs, such as compliance monitoring and 303(d) listing. He said the caucus is also interested in the issue the environmental community raised: what do you do with results that are between detection and quantitation? Building on what industry said – that policy drives technical – public utilities have to solve these policy issues before selecting a procedure. For future meetings, Mr. Hornback suggested having more time to discuss policy issues. Forming a separate Policy Work Group will help by organizing the policy issues so they can be presented in a consistent way to the committee and can be discussed in a more coherent way than heretofore. Until now, it has been hard to have discussions while getting organized.

Mr. Hornback said it is a daunting task to take on all of these issues. Public utilities know that the sooner the committee can reach some sort of resolution, the better off all interests will be. However, Mr. Hornback said the public utilities caucus does not want the schedule, budget, or anything else to drive the process. In the three months between the June meeting and this one, the Technical Work Group did not have the time it needed to reach consensus on a lot of the things the committee asked them to do. Committee members need to be mindful of the time constraints between meetings as well as the time constraints on Technical Working Group members. The committee must provide more realistic objectives and direction.

With respect to schedule, Mr. Hornback suggested the committee ensure it has an opportunity to review work products well in advance of committee meetings. He said the public utilities caucus did not have an opportunity to meet together and discuss its

consensus opinions on some of these issues. He said that would be important before the committee convenes again.

Comment (Mike Shapiro): I understand you are saying that these are very tough issues to work through and that we're using the time of the Technical Work Group members to focus on these issues. You feel you need more time to absorb what the Technical Work Group has done and to vet it with your community. Is that right?
Response (Chris Hornback): That's it.

Environmental Laboratory Caucus

Richard Burrows with Severn Trent Labs and representing the American Council of Independent Laboratories (ACIL) introduced his colleagues: Steve Bonde (Battelle), Cary Jackson (Hach Instrument Company), and by phone, Nan Thomey (Environmental Chemistry, Inc.), who could not attend because she had close misses from hurricanes Katrina and Rita, but is listening in and contributing.

At the first meeting, the committee was asked to say what each interest group needed from a final package of methodologies. For the laboratory caucus, the answer seemed fairly simple: clear, consistent and technically-valid procedures to replace the existing procedures at 40 CFR part 136 appendix B. He said the laboratory caucus still believes that is what is needed. Committee members were also asked what it was that needed fixing. The answer is the current procedures at appendix B, which, Mr. Burrows said, do not effectively identify the detection and quantitation limits.

Mr. Burrows said that leads to the real issue for the laboratory caucus, which is that the laboratory community wants to generate good quality, reliable data. He said that the detection and quantitation limits derived through the current procedures are causing the laboratory community to potentially miss contaminants of concern and, also, to find contaminants of concern when they do not really exist. Both are problems. Having a better set of procedures that really identify the limits of the methods is going to help the laboratory community focus its attention on method development needs. Mr. Burrows said the current methods, which might appear to be adequate now, in some cases, are not.

As far as current progress is concerned, Mr. Burrows said the committee has accomplished getting to a fair degree of consensus on definitions of what is meant by various detection and quantitation limits. That is a key foundation unto which the committee can build.

Now, the committee is starting to talk about pilot testing. Mr. Burrows emphasized that there are two things to evaluate in pilot testing. First, the committee will need to look at a new procedure and see, for a variety of different methods, if it works effectively to generate numbers for detection and quantitation limits. An equally, or even more, important part of the test needs to be determining if a procedure generates the correct numbers. He said there is nothing really wrong with the statistics that go into the MDL procedure. The problem is that some of the assumptions that are made are frequently not

valid. That is where the MDL procedure starts to fail. The committee must be very careful that it does not gloss over assumptions that a new procedure makes and assume that users are clever enough to come up with the right theory to back up a procedure. The committee must test it rigorously. That is what the interested community failed to do with the MDL and it has been used for 20 years before users really started asking if there was a problem.

Mr. Burrows said he was very encouraged when looking at the responses of the other interest groups to the question: "What does your interest group need from a final package of methodologies." The laboratory caucus can agree with just about all of them. So, Mr. Burrows said, the committee is at a good place from which to proceed. Members are at least all looking for the same goals. He said it will still be challenging, to get from here to there, but at least the interests are all pulling in the right direction.

