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, December 8-9, 2005

Final Meeting #3 Summary

Decisions at Meeting #3

The committee:

- Approved, by consensus, the summary of Meeting #2, as drafted.
- Approved changes to the description of the characteristics in the matrix, by consensus.
- Approved, by consensus, revised goals for a final package of detection and quantitation recommendations.
- Approved, by consensus, the draft pilot study purpose and objectives.
- Approved, by consensus, to drop L_D for use in the single-lab pilot study.
- Provided direction to the Technical Work Group in its further development of pilot studies requesting that the multi/inter-lab subgroup move forward with developing a pilot study design that incorporates a multi-lab study design and an inter-lab study design for the LCMRL procedure and present a draft design to the committee at the March 2006 meeting. The committee agreed to a stepwise pilot approach within the advisory process decision-making provisions. The term "multi-laboratory" will also be added to the glossary of terms.
- Recommended, by consensus, further narrowed procedures for consideration in pilot testing by removing the Office of Solid Waste (OSW), ISO/IUPAC Quantitation Limit and Water Research Centre (WRC) procedures from pilot testing.
- Agreed to the following responses to the Technical Work Group's questions related to a single-lab pilot study design:
    - The committee agreed that the single-lab pilot study should include both descriptive and prescriptive approaches.
    - The committee agreed that modification of procedures could be looked at, but that it should not be a high priority for the Technical Work Group. Most felt that changing procedures might happen after the pilot.
- Approved, with amendments and by consensus, a framework for an interim report. The Policy Work Group was tasked with drafting the report that will be made available in time for committee members to check with their constituencies before the March 2006 committee meeting.

DAY 1 – Thursday, December 8, 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 September 28-29 meeting. 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 maintaining that focus. She asked committee members to use the microphones and to 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 and Policy Work Groups for their hard work since the September meeting. She introduced Mr. Ephraim King, Director of the Office of Science and Technology at EPA.

Mr. King began by acknowledging the tremendous gathering of experts in the field of detection and quantitation around the table. He said that this was the right group of people to be tackling this very complex issue. He expressed strong support for and satisfaction at the committee's work to date. He said that having a federal advisory committee grapple with a complex issue and make recommendations to EPA was an opportunity that the agency did not often have, largely because of the amount of time it takes for everyone involved. Mr. King noted that the kinds of issues the committee was discussing went well beyond the Clean Water Act. For example, in the drinking water program, he said that one of the limiting factors was the fact that the method drives the limits. He congratulated members for reaching out to their constituents and stakeholder groups to find out what is important to them. He assured committee members that the agency was also reaching out to its constituents within EPA. At the end of the day, he said, it is important that we can all reach agreement and that our agreement is in line with what committee members' constituents want.

He urged the committee to narrow the number of procedures to pilot test to a few in light of EPA's limited resources and to increase the value of the committee's recommendations to EPA. He said he looked forward to hearing about the committee's progress.

Discussion and Approval of Meeting #2 Summary

After briefly reviewing the agenda for the two-day meeting, Ms. Shorett asked committee members for comments on the draft summary of the September 28-29 meeting. Michael Murray said that he had misspoken in his exchange with Michael Shapiro during the Day 2 environmental caucus report (p. 32, 2nd paragraph, his response). When he referred to the minimum level in reference to PCBs and 40 CFR, he said he had intended to refer to

the MDL in the 40 CFR Part 136 rather than minimum level. He said he did not feel it was necessary to correct the meeting summary as drafted. Ms. Shorett said his comments would be reflected in the summary of the current meeting.

Action: The committee approved, by consensus, the summary of Meeting #2, as drafted.

Constituent Outreach

Ms. Shorett called on caucus groups to report on their outreach since the last meeting.

Environmental Community

Richard Rediske reported that his caucus had received several more responses to its initial survey and that they were in line with the earlier responses. Generally, respondents are hoping for a more universal way to use detection and quantitation procedures to alleviate the potential of the regulated community to "shop around" for labs that produce desired results.

Laboratory Community

Nan Thomey said that most of the policy questions presented by the Policy Work Group for discussion during Day 1 seemed to focus on when to use L_C, L_D, and L_Q. She said that using different procedures for different applications would be extremely difficult for the laboratories to implement. Using L_C would be easiest to verify. She said the laboratory community recommended using only L_C and L_Q for reporting purposes. She said the caucus favored a descriptive rather than a prescriptive scientific process for determination.

Richard Burrows then read a letter from Joan Walsh Cassedy, Executive Director of the American Council of Independent Laboratories (ACIL) who made similar points. (The letter is available at http://epa.gov/waterscience/methods/det/). The committee, he said, needed to think about the technical as well as implementation and uses aspects of detection and quantitation procedures. The laboratory community, he said, favored the status quo – a two-tiered reporting system (L_C and L_Q). Rather than spending time on how to implement a three-tiered system (L_C, L_D and L_Q), he recommended that the committee better identify levels for L_C and L_Q.

States

Dave Akers said that his caucus had resubmitted surveys to those states that had not previously responded but had received no new responses. He reported a conference call, convened through the Association of State and Interstate Water Pollution Control Administrators (ASIWPCA), involving NPDES (National Pollutant Discharge Elimination System) and Clean Water Act program managers to clarify whether the states, in responding to the caucus questionnaire on uses of detection limits, were referring to the MDL. Eight states participated in the call, six of which were from outside the committee. Participants' response was that they were referring to the MDL. He said the eight states on the call also indicated that the use of a Practical Quantitation Limit (PQL) would be most important to them. Participants also asked how the work of the

committee would coordinate with the move towards Performance Based Measurement System (PBMS).

Mr. Akers said that his caucus would continue to try to get responses from the states that have not yet responded to get a broader sense of where the states are on the issue of detection and quantitation. In addition, he said the caucus planned to invite all states to participate in a web-based dialogue on detection and quantitation issues.

Public Utilities

Chris Hornback noted that he had committed to conduct a survey of National Association of Clean Water Agencies (NACWA) members on industrial pretreatment and whether detection and quantitation differed in that context. He reported that, with help from other caucus members, he had assembled a survey intended for a small group of respondents (referred to as a "screener survey"). He said the small group provided a good representative sample of the answers he was likely to get through a broad survey of all members. In addition, he said, David Kimbrough had sent out a survey to California laboratories.

He said he had adjusted the description of the pretreatment use in the Policy Work Group Uses document to reflect results from the survey. Basically, he said, uses of detection and quantitation in pretreatment did not appear to differ from those in Clean Water Act programs such as the NPDES Permit program.

He said the public utility caucus used essentially the same questions that the states had used in the state survey. He said that there was a great deal of variation in what is used to determine compliance levels. Most use MDL- or ML-based approaches. In California, a lot of different compliance levels are being reported. For example, one respondent indicated the L_Q was used for general compliance while L_D was used for compliance for pollutants that are not allowed to be discharged. He also said while data-reporting requirements varied significantly, virtually all of the limits were above the quantitation limit. He reiterated that policy issues associated with pretreatment closely tracked NPDES issues, although they were somewhat less complicated because there were fewer instances of compliance levels below L_Q (although there were potentially more matrix effects).

David Kimbrough presented information from a single laboratory verification study he was involved with in California on L_C and L_D. (See the "facdq.1205" presentation at EPA's website http://epa.gov/waterscience/methods/det/.) He presented some of the data that had been collected for various analytes and offered the following observations:

- With the exception of the Hubaux & Vos procedure, the various descriptive candidate procedures produce very similar results;
- Verifying L_C and L_D is a huge amount of work, even for "simple" analytes and methods;
- Results are often ambiguous;
- None of the analytical procedures contained both false positives in the un-spiked blank and false negatives in the spiked blank; it was one or the other; and

- L_C was not found for any method.

Industry (John Phillips)
John Phillips said that the industry caucus had a strong consensus that compliance must be set at L_Q. What most concerned the industry caucus, he said, was certainty in operations for compliance purposes. With regard to the issue of efficacy for L_D, he said the caucus regarded both false positives and false negatives as important. If L_D were eliminated, it could take away data usability below L_Q.

EPA
Mary Smith reported that her office had met internally in a two-hour meeting with other EPA offices to provide information about this advisory committee and why it was created and to gather information about other Clean Water Act programs. In particular, she said she wanted to familiarize everyone with the issues, answer questions, and to identify any show-stoppers. The group had had to set up an additional session to go through the more technical issues. She said the meetings were good, with both policy and technical staff participating from various EPA program offices.

