

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

FDIC Seidman Center, Rooms 203 & 205
3501 Fairfax Drive, Arlington, VA
Wednesday – Thursday, March 29-30, 2006

Final Summary of Meeting #4

Decisions at Meeting #4

The committee made the following decisions:

Meeting #3 Summary

- Approved by consensus the final summary of meeting #3 with amendments.
Vote: 20 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

What We Need Procedures to Do

- Approved, by consensus, the following list of priority characteristics (not in priority order) for evaluating procedures* :
 1. Is bias explicitly derived by the procedure?
 2. Is precision explicitly derived by the procedure?
 3. Does the procedure provide for selection of a Type I error tolerance limit (false positive)?
 4. Does the procedure provide for selection of a Type II error tolerance limit (false negative)?
 5. Does the procedure require that qualitative identification take place at the determined detection and quantitation limit?
 6. Does the procedure adequately represent variability in lab performance?
 7. Does the procedure describe how to modify a detection or quantitation limit for applicability to real world samples?
 8. Does the procedure evaluate the entire test method, including sample preparation and clean-up steps?
 9. Does the procedure explicitly adjust or account for situations where method blanks always return a non-zero result/response (e.g., defects in calibration or consistent or chronic blank contamination of laboratory blanks)?
 10. Does the procedure explicitly adjust or account for situations where method blanks are intermittently contaminated?
 11. Is the procedure clearly written with enough detail so most users can understand and implement it?

* For a more thorough understanding of these characteristics, please refer to the following documents: “What Does the FACDQ Need a Procedure to Do?” (document #4 from the March 29-30, 2006 advisory committee meeting) and “Interpretation of Detection and Quantitation Procedure Evaluation Characteristics,” from the December 8-9, 2005 FACDQ meeting.

12. Is the procedure cost-effective?
13. Is the procedure applicable to all users and test methods?
14. Does the procedure consider the differences between multi- and inter-lab approaches?

With respect to these characteristics, the committee also agreed to the following stipulations:

1. The characteristics depend on the uses the committee agrees to.
2. It is important to understand the specifics of the characteristics.
3. The characteristics for the procedures need on-going verification.

Vote: 20 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

- Tasked a subgroup consisting of Richard Burrows, Tim Fitzpatrick, Michael Murray, John Phillips and Jim Pletl with incorporating comments from the five caucus groups into the narrative of what the committee needs procedures to do. The revised narrative will be presented to the committee in July.

Vote: 20 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

Uses of Detection and Quantitation

- Tasked a subgroup consisting of Chris Hornback, Larry LaFleur, Tom Mugan, Michael Murray and Mary Smith to develop a straw proposal on the uses of detection and quantitation approaches in Clean Water Act programs, including permit limits, compliance enforcement, data reporting, and data reporting for reasonable potential determinations. In particular, the group will develop options to address the “delta” between L_C and L_Q and other uses taking into consideration the committee’s discussion of these topics.

Vote: 20 Agree, 0 Not Opposed, 0 Opposed; 1 Absent

Measurement Quality Objectives

- Agreed, for purposes of pilot testing, and by consensus, to set the false positive rate equal to or less than 1%.

Vote: 18 Agree, 1 Not Opposed, 0 Opposed, 2 Absent

- Agreed, by consensus, that if or when data is reported below L_Q , then the data points that fall between L_C and L_Q would be reported, for example, as detected but not quantified (e.g., DNQ).

Vote: 19 Agree, 0 Not Opposed, 0 Opposed, 2 Absent

- Agreed, by consensus, that determination of L_D is not a requirement for purposes of pilot testing, so long as data between L_C and L_Q is reported, for example, as detected but not quantified.

Vote: 19 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

- Agreed, by consensus, to set, for purposes of pilot testing, the false negative rate equal to or less than 1% measured at L_C for the true value at L_Q or L_D .

Straw vote: 12 Agree, 8 Not Opposed, 0 Opposed, 1 Absent

- Agreed, by consensus, that the goal for the pilot test of 20% relative standard deviation (RSD) is based on the mean recovery, understanding that there will be instances where this % RSD may show conflicts with accuracy (that is, set precision targets may inherently define accuracy targets). This may not be applied universally after the pilot study is complete. The study design team will consider higher precision targets (higher % RSD) if the goal cannot be met.