EPA
Mary Smith said that she and her staff had said, repeatedly, that EPA was lucky to have this group of stakeholders at the table, because they are very bright, hard working and really committed to the process. Short of a couple of hurricanes (which is a good excuse), everybody is here. She said that she would echo what other people had said, about the collaborative nature of the process. She also complimented members for doing their homework, coming prepared, and participating in productive discussions. She said she was very pleased with the group's progress. She acknowledged that the committee had not yet made the hard decisions, but typical of these processes, they would come at the end. She said the committee needed more data and more discussion to get to that point.

Mr. Shapiro thanked committee members again for their hard work and said that he would continue to monitor the group's progress.

Public Comment
Ms. Shorett briefly reviewed the ground rules for public comment and invited the individual who had asked to comment to step to the microphone.

Peter Ciarleglio, URS Corporation
Mr. Ciarleglio said he wanted to briefly comment on the role of detection limits and the establishment of regulatory limits and effluent guidelines that was briefly touched upon in the morning discussion. As members know, EPA typically calculates the regulatory limit based on the product of a derived Long-Term Average (LTA) (although it sometimes works out to be medium) and a variability factor (V_F). Many people think this comes from a lot of accumulated data, but in his experience, this is not the case. Mr. Ciarleglio said that in representing clients in a half dozen cases, the typical effluent limit guideline is derived from 6-12 actual sample analyses from 1-3 facilities. That is an awfully small number of samples.

The detection limits come from a policy standpoint and are affected in two ways.

First, out of about 8 samples collected, in some instances four will be non-detects. Yet, EPA derives a variability factor and an LTA from the data. Mr. Ciarleglio said he has seen variability factors for a monthly average as low as 1.06 and daily maximum variability factors being only 1.10. As an analytical chemist, he said he knows that when calibration checks are done, they are typically plus or minus 10%; for organics they are plus or minus 20%. A variability factor across the nation of only 6% above an average is probably not a real view. The calculations of these results get skewed by the way the detection limit comes from the EPA data collected for the effluent limit guideline. Another reason there are so few facilities is that in an effluent limit guideline, industries are divided into subcategories and they have to have the proper Best Available Technologies; other reasons ultimately winnow the data. The actual regulatory limit for a subcategory gets done on very little data.

Second, users often propose that EPA, to supplement this data, use the DMR data from different industries. As the environmental caucus pointed out, there are a lot of inconsistencies in the way these data are reported, and sometimes data are reported as non-detect or zero, but that is not very informative. In many instances EPA is reluctant to use additional DMR data to promulgate these limits. While there are a number of reasons why, one of the biggest is because of the detection limit. Either a result is reported as a non-detect or if there is a detection limit reported, EPA is not sure what kind of detection limit it is (i.e., Lc, L_D or L_Q).

On an official form like a DMR, there needs to be a consensus way of reporting the data as far as the detection limit is concerned. Even if originally intended for determining compliance with an effluent guideline standard, the data cannot be easily used without a standard reporting procedure. Mr. Ciarleglio suggested the committee consider this when it gets into determining how and for what purpose detection limits are going to be reported.

Draft Agenda Items for the Committee's December Meeting
Ms. Shorett indicated that the draft agenda for the December 8-9 committee meeting would include the following items:

- Meeting summary approval
- Reports from caucuses on their outreach and the input from their constituents
- Discussion of policy issues
- Discussion of Policy Work Group's work on uses of detection and quantitation
- Evaluation criteria (to finalize)
- Review and discussion of the Technical Work Group's report on a pilot study and finalizing the pilot study purpose, objectives, design and next steps
- Narrowing the list of procedures to test
- Review and discussion of other Technical Work Group products, if any

Committee members requested that Technical Work Group and Policy Work Group products be distributed well in advance of the December meeting. In addition, it was

suggested that caucus groups be given time both in advance and at the meeting to review and discuss the materials as a caucus.

Wrap-up and Next Steps
Ms. Shorett read a brief summary statement of the meeting. She noted that the December 8-9 meeting would be in the same facility, at the FDIC William Seidman Center. Looking ahead to the March meeting, she said the facilitation team would try to avoid spring break and asked members to let the facilitators know via email or phone if there were dates that were a problem.

Mary Smith thanked everyone for coming prepared, for participating, and for being engaged. She said she thought the committee had made a lot of progress and looked forward to the next meeting.

Richard Reding adjourned the committee meeting at 3:30 p.m.