She noted that an earlier interagency group had initially consisted mostly of the Office of Ground Water and Drinking Water (OGWDW) and other EPA methods staff. Because of the "uses" issues, the interagency group for this set of meetings was expanded and now includes the following Water Program offices (Water Quality Standards, ELGs/CWA methods, Safe Drinking Water Act methods, Monitoring, Permits) and other EPA program offices. (The others were: Prevention, Pesticides and Toxic Substances (OPPTS); Solid Waste and Emergency Response (OSWER); Enforcement and Compliance Assurance (OECA); Research and Development (ORD); and General Counsel OGC. Air and Radiation (OAR) was absent.)

Mary Smith presented the results of the interagency meeting as follows:

Agenda Topics	EPA Interagency Meeting Results
Uses of Detection and Quantitation	On uses, there was a lot of interest in possible ramifications. Thus far, no showstoppers were identified but at least one organization planned to brief its Office Director. The Standards Program indicated it was working with a state now on a TMDL list where the degree of analytical error and how to account for it has come up. The Permits Program acknowledged the current applicability of the 1991 guidance document. Other programs emphasized the applicability of this to Clean Water Act only. OECA would prefer that permits not contain quantitation limits, rather levels below the quantitation limits with some qualifier about the uncertainty of the measurement.

Draft FACA Definitions, particularly the blank vs. zero issue	EPA formally withdrawals its opposition to the "blank" issue as presented at the last meeting.
Evaluation Criteria for Selection of Detection and Quantitation Procedures	No new evaluation criteria were identified. A few attendees mentioned that some of the criteria were duplicative.
Pilot Testing of Detection and Quantitation Procedures – list of procedures, overarching design issues	No new procedures were identified. OSW acknowledged that their method might be dropped and did not express concern. OGC indicated that, to be binding, procedures had to be in regulations; guidance is just that, guidance. On detection, EPA participants thought we could retain MDL, IDE and Hubaux & Vos. The group wanted to eliminate the following detection procedures from the pilot: WRC, Osborn Lab. On quantitation we could retain: ML, IQE and LCMRL. EPA suggested eliminating the following quantitation procedures from the pilot: ISO/IUPAC, OSW.
Attributes of Detection or Quantitation limits can include: accuracy/bias (blank correction and recovery correction), precision, false positives and false negatives, minimum number of laboratories, matrices.	The group talked a lot about attributes: false positives/negatives, precision, bias, etc. There was some question about the value of false positives/negatives. In general, the group was not comfortable with fixed limits.
Multiple vs. single lab issue	▪ With regard to the minimum number of labs, data from 6 labs is a nice goal. Drinking water wanted some flexibility in this. ▪ With regard to routine lab analysis, allowing recovery correction and blank correction was a show-stopper. There was some concern that this could become a slippery slope and could encourage sloppy lab practices. ▪ There was no particular concern about pooling data or capturing sources of variability except that labs should be pre-qualified. ▪ There was no strong opposition about getting rid of L_D. The group acknowledged that L_C is functionally equivalent to the L_D.

Staying in touch	Mary Smith and her team will be keeping this group informed about the progress of the FACA and the Policy and Technical Work Groups. There will be at least one meeting with this same interagency group in early March before the next FACA meeting.

Question: Regarding the L_C/L_D issue, I thought you said the MDL is an L_D. Is that what you meant?
Response (Mary Smith): No. If I said that, I was incorrect. MDL is largely L_C.

Question: What is EPA's rationale for dropping the Osborn Lab Q/C procedure from pilot testing?
Response: (Richard Reding) It is not because some of these procedures are not good, basic procedures. It relates to what Ephraim King said this morning. We need to make some difficult decisions with respect to narrowing down to a reasonable number of procedures to pilot test.

Policy Issues Related to Uses of Detection and Quantitation Approaches
After a brief break, Ms. Shorett introduced the discussion of policy issues related to uses of detection and quantitation. She reviewed the assignment given to the Policy Work Group at the September committee meeting, which was to:

- Describe the categories of uses identified during the second committee meeting;
- Describe the existing situation for each use category and identify the data quality objectives for each type of use and user; and
- Pose, prioritize and frame the policy issues associated with each use.

She noted that the Policy Work Group consisted of the following committee members:

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

She reported that the Policy Work Group had met four times, had written descriptions of each of the uses, and had prioritized the list of uses. She said that Policy Work Group members had prepared a white paper comprised of descriptions of the uses, the existing situation for each, and a series of "decision trees" (decision-making flow charts) for the prioritized uses. (The white paper was sent to committee members in advance of the meeting and is available at the EPA website as "Consolidated Description of Uses.") At this meeting, Ms. Shorett explained, Policy Work Group Members would give presentations on the continuum of uses to orient committee members to the existing uses and then would present policy issues related to the top three prioritized uses: permit

applications, permit compliance and enforcement, and data reporting. (The presentations from this session can be found at the EPA website.)

Continuum of Uses

Mary Smith, EPA, gave an overview of the existing Clean Water Act program uses of detection and quantitation. She identified several potential issues with respect to current uses if detection and quantitation procedures were to change.

Ms. Smith noted that National Water Quality Criteria (WQC) and State Water Quality Standards (WQS) can be below detection and quantitation limits. She said that water quality criteria need to be protective of public health and aquatic life (and wildlife in the case of the Great Lakes Initiative). She added that states need the flexibility to establish water quality standards to address site-specific issues.

She said there were two type of monitoring uses for detection and quantitation procedures: ambient monitoring and stormwater monitoring. Ambient monitoring is done to assess the quality of surface waters to determine trends over time, support development of water quality based effluent limits (WQBELs), and to assist in decisions of reporting/listing of water bodies. Ambient monitoring varies from state to state. She said some issues to consider are whether there is a need for consistency in the use of detection and quantitation, and water body assessment and status if there is a change in procedures for detection and quantitation limits. She said stormwater monitoring requirements vary for industrial sources and large municipalities, and that they are not tied to compliance. Again, the issue for stormwater monitoring is whether there is a need for consistency in reporting.

National Effluent Limit Guidelines (ELGs) are generally established at or above the quantitation level of the available method. The issue here is whether a change in detection and quantitation procedures would affect previously promulgated ELGs.

With respect to methods development, validation and promulgation, Ms. Smith said the MDL and ML were established through a validation process and incorporated in 40 CFR Part 136. She identified two issues here: (a) If detection and quantitation procedures change, what effect will that have on previously promulgated EPA reference methods and testing protocols?; and (b) How can we ensure development of more sensitive methods? She also said there is currently no consistent reporting practice, which is confusing for laboratories.

She finished her presentation by explaining that for permitting direct and indirect dischargers, permits are issued by state and local governments, and by EPA in non-delegated states. She said permit limits are set at the ELG, WQBEL, or local pretreatment limit. Ms. Smith posed the following issues for this topic:

- How monitoring data below the detection and quantitation limits should be used when determining what limits are in the permit?
- For compliance purposes, how is data below the detection and quantitation limit reported?

- What should be the compliance/enforcement limit?
- What other responses are available when monitoring data is below detection and quantitation limits (e.g., increased monitoring; for GLI, pollutant minimization program)?

Decision Trees (Flow Charts)

Larry LaFleur briefed the committee on the Policy Work Group process to prioritize the uses. He explained that the Policy Work Group had identified two priority issues: NPDES compliance and enforcement, and NPDES permit applications. Using a PowerPoint presentation, he walked the committee through four slides showing decision flow charts including a set of questions or "trees" to explain the series of decisions that had to be made for each of the priority issues.

Comment: Another consideration for EPA is TMDL (Total Maximum Daily Load) calculations, although there may not be short-term implications to water quality criteria. When we see water quality standards go beyond our limits that may serve as a trigger to review methods to make them more sensitive.

Response (Mary Smith): I see states moving forward to set standards on ecological issues rather than detection and quantitation issues. But, you are right, there will be an impact.

Comment: That is one of the main reasons the committee is here. Maybe we need to recommend that detection/quantitation and water quality standards need to be linked.

Comment: There are hundreds of methods listed at 40 CFR136, but only a few of those list MLs and MDLs. Changing what is published at 40CFR136 is not going to have a huge impact on methods.

Comment: I would caution that changes in quantitation procedures will not result in significant impacts. Also, I will mention that these flow charts would be much simpler without L_D.