Vote: 18 Agree, 1 Not Opposed, 0 Opposed, 2 Absent

- Agreed, by consensus, that, for the pilot, the study design team will ask participating laboratories to use accuracy based on mean accuracy and that the Technical Work Group study design team should make decisions on specific goals for accuracy based on an evaluation of existing data. The study design team will ensure that the batch-by-batch data is available for the FACDQ to have analyzed.

Vote: 16 Agree, 3 Not Opposed, 0 Opposed, 2 Absent

Pilot Study Design

- Agreed, by consensus, to task the Technical Work Group and a “Study Design Team” consisting of one person from each caucus on the Technical Work Group with scoping the details of the pilot study.

Vote: 19 Agree, 1 Not Opposed, 0 Opposed, 1 Absent

- Agreed, by consensus, to proceed with pilot testing the following five analytical methods:

- 200.7 (metals),
- 300.0 (ions),
- 625 (SOCs),
- 608 (PCBs, pesticides)
- 335.3 (cyanide)

Vote: 18 Agree, 1 Not Opposed, 0 Opposed, 2 Absent

DAY 1 – Wednesday, March 29, 2006, 9:00 AM – 5:30 PM

Opening and Introductions

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 December 8-9, 2005 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. Mr. Reding noted that the meeting would conclude at 5:30 pm on Day 1.

Welcome from EPA

Mary Smith, Director of the Engineering and Analytical Support Division at EPA, welcomed committee members to their fourth meeting. She acknowledged the tremendous amount of work that had gone into moving the process forward and preparing for this meeting.

She said that since the December meeting, she had thought a lot about where the committee was with respect to the timeline, its charter, and what was to be done with the committee's recommendations after the charter expired. She presented a timeline showing key remaining steps in the advisory committee's process and a subsequent schedule for concluding rulemaking by 2009 (Figure 1).

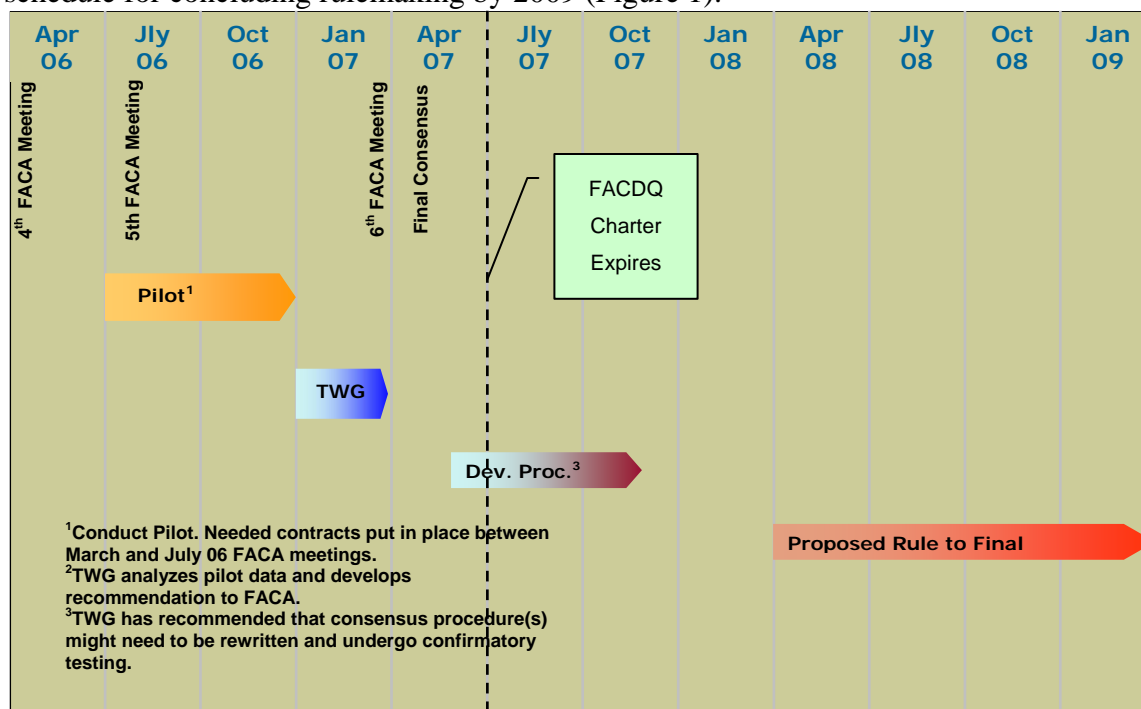


Figure 1

*Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs
 Final Meeting Summary March 29-30, 2006*

This timeline showed the necessity of completing a pilot study in six months.