MEETING ATTENDANCE

Committee Member	Affiliation
Environmental Community	
Rob Moore	Environmental Advocates of New York
Michael Murray	National Wildlife Federation
Richard Rediske	Grand Valley State University
Barry Sulkin	Environmental Consultant
Environmental Laboratories	
Steve Bonde	Battelle
Richard Burrows	Severn Trent Labs
Cary Jackson	HACH Company
Nan Thomey (via phone)	Environmental Chemistry, Inc
Industries	
Roger Claff	American Petroleum Institute
Larry LaFleur	National Council for Air and Stream Improvement
John Phillips	Alliance of Auto Manufacturers (Ford Motor Co.)
David Piller	Exelon Corp.
States	
Dave Akers	Colorado Dept of Public Health and Environment
Bob Avery	Michigan Dept of Environmental Quality
Timothy Fizpatrick	Florida Department of Environmental Protection
Thomas Mugan	Wisconsin Dept of Environmental Protection
Public Utilities	
Zonetta English	Louisville/Jefferson Co Metropolitan Sewer District
Chris Hornback	National Association of Clean Water Agencies
David Kimbrough	Castaic Lake Water Agency
Jim Pletl	Hampton Roads Sanitation District
EPA	
Mary Smith	US Environmental Protection Agency

Designated Federal Officer	
Richard Reding	US Environmental Protection Agency

Invited Speakers/Participants	
Michael Shapiro	US Environmental Protection Agency

Facilitators	
Alice Shorett	Triangle Associates, Inc.
Bob Wheeler	
Derek Van Marter	

Observers	
Brian D'Amico	US Environmental Protection Agency
Joanne Dea	
Meghan Hessenauer	

Marion Kelly	
Michael Papp	
Danielle Tillman	
Brad Venner	
Steve Wendelken	
Shen-Yi Yang	
Kevin Bromberg	US Small Business Administration
Ray Anderson	SAIC
Sharon Drop	
Jim Christman	Hunton & Williams
Peter Ciarleglio	URS
Colin Finan	Inside EPA
Ken Miller	CSC
Jenny Van	ERG

DISTRIBUTED MATERIALS

Committee's Packet of Materials

Agenda (September 29-30, 2005)
Draft Meeting #1 Summary (June 21-22, 2005)
Common Base of Information
Definition Options for Detection and Quantitation
Issues to Consider When Defining Detection and Quantitation (White Paper)
Glossary of Terms
Concerns with the EPA Method Detection Limit (MDL) and the EPA Minimum Level (ML)
Comparison Matrix of Detection and Quantitation Procedures (Version 6, September 16, 2005)
Interpretations of Detection and Quantitation Procedures Evaluation Characteristics
Footnotes to Procedures-Characteristics Matrix
Facilitator Summary of Key Issues
Preliminary Draft Evaluation Criteria

Distributed at Meeting

State Survey for MDL/QL Use Presentation Handout
Process Schematic
Facilitator Status Report on Definitions
Revised Definition Options for Detection and Quantitation
Draft Evaluation Criteria That Must Be Met

Attachment A

REVISED DEFINITION OPTIONS for DETECTION & QUANTITATION
from the TWG Definitions Subgroup

L_C DETECTION – LAYPERSON'S DEFINITIONS

1. **Critical Value (L_C)** - The minimum result which can be reliably discriminated from a blank**** (for example, with a 99% confidence level).

2. **Critical Value (L_C)** – The lowest result that can be distinguished from the blank**** at a chosen level, a, of statistical confidence.

**Note: The committee acknowledged that the use of "blank" versus "zero" needs further discussion.

~~3. **Critical Value (L_C)** - The concentration which a sample result must exceed in order to conclude (with 100a percent chance of being wrong) that the analyte is present.~~

~~4. **Critical Value (L_C)** - The lowest result that can be distinguished from a blank with no more than α chance of reporting a false positive. (e.g., where α = 10%)~~

~~5. **Critical Value (Lc)** – The Critical Value (Lc) is the upper 1% limit for the distribution of measurements with a true mean of zero.~~

L_D DETECTION – LAYPERSON'S DEFINITIONS

1. **Detection Limit (L_D)** - The lowest true concentration that will almost always be detected. (The Committee wants the term "detected" to be modified.)

2. **Detection Limit (L_D)** - The minimum detectable value is smallest amount or concentration of a particular substance in a sample that can be reliably detected by a specific measurement process.

3. **Detection Limit (L_D)** - The minimum true concentration that will return a result above the critical value given a specific measurement process and confidence level.

~~4. **Detection Limit (L_D)** - The Minimum Detectable Value (L_D) is the lowest true concentration at which the probability of a measurement less than L_C is beta.~~

5. **Detection Limit (L_D)** – The lowest concentration for which there is a desirably small probability, ß, that the determinand will not be detected - i.e. that as a result of random errors the observed result will be less than the Critical Level.