Great Lakes Initiative

Tom Mugan, State of Wisconsin, presented examples of setting permit limits, determining compliance and enforcement, and reasonable potential analyses from the Great Lakes Initiative. (See the "Great Lakes Initiative" presentation on the EPA website.)

Comment: These are all general cases of looking at numbers below L_Q. States need to use sound statistical procedures to resolve these numbers. For example, for numbers between L_Q and L_C, limits should be set half way between the two.

Question: When you reference ML in the Great Lakes Initiative, is that the Part136 ML or another?

Response (Tom Mugan): I would need to look at the Great Lakes Initiative. I am not sure it is specified, but I think it means the EPA ML referenced through Part136. It does say that if there is no ML specified, it needs to be the lowest

practicable quantified level. (Larry LaFleur confirmed that the reference in the Great Lakes Initiative is the EPA ML.)

State Approaches

Dave Akers, Colorado, presented examples of setting permit limits, determining compliance and enforcement, and approaches to reasonable potential analyses from the perspective of the state caucus. (See "DQ Uses – Other State Approaches & Outreach" presentation on the EPA website.)

California Toxics Rule

David Kimbrough presented to the committee information on how the Water Quality-Based Effluent Limit (WQBEL) is established under the California Toxics Rule. (See slide in the "Final_FAC#3_12-8_9-05" presentation on the EPA website.)

Comment: EPA Region 10 guidance (included in the committee packets) is a good example. Numbers get reported to states. All of those numbers then get put into the national database. The national database will need to account for the variability in determining compliance. States also use sources of data other than what the permittees report. If we are going to apply criteria to what permittees report, the criteria should apply to other sources of data. This ostensibly means state data.

Comment: On this example, where we are below L_Q but above L_C, there are some other conditions (e.g., whole effluent toxicity or WET testing, frequent monitoring) that could be put into the permit. This could be palatable if the permit had those other conditions of protection that not all states put in permits.

Question: How would you use WET testing in a situation where you have a number of toxins?

Response (Rob Moore): That is when one would follow the procedures of TIE (Toxicity Identification Evaluation) or TRE (Toxicity Reduction Evaluation).

Comment: We are talking about methods referenced in 40CFR136. The problem is three methods may be referenced for a given analyte, and all three may have different levels of detection. If we intend that people use the lowest level, then why have three listed? This is one of the reasons laboratories want a PBMS-based approach rather than the method-based approach.

Response (Mary Smith): We have so many because it is always so difficult to remove methods once they are approved. Also, the 1991 guidance says that the most sensitive method should be used.

Comment: In reviewing the California Toxics Rule, there are a few analytes that are below L_Q.

Comment: I want to comment on a point made earlier that only a small number of analytes are below L_Q. In the Great Lakes Initiative, 22 of 25 chemicals of concern are below L_Q. The criteria developed under the Great Lakes Initiative

were quite low. On the one hand, it could be specific to the Great Lakes. On the other, it could be that we may not yet see where we need to be across the rest of the country.

Comment: If you look at 303(d) lists, nutrients are the primary ones where levels below the L_Q might be a concern. What shows up in most permits? In looking at detection and quantitation issues, we need to keep the big picture in mind. The starting point should be the situation for the majority of uses and users.

Ms. Shorett then asked caucuses to meet during a working lunch and use the decision tree from the morning discussion to prepare responses to the following three questions:

1. What limits should go in permits?
2. What limits should be complied with/enforced in the permit?
3. What should be reported?

Caucus Reports and Committee Discussion of Policy Issues

After lunch, Ms. Shorett reconvened the committee and asked caucus members to report their responses to the three questions above.

States

Permit limits: Bob Avery reported that the state caucus was in favor of the WQBEL. He explained that if the limit were set at L_Q, L_D or L_C, it would be very difficult to change those limits in permits as technology changed except when permits were reissued.

Compliance/enforcement limits: Noting the existing variability in practice among the states, Mr. Avery said the caucus was presenting an option for what it would like to see in the way of enforcement. If the WQBEL is less than one-half of L_C, then the compliance limit would go to L_C. If the WQBEL is greater than one-half of L_C but less than L_Q, then the compliance limit would go to L_Q. If the WQBEL is greater than L_Q, the compliance would automatically go to the WQBEL.

Reporting limits: Mr. Avery said both the L_C and L_Q could be reported, with flags and qualifications for numbers between L_C and L_Q. If the value were a "non-detect" or zero, then the laboratories should report a non-detect. However, Mr. Avery said that for uploading data into state and national databases a non-detect could be considered a zero.

Utilities

Chris Hornback began by identifying the following assumptions the caucus had made in answering the three questions:

- National standards exist for laboratory performance.
- Laboratories initially calculate intra-lab capability.

- On-going quality control procedures are in place after the initial demonstration.
- L_D is a component of the overall equation.
- Issues primarily occur when L_Q > water quality benchmark.
- Measurement Quality Objectives (MQOs) are set and acceptable.

Permit limits: Mr. Hornback said the limit should be the calculated permit limit in all cases. Where the permit limit is below the level of quantitation, a compliance evaluation threshold would be set, which his caucus would set at the L_Q.

Enforcement/compliance limits: Mr. Hornback said that his caucus believes the compliance and enforcement limit should be set at L_Q.

Reporting limits: Mr. Hornback responded that for regulatory reporting purposes – which are separate from laboratory reporting – all data should be reported that meet specified MQOs. If the number is above L_Q, then the calculated number is reported, assuming specified MQOs are met. If the number is below L_Q, then "less than MQO" is reported.

Environmental Community

Rob Moore reported out the results of the environmental community caucus as follows:

Permit limits: The limit should be set at a properly calculated WQBEL that comes from water quality criteria, taking into account all the clearly defined requirements for calculating a water volume base.

Enforcement/compliance limits: The Clean Water Act is about water quality protection and about protecting designated uses. The Clean Water Act is clear that permit limits cannot be issued that do not ensure compliance with water quality standards. A permit cannot be issued where conditions would cause or contribute, or have reason or potential to cause or contribute, to a violation of water quality standards. He said he was unsure how to write a compliance enforcement limit that was not a water-quality-based effluent. He said there were other ways to address the problem when a permit limit was below the L_Q or L_C.

Mr. Moore said that his caucus liked the idea of dropping L_D.

His caucus recommended that, when a permit limit is below L_Q or L_C, the sampling frequency should automatically go up to determine the precise level of the pollutant coming out of a pipe. There should be an obligation to gather more data on a specific parameter to glean some statistical information about it. More rigorous testing should also be mandatory. He said he had previously mentioned that when this situation exists, there should be mandatory WET testing.

In addition, protecting the resource, which is what the Clean Water Act is about, there should be blanket boilerplate language in every single permit that causing or

contributing to a violation of water quality standards is a violation of the permit, particularly in a situation where the water quality criteria is less than L_Q or less than L_C. Many states do not now include this boilerplate language. Water quality standard case law exists that says water quality standards are not independently enforceable. So, there could be a situation where water quality standards are exceeded, but because the permit does not explicitly identify that as a violation, it is not easily enforced.

Reporting limits: Mr. Moore said that when the permit limit or water quality criteria is greater than L_Q, the value should be reported. When the criteria are less than L_Q, a zero value should be reported even though we recognize that the value may not be zero. Michael Murray added that reporting zero for limits below L_C might not be appropriate because of scale. If, for example, the limit were quite a bit away from L_C, it might not appear that way on a plot. In fact, the ecological impact could be substantial. For just about any parameter, we could develop a technology that does not currently exist to be able to measure it. It would likely never be zero. (Later in the discussion, the environmental community indicated a preference to report a non-detect.)

Industry

John Phillips began by identifying the assumptions his caucus had made in responding to the three questions:

- L_Q is an inter-laboratory value that is published in a validated method and nationally promulgated.
- An ongoing performance standard for achievement exists.
- There is acceptable precision and bias.
- There is an acceptable false error rate.

Permit limits: Mr. Phillips said that if the limit is greater than L_Q, the limit should be set at the value. If the limit is below L_Q, it should be set at L_Q. The reasons industry has for setting the permit limit at L_Q across the board are (a) fair notice of what is expected for uniformity; (b) predictability and (c) assurance that reporting is true and accurate – L_Q is the only place one can do that.

Enforcement/compliance limits: For the same reasons, the industry caucus wants compliance and enforcement set at L_Q. He said there was precedent in EPA's 1991 guidance that there is less impact on matrix effects at the quantitation limit and a requirement that the permittee must certify results.