She said that the committee would officially kick-off the pilot study at its July 13-14 meeting. Upon completion of the pilot study, the committee would come back together to review the outcomes and to formulate final recommendations. A final meeting would be needed to synthesize all the information and complete the recommendations to EPA before the committee's charter expires in May 2007.

Ms. Smith said that EPA would develop final procedures. Rulemaking -- from proposal to a final rule -- would take about a year if there was consensus around the issues. Without consensus, she said, rulemaking would take longer.

Discussion and Approval of Meeting #3 Summary

After briefly reviewing the agenda for the two-day meeting and the committee's rules for decision-making, Ms. Shorett asked for comments on the draft summary of the December 8-9, 2005 meeting.

Committee members had several clarifying comments and edits to the draft summary. After considerable discussion, the final summary was approved as amended.

Action: The committee approved by consensus the final summary of meeting #3 with amendments.

Vote: 20 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

Caucus Reports of Outreach

Ms. Shorett called on representatives from each caucus group to report on their outreach since the last meeting.

States

Dave Akers reported on outreach to states which did not respond to the state caucus' initial survey. Since December, he said, the caucus set up a "Google group" -- an e-bulletin board where representatives from other states could share information and respond to questions posed by the caucus.

From the Google group, the state caucus had some additional findings mainly related to setting permit limits and reporting for compliance purposes. All eight states that responded to a question about where they set permit limits (at the WQBEL, L_Q, or L_C) said they set limits at the WQBEL. Most responding states said they require reporting at the ML (PQL). Other states indicated they may require reporting at a level less than the ML (PQL), perhaps at the MDL.

Bob Avery said that, based on discussion that occurred at the Technical Work Group, the caucus asked a pointed question regarding the prescriptive vs. descriptive issue:

- Would your state program like compliance and enforcement limits (L_Q – quantitation limit) promulgated by EPA? This would be a prescriptive approach similar to the Safe Drinking Water Act.
 - “Absolutely no!” were the two responses received.

He said the state caucus had discussed this issue and generally agreed with the two responses because the caucus was concerned that EPA did not have the resources to maintain and update those limits.

The caucus also asked, “If the compliance and enforcement limits (L_Q) were promulgated by EPA, do you need the non-detect [values] reported to the L_C (MDL), the proposed promulgated L_Q , or zero?” The two states that responded said that they reported down to L_C (MDL).

Mr. Avery suggested that it could be helpful to develop a uniform set of questions for all caucuses to ask their constituents so the responses could be readily correlated across caucuses.

Environmental Laboratories

Richard Burrows presented his report using PowerPoint slides. (See the “Caucus outreach presentation - Env Labs RB SB” presentation at EPA’s website [http://epa.gov/waterscience/methods/det/.](http://epa.gov/waterscience/methods/det/))

In talking with the labs, Mr. Burrows said, the most consistent feedback the caucus had received was that procedures needed to be as simple as possible. They should be useful for a variety of detection and quantitation uses as well as being widely adopted.

In line with its goal of simplicity, the environmental laboratory caucus was proposing to eliminate use of the terms L_C , L_D and L_Q and to replace them with two common terms: MDL (minimum detection limit) and MRL (minimum reporting limit). These terms would be defined much as they are now defined, but a better procedure would be implemented for estimating the values of these terms. He said that the committee had tweaked the existing ISO/IUPAC definitions of L_C , L_D and L_Q to make the detection and quantitation procedures work with the EPA analytical methods being used.

Mr. Burrows said that at the last meeting, the caucus had been very much in favor of eliminating the use of L_D , and the caucus was now even more in favor. He said that if L_D were going to be determined, it had to be done parametrically – that is, by experiment.

He said that an L_D value could be statistically predicted, but it would be predicated on so many assumptions that it was not likely to be that useful. For multi-analyte tests, L_D was unique to each analyte and would have to be tested for every analyte at the calculated concentration, which was completely impractical.

He said that the existing definitions for L_C and L_Q could be used for the MDL and MRL, but the definitions might need additional alterations to allow for consistency with EPA

purposes (e.g., censored and uncensored methods). He noted that the MDL is a detection decision point. If you get a result above the MDL, that is when there is a real result. The MRL is the minimum quantifiable true value.