6. **Detection Limit (L_D)** – The concentration of analyte which must be present in a sample in order to be 100*(1-ß) percent certain of detecting its presence without a false negative as well as a 100*a percent chance of not detecting a false positive. (i.e., 100(1-ß) percent certain that the result will be greater than the Critical Value).

L_C DETECTION - STATISTICAL DEFINITIONS

1. **Critical Value (L_C)** - The upper limit for a distribution of sample measurements with a true mean of zero, such that a future sample measurement that exceeds L_C has a probability of a false positive of 1% or less that the true sample concentration is zero. Algebraically, this is expressed as $L_C = z_{(1-\alpha)} * \sigma_{(0)}$ where alpha is the probability of a Type I error, $z_{(1-\alpha)}$ is the (1-α) percentage point of the standard normal variable, and $\sigma_{(0)}$ is the standard deviation of the population of all possible measurements of a sample with a true value of zero.

2. **Critical Value (L_C)** - Smallest measured amount or concentration of analyte in a sample that gives rise to a Type I error tolerance of alpha under the null hypothesis that the true amount or concentration of analyte in the sample is equal to that of a blank. (The alternative hypothesis is that the true amount or concentration of analyte is greater than that of a blank.)

3. **Critical Value (L_C)** - The minimum observed result such that the lower 100 (1-α)% confidence limit on the result is greater than zero.

4. **Critical Value (L_C)** - The minimum observed result such that the lower 100 (1-α)% confidence limit on the result is greater than the mean of the method blanks.

L_D DETECTION - STATISTICAL DEFINITIONS

1. **The Minimum Detectable Value (L_D)** - The lowest true concentration at which the odds of a future false-negative measurement that is less than the Critical Value, L_C, is equal to beta. Algebraically, this is expressed as $L_D = L_C + z_{(1-\beta)} * \sigma_{(L_D)}$, where beta is the probability of a Type II error, $z_{(1-\beta)}$ is the (1-β) percentage point of the standard normal variable, and sigma (L_D) is the

~~standard deviation of the population of all possible measurements of a sample with a true value of L_D.~~

2. **The Minimum Detectable Value (L_D)** - Once L_C is established, L_D is the smallest concentration or amount of analyte at which the tolerance for Type II error is equal to beta.

3. **The Minimum Detectable Value (Ld)** - The lowest true concentration such that the frequency that the result is greater than L_C will be 100% (1-β).

L_C & L_D DETECTION - STATISTICAL DEFINITION

~~**Detection (L_C and L_D)** – Following the statistical theory of Hypothesis Testing we consider two kinds of errors (really erroneous decisions): the error of the first kind ("type I, " false positive), accepting the "alternative hypothesis" (analyte present) when that is wrong; and the error of the second kind ("type II," false negative), accepting the "null hypothesis" (analyte absent) when that is wrong. The probability of the type I error is indicated by α; the probability for the type II error, by β. Default values recommended by IUPAC for α and β are 0.05, each. The Critical Value, L_C, is set at a specific value of α (0.05 default) and the Minimum Detectable Value, L_D, is set at a specific value of β (0.05 default), once L_C has been established.~~

L_Q QUANTITATION DEFINITIONS

1. **Quantification Limit (L_Q)**: The smallest detectable ~~amount or~~ concentration of analyte greater than the detection limit where the required** accuracy (precision & bias) is achieved for the intended purpose.

**Note: EPA requested additional conversation around the use of the word required in the definition.

2. ~~**Quantification Limit (L_Q)**: The smallest amount or concentration of analyte greater than L_D where some specified tolerance for uncertainty is met.~~

3. ~~**Quantification Limit (L_Q)**: That concentration above which a given value of ρ is achieved, where ρ is the relative percent standard deviation; ρ = 10 has been suggested as suitable. If the chosen value for ρ is denoted by ρ_Q, the Lower Limit of Determination, L_Q, is given by:~~

~~$$L_Q = 100\sigma_t / \rho_Q$$~~

~~where σ_t is the total standard deviation of analytical results at a determined concentration L_Q.~~

4. **Quantification Limit (L_Q)**: The smallest amount or concentration analyte equal to or greater than L_C at which some specified tolerance for uncertainty is met. The uncertainty for a variable of interest X (e.g., the concentration of an analyte in a sample) refers to the range of values (a, b) containing the true value of X at the required level of confidence gamma.