Reporting limits: Mr. Phillips said that all data should be reported above L_Q without qualifiers. Below L_Q, if there were a single value, it should be reported as L_Q because of the uncertainty associated with the number. Mr. Phillips said that data flags are easily lost, and that uncertainty associated with a value is often ignored. If multiple-value sets of data are reported, there could be some different levels that could be reported, depending on the use (e.g., NPDES reporting). Mr. Phillips said his caucus

agreed with eliminating the use of L_D as long as it was maintained as the floor for L_Q. Eliminating L_D would restrict flexibility for specific uses.

Environmental Labs

Steve Bonde said his caucus believes it needed to recuse itself from responding to the first and second questions. Resolution of these questions, he said, was best left to the other stakeholders.

Reporting limits: Mr. Bonde said the first option was that anything less than L_Q should be reported "as less than L_Q" for many of the same reasons that the industry caucus outlined. However, he said they knew that might not be realistic. The second option, assuming there are data of known and documented quality, is between L_C and L_Q. Mr. Bonde said that when the limit goes lower than L_Q, a boundary has been crossed where the laboratories no longer have as much confidence in the quantification or the number.

Mr. Bonde said that the environmental laboratory caucus unanimously agreed that zero was not a real data point and the caucus opposed reporting zero. For reporting purposes of anything less than L_C, he said the caucus recommended reporting non-detect or "less than L_C." Mr. Bonde said the caucus recommended eliminating L_D. Reporting between L_C and L_Q should be "less than L_Q" or "detected, not quantified." If there were a drive for a specific number, he said the caucus' third choice was a specific number with a flag, but that some caveats were needed for a numerical value that was reported with a limit on an allowable number of significant figures. Mr. Bonde said that reporting above L_Q should include all data points.

EPA

Permit limits: Mary Smith said the limits should be set at the WQBEL. It's the most protective limit. EPA guidance is pretty clear and the agency would not want to deviate from that. Methods change over time so the WQBEL gives notice to everyone of the water body's needs in order to be pristine.

Enforcement/compliance limits: Ms. Smith said that longstanding EPA policy has been to enforce at the L_Q when the WQBEL is less than L_Q. Above L_Q, Ms. Smith said EPA enforced at the WQBEL. Ms. Smith said that it was clear from the research her team had done of guidance throughout the agency's regions and from the discussion today that there was a need to define L_Q, because it is clear there is wide variability, even within EPA, on setting L_Q in a permit, ranging from a MDL to a ML.

She said her caucus agreed that L_D could be dropped under the assumption that there is very rarely a permit with a zero discharge. Therefore, the permit limit is greater than zero.

Reporting limits: She described scenarios her staff had created and approaches they used, based on Region 10 Guidance, to calculate a monthly average. They decided to use a zero in calculations if the value was between zero and L_C. For reporting, they

would use "less than L_C." For values between L_C and L_Q, they would report the specific number with a flag or qualifier. For values greater than L_Q, they would report the actual value.

Summary of Policy Issues Discussion
The facilitation team summarized the caucus deliberations as follows:

What limits should go into permits?

Above L_Q, the caucuses agreed the actual calculated value should be used. Below L_Q, four caucuses wanted the permit limit set at the WQBEL and one caucus wanted it set at L_Q. The environmental laboratory caucus passed on this question.

What limits should be complied with/enforced in the permits?

Above L_Q, caucuses agreed the actual value or WQBEL should be used. For calculated limits below L_Q, three caucuses felt compliance/enforcement should occur at L_Q, one caucus at the WQBEL, and one caucus proposed an option that either L_C or L_Q would be used depending on where the WQBEL was calculated. (If the WQBEL is less than one-half of L_C, then the compliance limit would be set at L_C. If the WQBEL is greater than one-half of L_C but less than L_C, then the compliance limit would be set at L_Q). The environmental laboratory caucus passed on this question. There were numerous qualifiers related to the compliance/enforcement use.

What should be reported?

All caucuses agreed that the actual value above L_Q should be reported. For values between L_Q and L_C, three caucuses felt the actual value with a qualifier should be reported while three felt that "less than L_Q" should be reported. Less than L_C, two caucuses felt that "less than L_C" should be reported, one felt that "less than L_Q" should be reported, one indicated that "non-detect" should be reported, and one indicated that zero should be reported.

Committee Discussion of Use of L_D for Single-lab Pilot Testing and Data Reporting
Ms. Shorett then asked caucuses where they were on the need for L_D. In the discussions that followed, many committee members agreed that dropping the concept of L_D from further consideration was acceptable, particularly for single-lab pilot testing, as long as there was a "floor" for L_Q at L_D. However, they wanted flexibility to return to the concept, depending on results of the pilot test. If the results indicated that L_D was a better indicator of detection, then it might be important to keep it under consideration. Many also recognized the reporting issues associated with keeping L_D.

Ms. Shorett asked caucuses to report back after a brief break on where they were with respect to removing L_D from consideration in designing a single-lab pilot project and in reporting data.

States
The caucus had no objection with eliminating L_D within a single-laboratory framework so long as L_C remained. The caucus said that L_D has value in interpreting data between L_C and L_Q, but the caucus agreed that it would be difficult to implement in a laboratory.

Environmental Community
The caucus agreed that either L_C or L_D is needed, and the caucus could support removing L_D. If there were situations where follow-up actions were needed in response to values between L_D and L_Q, the caucus could support revisiting this decision. The caucus felt this decision was really a policy judgment.

EPA
The caucus did not object to dropping L_D for the pilot study or for the various tiers of reporting.

Environmental Labs
The caucus supported dropping L_D for purposes of pilot testing the single-lab approach. If there were a situation where the data quality objectives that the laboratory had to meet were satisfied by reporting to some level at or above L_Q, there should be no need for that lab to determine an L_C. On the other hand, if the data quality objectives required reporting below L_Q, the lab was going to have to determine L_C.

Industry
Assuming alpha were set at 1% and the need for a single L_Q were identified, the caucus would want to resubmit having L_D as a floor for L_Q. Otherwise, the caucus supported the option of dropping L_D, for the single lab pilot study.

Ms. Shorett summarized that there was unanimity to drop L_D for purposes of single laboratory pilot testing.

At the conclusion of the policy discussion, the following action items were identified:

1. EPA formally indicated that it found the L_C definition could refer to the method blank. The committee agreed that the definitions could be changed.
2. The committee requested the following from EPA:
    - When the WQBEL is less than L_Q, provide a list of analytes for which this is true.
    - Periodic reviews for more sensitive methods for these analytes.

Other committee discussions reflected a desire to see incentives for developing more sensitive methods, committee recommendations go into rulemaking, and a need for educational outreach on what the committee ultimately recommends, especially to the States and regulatory agencies.

The committee agreed that there is currently a lack of consistency as to how MDLs and MLs are used and applied (especially the ML for states and EPA), and the committee indicated a desire for more consistency.

Introduction of Goals for a Final Package of Recommendations
Ms. Shorett asked committee members to read the revised draft evaluation criteria in their packets over the evening break. She explained that the draft document reflected the committee's discussion of the preliminary draft evaluation criteria during the September meeting. Ms. Shorett asked for one member from each caucus to meet with the facilitators in the morning before the Day 2 meeting to discuss possible refinement to these criteria. The following members volunteered: Jim Pletl, Richard Burrows, John Phillips, Tim Fitzpatrick, Rick Rediske and Mary Smith.

Technical Work Group Report: Matrix Characteristics
Bob Wheeler briefly identified the assignments the Technical Work Group had been given at the September meeting:

1. Expand the glossary of terms.
2. Refine the matrix characteristics based on the committee discussion.
3. Recommend procedures to include and procedures not to include in pilot testing; identify procedures that need to be modified.
4. Develop concepts for a draft pilot study design:
    a. Propose purposes or objectives for a pilot study, recognizing that the committee will make the final decision based on policy considerations.
    b. Look at existing data that might be useful in a pilot study and suggest how such data could be used.

He then reported the Technical Work Group's progress, referring to materials in member packets. First, he noted the changes that were made to the glossary of terms. He also indicated that Jim Pletl would report at this meeting on additional work that had been done on the characteristics in the matrix. He reviewed briefly the other Technical Work Group documents in member packets that would be the focus of discussion on Day 2 and asked committee members to review them overnight.

<u>Matrix Characteristics</u>
Jim Pletl presented the work the Technical Work Group had done since the September meeting to add clarity to the characteristics in the matrix. (See "Interpretations of Detection and Quantitation Procedures Evaluation Characteristics" at the EPA website.)

Question: we may need a clear definition of scientific and legal defensibility. There will be judgment calls that will be needed. Does the committee need clarity on these prior to making decisions?

Response: (Mary Smith) we will make a policy call eventually based on sound science and what makes sense. If something is going into rule, we will need to make sure we meet all the requirements of rulemaking.

Comment: (Larry LaFleur) With respect to scientific and legal defensibility, in our interest statements starting this process, we all said that we wanted that. However, in responding to it in the matrix, it was clear that there were different interpretations of what that meant. It was also clear that these criteria were not going to be very helpful to the committee in their present form. The intent of clarification was to see if there was a way to pull this apart a little more to make it more helpful to the committee.

Comment: (David Kimbrough) on scientific defensibility, the court will look to see if you followed established procedures. Judges are pretty lenient as long as the decisions followed some logical procedure based on evidence and scientific practice.

Comment: (Bob Avery) David's right. In Michigan, we have gone through hearings where we needed to defend a couple of methods, particularly in the crime lab. Sometimes, there is another hearing that goes back to validating the particular methods used.

Comment: (Nan Thomey) on legal defensibility, this issue has come up in another federal advisory committee of which I was a part. In that instance, we looked at the *Daubert* Supreme Court decision. Ultimately, and after much discussion, putting a "yes" or "no" on legal defensibility was something we thought we should not tread into.

Comment: (Richard Burrows) The original idea of a matrix was to develop a tool that could help us rank the procedures based on some desired characteristics.

Mr. Wheeler asked the committee to approve the three changes to the matrix characteristics suggested by the Technical Work Group: (a) "non-zero" would be changed to read "non-positive"; (b) the "one size fits all" criterion would be scaled from 1-10; and (c) the "defensibility" criterion would be removed.

Action: The committee approved the above changes to the description of the characteristics in the matrix, by consensus.

Public Comment
No public comments were made during Day 1.

Wrap-up and Summary
Alice Shorett reminded committee members that reservations were made for a group dinner at the Flat-Top Grill. She said Day 2 would begin at 8:00 a.m.; a subgroup working on evaluation criteria would meet with the facilitators at 7:00 a.m. in preparation for the meeting. She asked committee members to review the documents from the Technical Work Group before the meeting.

Richard Reding adjourned the meeting at 5:00 p.m.

DAY 2 – Friday, December 9, 2005, 8:00 AM – 4:00 PM

Richard Reding opened the meeting at 8:15 a.m.

After reviewing the agenda for the day, Alice Shorett explained that a working group of committee members had met for an hour before the start of the meeting today to refine the draft evaluation criteria. The working group recommended replacing the draft evaluation criteria with the following goals for a final package of detection and quantitation procedures:

- A complete, tested, understandable, written procedure(s) that addresses both detection and quantitation and reflects routine lab operations.
- A technically valid procedure(s) that provides information to determine if data quality objectives for use in the Clean Water Act are met.
- Considers cost and rigor for both validation for Part 136 methods and routine laboratory procedures.

After committee discussion of the proposed three goals, Ms. Shorett asked for committee approval of the language to be used by the committee as goals for a final package of detection and quantitation procedures.

Action: Committee members approved, by consensus, the revised goals for a final package of detection and quantitation recommendations. (Member Rob Moore was absent.)

Technical Work Group Report: Pilot Testing Study Design

Bob Wheeler again reviewed the assignment given to the Technical Work Group from the September meeting. He reported that, in addition to refining the matrix characteristics discussed on Day 1, the Technical Work Group had developed draft purpose and objectives for a pilot study design. Then, working in two subgroups, the Technical Work Group had developed concepts for a multi-lab pilot study and for a single-lab pilot study. Finally, he said, the Technical Work Group had drafted an issue paper on blank subtraction.

In the course of developing the pilot study design, the Technical Work Group identified several policy questions to develop a thorough study design. Mr. Wheeler quickly reviewed the questions the Technical Work Group wanted the committee to address.

<u>Technical Work Group Questions for the FACDQ to Address</u>

1. Evaluation Characteristics (addressed during Day 1) –
    a. Should the characteristics and measures currently presented in the Matrix be used? If not, what changes should be made so that they can be used in the Matrix?
    b. Should any procedures be dropped from the Matrix?
2. Pilot Study Purpose and Objectives –

   a. Should the proposed pilot purpose and objectives be changed/approved by the FACDQ?
3. Multi-lab Pilot Study Design –
   a. For LCMRL - In considering the detection limit (DL) and quantitation limit (QL) uses where it is determined that an inter-laboratory DL or QL would be most appropriate, should this be implemented through a multi-laboratory design (e.g., pooling or otherwise using single laboratory data) or through a true inter-laboratory design? (See the glossary for a description of an inter-laboratory design.)
   b. Should the Technical Work Group continue to design the pilot study, incorporating and detailing how a stepwise approach would be used with the understanding that the committee would approve the initial plan, but it would not be required also to approve implementation? Rather, the Technical Work Group would track the results.
4. Single-lab Pilot Study Design –
   a. Are procedures intended to identify the absolute detection and quantitation limits achievable by a laboratory? (This would be a "descriptive" approach where each laboratory would show the level to which it could measure.) Or, are the procedure(s) intended to provide a demonstration that the detection and quantitation limits claimed by the laboratory are as high as or higher than the absolute detection limits? (This would be a "prescriptive" approach, where a level would be set based on measurement objectives and a laboratory would need to show that it could meet that level.) Or, should procedures do both?
   b. Depending on the answer to the first question, should any procedures be modified?
   c. Should the Technical Work Group continue to examine candidate statistical procedures for L_D and L_C that require the use of blank subtraction?
5. Blank Subtraction –
   a. Should the Technical Work Group continue to examine candidate statistical procedures for L_D and L_C that require the use of blank subtraction?
   b. Does the FACDQ want to consider a detection limit procedure that would require the complete revision of some or all 40 CFR 136 analytical methods?

<u>Pilot Study Purpose and Objectives</u>

Mr. Wheeler asked the committee to review the draft pilot study purpose and objectives in their packets and then briefly summarized the information within. (These are available for review at http://epa.gov/waterscience/methods/det/.)

Comment: The way the multi-lab study may be designed could influence the outcome. I wonder if we want to capture that in our objectives.

Response (Larry LaFleur): It is a good point. In some ways this is a classical inter-lab issue. It is something we have talked about in the multi-lab subgroup and could consider documenting further.

Comment: we don't necessarily need to control it, but, if we captured the essence, then you have the option to address that when evaluating the data. This is a concern for the states.

Question: I have a question on objectives #1 and #3. Considering that we are looking at creating several datasets that will evaluate several different procedures, how do you evaluate whether those procedures will meet those objectives?

Response (Richard Burrows): When I give the presentation on the single-lab, I will explain that one of the things we propose to do first is to look at existing data. We hope to get an idea of how these procedures will work through the evaluation of existing data. Our hope is that we will be able to further narrow what we actually need to look for in the pilot study.

A lengthy discussion ensued. Some committee members expressed concern about the existing distribution of laboratories that are able to achieve low detection and quantitation levels. Some members commented that "shopping around" occurs for labs that produce a desired number. There is a need to create a more level playing field across and within states that accurately reflects routine performance. Other members stressed the need to use existing data as much as possible to help narrow the number of procedures that need to be pilot tested. At the end of the discussion, Mr. Wheeler asked for and received unanimous committee agreement to make the following changes:

- Add a sentence at the end of the note on objective 3, stating: The intent is to gauge whether a lab is following and interpreting the procedure correctly, completed through written evaluations from the lab.
- Rewrite objective 4 to read: How did or will the experimental design influence the outcome of the study?
- Change objective 4j to read: Number and type of instruments per study or per laboratory.

Action: The committee approved, by consensus, the draft pilot study purpose and objectives with three amendments.

<u>Multi-lab Subgroup Progress Report</u>

Larry LaFleur explained the multi-lab study design concepts to the committee using a PowerPoint presentation. (See "Multi-lab Pilot Study Design Progress Report" on the EPA website.) He noted that members were being asked two questions (#3a and 3b, above).