Attachment B

Preliminary Draft Evaluation Criteria

September 30, 2005

At the June 21-22 meeting, you developed a list of "desirable characteristics" for the Technical Work Group to use in its initial analysis and evaluation of the technical merits of detection and quantitation procedures. You will see the results of this initial evaluation during this meeting.

You, as a Committee, also need to develop broad, policy-level criteria for evaluating a final package of detection and quantitation procedures to recommend to EPA. At the June meeting, you began the process of identifying these criteria by responding in your respective caucuses to the question, *What does your interest group need from a final package of methodologies*?

The table below presents the broad, policy-level criteria that each caucus identified as necessary in a final package of procedures. The facilitators have grouped these elements into three categories: those that must be met; those that are highly desirable; and those that are goals to work toward.

On Friday you will take the next steps to develop evaluation criteria for the package of recommendations as a whole.

Draft Evaluation Criteria based on Caucus Discussions, June 21, 2005			
Caucus	**Must Be Met**	**Highly Desirable**	**Goals to Work Toward**
States	Address both detection and quantitation procedures (Labs agree)	Provide flexibility to implement use of detection and quantitation limits as public policy evolves	Reward entities that strive to attain lower detection and quantitation limits where necessary (e.g., water quality) States require performance levels for labs to achieve D/Q (EPA-ensuring more sensitive methods do not run afoul and that new, innovative methods will work)
	Balance, cost and rigor (Labs agree; Industry agrees; EPA	Include protocols for advancement of	

Draft Evaluation Criteria based on Caucus Discussions, June 21, 2005			
Caucus	**Must Be Met**	**Highly Desirable**	**Goals to Work Toward**
	agrees)	technologies/sensitivity	
Environmental Laboratories	Provide clear, consistent, technically-valid procedures to replace existing procedure in 40 CFR part 136 appendix B		Entice "non-compliant" laboratories to comply
	Provide guidance document (e.g., SW846 – method 5035A)		Be easy to use in a competitive environment
Environmental Community	Provide confidence in detection and quantitation procedures at low enough levels to protect human health and the environment (States agree; Utilities-this is consistent with our first criterion, depending on interpretation. A balance must be achieved between confidence and sensitivity; EPA-CWA has as its goal zero discharge)		
	Give equal attention to false positives and negatives (States agree – may be different for various applications)	Choose procedure(s) that encourage more sensitive methods and equipment (Labs-this is inherent in developing good procedures)	
	Address matrices (e.g., sample interference) States-flexible enough to address matrices if appropriate for certain circumstances (EPA-reflect routine lab operation)		
	A procedure that reflects routine laboratory operation (Labs agree)		
Industry	Provide explicit definitions for a		Detection and

Draft Evaluation Criteria based on Caucus Discussions, June 21, 2005			
Caucus	**Must Be Met**	**Highly Desirable**	**Goals to Work Toward**
	detection limit and a quantitation limit		quantitation procedures must be consistent with different procedures for different regulatory uses
	Detection: Must address false positives and false negatives Reflective of routine performance Define procedures for addressing matrix effects		
	Quantitation suitable for regulatory compliance: Explicit measurement quality objectives including precision and bias and accounting for lab variability Appropriate quality control procedures Reflective of routine performance (States agree)		
Public Utilities	Procedures that determine in an unambiguous and legally-defensible manner compliance with the Clean Water Act	Procedures should apply to labs and analytical methods	
	40 CFR promulgated procedures that clearly define measurement quality objectives for different uses-may realize that they are all the same	Procedures shouldn't preclude a qualified lab from conducting them	Within reason, procedures should be driven by quality, not cost
	Procedures allow assessment of ability to meet the measurement quality objectives on an ongoing, batch-by-batch basis Calibration check at the		

Draft Evaluation Criteria based on Caucus Discussions, June 21, 2005			
Caucus	**Must Be Met**	**Highly Desirable**	**Goals to Work Toward**
	quantitation limit with predetermined recovery rates Method blank with maximum acceptable concentration as a percentage of the quantitation limit (States think this may be too prescriptive for testing; Utilities-we can move the indented pieces to highly desirable and the general statement at must be met)		
EPA	Be a complete, tested, understandable, written procedure (Labs agree and it needs to be promulgated at 40 CFR, appendix b)		
	Include a statement of uncertainty level around detection and quantitation levels (States seeking clarification on what a statement of uncertainty means; Utilities agree with this criterion; Industry wants clarification) EPA clarification-confidence interval around		
	Include a procedure for validation and a procedure for laboratories		