Mr. Wheeler facilitated a committee discussion focused on the subgroup's first question. After hearing from each caucus, Mr. Wheeler summarized the committee responses to the multi-lab subgroup as split, with some supporting a multi-lab approach and others supporting a true inter-lab approach. In light of this, he suggested the subgroup develop a

design for both approaches. He also said that committee responses to the stepwise approach in question 3b indicated general support for the concept as long as the subgroup remained mindful of the Federal Advisory Committee Act and associated process.

Action: Committee members unanimously requested that the multi/inter-lab subgroup move forward with developing a pilot study design that incorporates a multi-lab study design and an inter-lab study design for the LCMRL procedure and present a draft design to the committee at the March 2006 meeting. The committee agreed to a stepwise pilot approach within the advisory process decision-making provisions. The term "multi-laboratory" will also be added to the glossary of terms.

Single-lab Subgroup Progress Report and the Issue of Blank Subtraction

Richard Burrows used a PowerPoint presentation to explain the concepts of the single-lab pilot study design. (See "Single-lab Pilot Study Design Progress Report" on the EPA website.)

The committee first discussed the issue of developing a prescriptive approach versus a descriptive one. Committee members were careful to distinguish between allowing for reagent correction in a procedure and allowing for blank subtraction in analytical methods. Many members felt that the concepts of the ISO/IUPAC procedure were implemented in other procedures. Furthermore, these other procedures (e.g. Consensus Group, ACIL) could accommodate for blank subtraction in the future.

On the other hand, the Water Research Centre (WRC) procedure mandates blank subtraction and many committee members agreed that that approach was not consistent with many of the EPA-approved analytical methods. Some committee members expressed concern that this approach could compromise a lot of historical data.

Mr. Wheeler asked for responses from each caucus to questions 4 and 5.

Public Utilities (Chris Hornback): We prefer a prescriptive approach. On question 4b, we are not prepared to address potential modifications to the procedures, but this should be an action item for the Technical Work Group to propose to the committee. The answer to 4c, 5a and 5b is no.

Environmental Laboratories (Richard Burrows): For question 4a, we think that detection procedures should be descriptive but that they should include options for a reduced level of effort if a prescriptive limit has been met. Some procedures should be modified based on that answer (4b). Both 4c and 5a say the same thing; we answer no for both 5a and 5b.

Industry (John Phillips): For question 4a, there is a benefit to have both prescriptive and descriptive approaches, and since we have not defined uses definitively, we probably need to do both. That makes 4b inapplicable. For 5a and 5b, we answer no.

States (Tim Fitzpatrick): We presume these are questions for moving forward with pilot testing. We are in favor of looking at all descriptive methods and, if they include prescriptive components, those need to be tested. For question 4b, we think they should not be modified for pilot testing. We acknowledge there are situations that require blank correction, but for questions 5a and 5b, we do not think blank subtraction should be considered.

Environmental Community (Richard Rediske): We think that for question 4a, it should be both prescriptive and descriptive. We want an idea of what these methods can do. For question 4b, yes, we agree there may need to be modifications depending on the answers to the pilot. For questions 5a and 5b, our answer is no. We do not think blank subtraction should be allowed.

EPA (Richard Reding): For question 4a, we think it should be both prescriptive and descriptive. We also want to emphasize that we are not generating new numbers during the pilot study for purposes of comparison to existing limits. For question 4b, we think the question is not so much about changing procedures as it is about possibly allowing for changes in concentrations. For questions 5a and 5b we answer no.

In the discussions that followed, many committee members expressed concern at moving forward with a pilot study design without having first defined measurement quality objectives.

Mr. Wheeler asked the caucuses to discuss this issue in caucus during the working lunch session, for committee discussion after lunch. With regard to procedures, he noted that EPA had recommended specific procedures to pilot test during yesterday's meeting. Mr. Wheeler asked for committee confirmation to focus on the specific procedures that would be carried forward in pilot testing.

Comment: In terms of combining the ACIL, Consensus Group and LTMDL procedures, we talked about using the same data to evaluate all three rather than simply choosing one over the other.

Comment (Public Utilities): I really would prefer not to see the Hubaux-Vos procedure go forward. It is extremely complicated to do. Additionally, I agree with EPA that the WRC procedure should be removed from pilot testing.

Response (Richard Reding): We also mentioned yesterday that the Office of Solid Waste quantitation procedure was pulled from pilot testing at this time because it is not a written procedure.

Question (Industry): We concur with dropping the WRC and OSW procedures from pilot testing. Are we looking at this from the perspective of piloting for single- and multi-lab for detection and quantitation?

Response (Richard Burrows): There does need to be a single-lab procedure pilot tested.

Comment (States): We also concur with removing the WRC and OSW procedures from pilot testing. We also have consensus that the Hubaux-Vos procedure is a bit onerous.

Comment (Environmental Community): We also concur with removing all three procedures – OSW, WRC, Hubaux-Vos – from pilot testing.

Comment (EPA): We concur with dropping the OSW and WRC procedures from pilot testing. We need to caucus on the Hubaux-Vos procedure.

Action: The committee recommended, by consensus, removing the Office of Solid Waste, ISO/IUPAC Quantitation Limit and Water Research Centre procedures from further consideration in pilot testing, and leaving for further consideration in pilot testing and the matrix:

- Detection
    - MDL
    - IDE
    - ACIL Critical Value
    - Hubaux & Vos
    - LT MDL
    - Consensus Group
    - Osborn Lab QC
- Quantitation
    - ML
    - IQE
    - LCMRL

Action: The committee agreed to the following responses to the Technical Work Group's questions related to a single-lab pilot study design:

- The committee agreed that the single-lab pilot study should include both descriptive and prescriptive approaches.
- The committee agreed that modification of procedures could be looked at, but that it should not be a high priority for the Technical Work Group. Most felt that changing procedures might happen after the pilot.

Framework for Interim Report

Ms. Shorett presented a framework for an interim report that, once drafted, could be used by caucus members to brief their respective constituencies on the committee's progress to date. The purpose of the interim report would be to serve as a record of where the caucuses were on each of the issues. She asked committee members to review the draft in caucus and prepare for a dialogue with Michael Shapiro immediately following the lunch break.

Committee Dialogue with Michael Shapiro
Ms. Shorett introduced Michael Shapiro, Deputy Assistant Administrator for the Office of Water at EPA, and welcomed him to the meeting. She explained that the purpose of the discussion was to hear reactions from caucuses to the framework for an interim report.

Environmental Community (Rob Moore)
Without going into specific details of what is listed in the framework, I think our underlying concern is to make sure that we maintain the bedrock principles of the Clean Water Act. All the decisions that are made – whether those decisions are regarding establishment of permit conditions or practical ramifications of enforcement, compliance assurance, or data collection or how that data is used – should be done within the existing Clean Water Act framework.

Those decisions are driven by the need to protect the resource so that water quality standards and water quality criteria are always driving everything. We want to avoid putting the cart before the horse within this committee. We recognize that there are certain legitimate issues with how lab methodologies influence collection of data, analysis of data, and how that data is applied within the regulatory framework. But we need to address that issue, not revise the Clean Water Act to fit the problem.

That is one of the main things that we want to get across. I think we are definitely moving in that direction. We had a very healthy discussion yesterday about various scenarios of some problematic parameters from a standpoint of lab technologies in relation to being able to set permit limits.

Comment (Michael Murray): A number of issues were raised this morning, particularly in context of pilot testing. We're all very interested in seeing that go forward but in a way that clearly defines objectives for the testing.

Question (Michael Shapiro): On one level, it is hard to disagree with the way you phrased your basic principle – in terms of not adjusting the policies underlying the Clean Water Act because of the measurement, but taking limitations of measurement into account as programs are implemented. But could you give me a more discrete example based on the discussions that you had over the last two days of, where you might be concerned or where your principle might lead directionally in terms of the quantitation limits?

Response (Rob Moore): Yes. During discussion yesterday, we talked about how to handle certain situations like the one Mike just described where the water quality criteria and, hence, the water quality based permit limits might actually be below the quantitation limit.

And there were a variety of opinions on that, some of which would have led to permit limits being driven by the lab procedures, which would be a complete paradigm shift on how the Clean Water Act is supposed to operate.

All the decisions in the Clean Water Act are supposed to be driven by water quality criteria that need to protect designated uses, and on top of that, they need to protect existing uses through the anti-degradation policy. We want to recognize that this situation does exist, and that we need to somehow resolve the fact we have scientific uncertainty in the information for certain parameters and under certain situations.

We think there are other ways to address that, either through alternative data collection or supplementary data collection, such as bringing whole effluent toxicity testing in and putting much more emphasis on that in those situations where water quality criteria may be below the ability of common lab methods to quantify a certain parameter.

Comment (Michael Shapiro): Just so I understand, what you are saying is that the water quality limit should be based on identifying what is protective of the particular body of water to which a discharge flows. If you cannot measure down to that level that should not necessarily change the limit. But it might, in practice affect how that limit is actually enforced in a practical sense.

Response (Rob Moore): Yes, I think that is absolutely the case. In fact, I think it was pointed out that, from a practical standpoint, regulatory agencies probably are not going to enforce in a situation where they do not have a good quantifiable, defensible figure, even if the permit limit is below the level of quantification. So, while it's certainly a concern and one that I think this committee agrees it would like to try to address, we don't want to see anything addressed by changing the basic functions of the Clean Water Act. We certainly understand why members of the regulatory community would like it addressed. The key is that we should not be reinterpreting the Clean Water Act to put more emphasis on the technology of lab methodologies and capabilities ahead of water quality.

States (Bob Avery)

It seems like our process is similar to that of a funnel. When we first started our meetings, we were circling around the very top of it in wide circles trying to identify the various issues that separated us. Now, we're coming down a little bit closer to the single spout of the funnel.

As we went through each of the stakeholders at the table and talked about what limits they would like to see in the permits, where compliance limits should be set – L_C, L_D, or L_Q – and how that data should be reported. We have minute differences. There may be obstacles that are going to be very difficult to overcome, but I think we can do that.

There are a lot of differences just among the four states represented here in how we report and what we want to see reported. There are differences among the stakeholders in the caucuses and what they would like to do or ideally what they would like to see.

Data quality objectives/measurement quality objectives are a big issue right now. I think we need to identify those before we can move completely forward. I'm hoping that we can get to some of those either today or before the next meeting.

> *Question (Michael Shapiro)*: I guess you mentioned that there is inconsistency across the states on some of these issues, especially how you operate when you have some of these challenging areas to deal with, such as the water quality base limit being below the level you can either detect or quantify.
>
> Knowing how these things work, I suspect that each state, in the absence of a requirement to do it one way, made the best judgment it did at the time and over time has followed a specific path.
>
> Do you see it desirable to maintain that variability or, conversely, desirable to move towards a more common interpretation?
>
> *Response (Bob Avery)*: I think many states would like to see more uniform movement. However, we're only four states representing fifty. I believe that the states are going to do what they individually decide, based on the federal guidelines. Where there is discretion, they will utilize that discretion because their mission is to protect the public health and the environment. So they may be more restrictive, or they may follow the federal guidelines. It all depends on what the federal guidelines are going to say.
>
> In the state of Michigan, part of the Great Lakes Initiative issues are that we identify quantification limits that are based on MLs that are promulgated within the methods. There are not a lot of methods that have MLs in them. So, we had to redefine what a quantitation limit was, and therein lies one of the problems that we have. That's why every state may have different roads or paths that they took. Once they headed down that path and started drafting rules, it's a very difficult process to pull back. But, once there's a uniform standard, then at least we have a goal to shoot for.
>
> *Comment (Tom Mugan)*: That's why we talked a little about this last time that we would hope that a result of this committee would be some rule making on the part of EPA that would tend to make our procedures more consistent.

<u>Industry (John Phillips)</u>
First, I would like to say that we definitely also feel that data quality objectives in light of uses need to be defined. The sooner the better because that impacts everything else we do, including the pilot studies, and other decisions we make. So, we feel that's real important to define.

In response to the framework that was provided earlier, we just want to make the comment that, when we're talking about detection and quantitation procedures for

piloting, we should really look at it for detection and quantification procedures for both single and multi-lab methods; it is essentially four different scenarios.

Also, we had agreed that we would drop L_D for single lab procedures. However, we want to emphasize that we need to continue to determine false negatives in the single lab procedure even though we have dropped L_D.

Environmental Laboratories (Richard Burrows)
In glancing at the framework, you see that the labs abstained on the issues of setting permit limits, and also compliance assurance and enforcement of those permits. That's not because we're not interested in those issues. It's really because we think that's not our place to determine how those should be set. It is our task to provide the means for regulated entities to comply with those limits once they have been set.

We are, however, very interested in the parts that do have an impact in the lab, particularly in how the detection and quantitation limits are going to be set and what kind of procedure we're going to go through. It is very important for us that the procedures that we develop are easily implemented as well as technically reliable. That is the reason we proposed that from a single lab perspective, we should not use L_D and instead have a detection/quantitation scheme that's based on L_C and L_Q.

We think this can greatly simplify implementation by making the procedures that we would use to determine detection and quantitation levels simpler and more straightforward. By making it easier for both the federal agencies and the states to fit into their current regulatory framework, we're saying that we will have a scheme that is consistent with the present use of the MDL and the ML, except that we will have better estimates of the MDL and the ML.

We are thinking about the pilot study on the single lab basis. We think that we can save money and do a better job starting off by doing a study of existing data that's already out there. In some cases there might even be enough existing data that with evaluation of that data we could drop some procedures out of the pilot study.

The states mentioned consistency. We, of course, remain very interested in consistency across EPA programs, not just in the Office of Water but, hopefully extending to the other EPA offices.

> *Question (Michael Shapiro)*: Was there agreement on the point of dropping Ld in the single-lab?
>
> *Response (Richard Burrows)*: Yes.

Public Utilities (David Kimbrough)
We know that public utilities certainly agree with everyone else that public health and environment are the drivers here. The problem, of course, is really that so many of the

procedures don't support all the activities. There are procedures that lack sufficient sensitivity, precision and accuracy to support all the different activities and all the components of the Clean Water Act. Fortunately, for most analytes, the methods are sufficiently sensitive.

Whatever process we come up with, we want to make sure it applies to all situations: both where the water quality criterion is very low; and for situations where it's higher than the laboratory's ability to quantify.

We have two big concerns. One is uniformity and equity. Every discharger, every permit holder that discharges into a given water body at a certain water quality objective reports to the same values, is held to the same standards so that there is uniform protection and uniform accountability by all providers. One of the key elements of this is verification. Right now, each state has its own procedures for doing this. Our concern is that the laboratories may or may not be able to actually do what's being proposed without ongoing verification, which I think is a big component that we're lacking right now.

The other component is that some of the methods are insufficiently sensitive, and there's a tendency to say "we should go to some lower level of reporting." The problem then is that we end up with lower quality data.

We think it's important that, if we're going to take and make an effort to protect the environment, commit public funds and private funds, we know what we're actually doing. If we don't have confidence in the data, we don't have a sense if the data's accurate – that it's even there, that it's not a false positive or even a false negative – then it's a bad decision to commit public funds and private funds to solve a problem that we're not actually sure is there.

EPA (Mary Smith)
We did spend some time internally before the meeting talking to all our internal stakeholder groups, which expanded over the last couple of months from other programs that might be interested in procedure issues to pretty much every Clean Water Act program. Because, when you're dealing with data, which, you are with detection/quantitation, you're dealing with every aspect of appropriate clean water. So, we have the monitoring people involved and permits and others.

We brought forward issues on behalf of EPA for the uses part of this based on existing EPA policy, which if this group came to a different kind of consensus, we'd be willing to take back and work with appropriate people at EPA.

There are some areas in which there is no consistent EPA policy such as how we report values. The regions, in fact, have a couple of different policies; the regions that actually issue permits on behalf of EPA for a couple of non-delegated states. So, clearly all of us have a charge on these usage issues to try to take some of the concepts and positions around the table back to our prospective constituencies and work them more between now and the next meeting.

EPA came in trying to narrow procedures, because that's going to be important in designing a pilot. Either you are going to get lots of procedures and a few procedures that we are going to test, or visa versa. I think we made some progress in narrowing procedures,, although probably not as much as we would like. On the other hand, we got some push back where people wanted to drop one of the drinking water procedures. We will take that back to the office and get back to you.

We also agreed to drop L_D, because we concluded that our MDL is really an L_C, not an L_D.

I think we had a good discussion on goals of the committee's final package of recommendations. It has been, again, a good meeting. The funnel analogy was a good one. The funnel narrows as we go down even more. Hopefully, we'll get down to the real narrow part and we will all be together. There is some more work to do, and these issues have been around for a while, so it's not surprising that we're struggling on some and clear on others.

> *Question (Michael Shapiro)*: How many pilots do you see emerging? Is that still a work in progress?
>
> *Response (Mary Smith)*: We have one pilot. We think there are a number of procedures that can be pilot tested, so you might take a couple of different procedures and create one data set that then you could feed into the calculations that occur in those procedures. The downside to that is that one of the things we want to test is how well labs can understand the procedures. If you use data sets for multiple procedures, you don't get at that. We are sending that back to the Technical Work Group to think through a little bit more about how we do that because whether the labs can, in fact, understand them is a really important criterion.

Discussion of Draft Framework for Interim Report
Committee members discussed the draft framework for the interim report. After lengthy discussion and several suggested revisions, the committee agreed to the following framework:

<u>Purpose</u>
The purpose of this document is to record tentative agreements from the first three FACDQ meetings. The charter purpose statement says the "major objectives of the FACDQ will be to provide advice and recommendations on approaches for the development of detection and quantitation procedures and uses of these procedures in CWA programs."

The intent of this document is for the education and engagement of constituents by caucus members. Members will bring this input from constituencies to the March 2006 FACDQ meeting for decision-making.

Package of Agreements and Recommendations

- Uses of Detection and Quantitation Procedures
  - Setting NPDES permit limits
    - Four caucuses (states, environmental community, EPA and utilities) agreed that the WQBEL is the limit that should be used. This is based on the requirements of the Clean Water Act.
    - The public utilities had a number of assumptions.
    - The industry caucus felt the NPDES permit limit should be set at L_Q and they had a number of assumptions.
    - The laboratories abstained from stating a position on this issue.
    - The group agreed to further consider the relationship between this issue and pretreatment.
  - Compliance assurance and enforcement in NPDES permits
    - When the water quality criterion is less than L_Q, there are a number of ways in which entities approach this across the US.
    - Three caucuses stated that compliance enforcement limit should be L_Q.
    - The states had specific options for compliance limits less than L_C.
    - The environmental community had specific options for a compliance limit less than L_Q.
    - The laboratories abstained from stating a position on this issue.
  - Regulatory Reporting data in NPDES permits
    - All six caucuses stated that the actual value would be reported above L_Q with no qualifiers. Utilities said this is true so long as the procedure meets specified measurement quality objectives.
    - Half of the caucuses thought that values reported less than L_Q should include the actual value with a qualifier. The other half of the caucuses thought that "less than L_Q" should be reported.
    - For reporting data less than L_C, two caucuses thought it should be reported as "less than L_Q," one thought it should be reported as "less than L_C," and three thought it should be reported as a "non-detect."
    - The state caucus said the L_C and L_Q should be reported with a value (meta-data).
- Detection and Quantitation Procedures: for purposes of filling in the matrix and pilot testing, the FACDQ narrowed a list of detection procedures from 13 to 7 and a list of quantitation procedures from 7 to 4.
  - The detection procedures to be piloted are the MDL, IDE, Hubaux & Vos (for inter-laboratory). The same data will be used to test ACIL, Consensus Group and LTMDL.
  - For purposes of the matrix and pilot testing, the WRC procedure will not be carried forward.
  - The quantitation procedures to be piloted include ML (3.18 x MDL), IQE, ACIL and the LCMRL.

  - Five detection and two quantitation procedures will be tested for single lab. Two detection and two quantitation procedures will be tested for multi-lab.
  - For purposes of the matrix and pilot testing, the ISO/IUPAC procedure will not be carried forward.
  - The EPA OSW procedure is being dropped from consideration at this point.
  - The Technical Work Group will continue to look at existing data for purposes of pilot testing.
- Interpretation of MDL/ML: there is ambiguity around MDL/ML and the intent of these procedures. Members of the FACDQ agree that for our purposes, the MDL is functionally equivalent to L_C and we will use the most recent EPA calculation of the ML as 3.18 times the MDL.
- Method Development: the FACDQ is exploring ways to provide incentives for the development of more sensitive analytical methods.
  - The committee agrees to a need for periodic review and incentives for developing more sensitive methods for those analytes where the L_Q is greater than the WQBEL.
  - EPA agreed to develop a list of analytical methods for which the quantitation limit is greater than the national criteria.
- Definitions for L_C, L_D and L_Q: the FACDQ narrowed lay and statistical definitions for L_C from 5 to 2 and from 4 to 2, respectively; lay and statistical definitions for L_D from 6 to 3 and from 3 to 2, respectively; and definitions for L_Q from 4 to 1. EPA is also withdrawing the footnote for the second L_C definition.
- Pilot Projects: the FACDQ agreed on the following purpose and objectives: Members agreed to the characteristics and metrics for evaluating the procedures in the matrix, as amended.
  - Members agreed to conduct a pilot test for single/inter/multiple laboratory procedures. The inter/multiple lab study would include replicates.
  - Members agreed to pilot test prescriptive/descriptive/both procedures.
  - Members agreed that L_D would not be determined in the pilot of single-lab procedures, with some qualifiers, however false negative rate would still be identified at L_Q.
- Goals for Final Package: the FACDQ agreed to goals for use in evaluating a final package of recommendations to EPA.
- No Blank Subtraction: unless specified in the method.
- Implementation: the FACDQ agrees that the recommended detection and quantitation procedure(s) from the committee should be codified in rulemaking.
  - The FACDQ wants consistency in use and application of recommended detection and quantitation approaches.
  - The FACDQ agrees that education is a necessary component of implementing recommended detection and quantitation approaches.

Action: Committee members approved, with amendments and by consensus, a framework for an interim report. The Policy Work Group was tasked with drafting the report that will be made available in time for committee members to check with their constituencies before the March 2006 committee meeting.

Technical Work Group Assignments
Mr. Wheeler reviewed the following assignments from the committee to the Technical Work Group:

- Further develop the pilot study design for multi and inter-lab procedures
- For single-lab procedures, analyze existing data
- Make further recommendations for removing procedures from consideration in the pilot test. Inquire if sponsors want to modify their procedures (e.g. ACIL)
- Update the Glossary of Terms, adding definitions for Multi-Lab and Inter-Lab

Policy Work Group Assignments
Ms. Shorett reviewed the following assignments from the committee to the Policy Work Group:

- Make recommendations related to MQO/DQO values and their inter-relationships with uses
- Continue development of/framing policy issues for the rest of issues on the uses list and in the decision trees
- Further develop the draft framework/interim report for the purposes of caucus "check-in"
- Further develop the Prescriptive v. Descriptive Procedures (background document from the Technical Work Group)

Public Comment
No public comments were made during Day 2.

Wrap-up and Next Steps
Ms. Shorett thanked committee members for their hard work and effort in preparation for and during this meeting. She said that the next committee meeting was scheduled for Wednesday and Thursday, March 29-30, 2006 at the FDIC Seidman Center.

Richard Reding adjourned the meeting at 3:50 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 Natural Resources
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	
Ephraim King	US Environmental Protection Agency
Michael Shapiro	

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

Observers	
Brian D'Amico	US Environmental Protection Agency
Deborah Dalton	

Meghan Hessenauer	
Marion Kelly	
Nicole Shao	
Danielle Tillman	
Steve Wendelken	
Jim Laity	Office of Management and Budget
Jim Christman	Hunton & Williams
Colin Finan	Inside EPA
Ken Miller	CSC

DISTRIBUTED MATERIALS

Committee's Packet of Materials

Agenda (December 8-9, 2005)
Draft Meeting #2 Summary (September 29-30, 2005)
Clean Water Act Program Uses Continuum
NPDES Permit Applications and Reasonable Potential Considerations: Decision Trees for Data Reporting, Evaluating Data to Determine RPTE, Setting Limits, and Permit Compliance/Enforcement
Policy Issues Identified by Policy Work Group Members
Revised Draft Statements of Current Uses of Detection and Quantitation, Data Quality Objectives and Policy Issues
Technical Support Document for Water Quality-Based Toxics Control
Draft Evaluation Criteria for a Final Package of Detection and Quantitation Recommendations
Interpretations of Detection and Quantitation Procedures Evaluation Characteristics
Blank Subtraction Issue
Summary of Technical Work Group Questions to the FACDQ
Draft Pilot Study Purpose and Objectives
Multi-lab Pilot Study Design Progress Report
Single-lab Pilot Study Design Progress Report
Background Document from Technical Work Group
Revised Glossary of Terms

Distributed at Meeting

Draft Goals for a Final Package of Detection and Quantitation Recommendations (December 9, 2005)