If L_D were eliminated, he said, then some procedures would need to be redrafted, including the ACIL procedure. This procedure and others, noted Mr. Burrows, could readily be modified to coincide with the committee's final recommendations. He said that the ACIL procedure had been redrafted to use only the MDL (L_C) and MRL (L_Q). This approach would allow EPA to establish a program that would meet its needs without conflicting with international standards.

He said that the ACIL procedure had been redrafted with certain measurement quality objectives in mind. The false positive rate of the MDL should be 1% or less. For the MRL, precision should be better than 20% relative standard deviation, accuracy better than 50-150%, a false negative rate less than 1% (to act as L_D as a L_D floor for the quantitation limit), and it should be at least three times the MDL.

Environmental Community

Barry Sulkin said that the caucus had not received a lot of feedback since the last meeting. To stimulate some outreach, in May, three of the caucus members will participate in a seminar at the seventh annual conference involving water-related environmental groups from across the country; it usually draws about 500 people. This will let them explain the issues the committee is dealing with and to solicit input and feedback.

Richard Rediske added that he had been working with an ad-hoc committee in the Great Lakes community to develop strategies for monitoring the Great Lakes, primarily for persistent bioaccumulative toxic materials. The ad-hoc committee will be meeting at an international conference in May to discuss monitoring.

In casual conversations with scientists from the area, Mr. Rediske said there was overwhelming agreement that science and policy should be driving detection limits. Many believed that, from a policy standpoint, the committee should focus on coming up with methods and ways to determine detection limits that are protective of the environment. He said that there was a concern that the tendency too often was to try to modify methods that could be widely implemented across the United States, rather than using the best technology in all cases.

Mr. Rediske said that there are special cases in the country where it may be necessary to have something specific to a region and that the Great Lakes were a good example. He said that once the committee had gone through this process, it might find that some of the commonly used methods did not provide the necessary detection limits and that EPA and the environmental community should search for methods that provide the necessary scientific rigor and protect the environment.

He said that this committee still needed to focus on better methods and to make sure that the final recommendations were driven by science and policy and not by widely available or outmoded technology.

Public Utilities

David Kimbrough reported for the caucus. After the last meeting, he said the caucus discussed measurement quality objectives. There was a lot of concern about the Synthetic Organic Chemicals (SOC's), particularly those analytes analyzed by method 625 because the way the method reads results in poor recoveries, even in the mid-range of the calibration curve. Since Mr. Kimbrough does not do that procedure in his laboratory, he wanted to get an idea of how up to date that data was. He sent an email to the Lab Accreditation Workgroup in California (about 200-300 people) asking people who do method 625 to respond regarding how up-to-date that data is. He learned that it is out of date, but it is generally a lot more accurate than he had previously thought. With the exception of Benzidine, for most analytes, the labs can get +/- 30-40% recovery, even down to relatively low concentrations. A number of labs had responded that +/- 40-50% recovery would cover most, but not all, analytes found in 625 and similar methods.

Industry

John Phillips reported for the caucus, saying that his caucus had conducted a number of conference calls, disseminated information and directed people to the website. There had also been a fair amount of email traffic. The caucus had received good input from constituents. Everyone believed that the issues now on the table, which the committee would discuss today, were the critical ones.

EPA

Mary Smith reported that her outreach had consisted of briefing senior managers from her office and the Office of Wastewater, meeting with the EPA internal workgroup, and a conference call with many regional branch chiefs who administer permits to discuss current practice for writing a permit or to report on permit practices by the state in their region. The consensus was that the WQBELs were the current permit limit, because that is required by the Clean Water Act. The enforcement limit for all the regions is at L_Q. Some of the regions do create their own ML to fill the vacuum when an ML does not exist in the Part 136 method. Most regions said they used zero to calculate monthly averages for values less than the ML. One region said that if the permittee is permitted to use a non-zero value and it is certified that way, they would use that value.

Reporting was more mixed. The regions talked about their policies and state policies. Some regions or states report zero when it is under the ML; others have their own policies and guidance on what to report when the value is less than the ML.

With regard to reasonable potential, they all referred to language in the *Technical Support Document* (EPA, 1991) that identifies things other than data one can use in a reasonable potential determination. Region 9 said California would use all data down to the MDL, but if data were below the MDL, then they used the MDL in the calculation. There were regions that use zero when the value is below the ML. Region 3 said West Virginia uses

twice the MDL if the value is less than the ML. Most regions said national consistency would be of value, but Region 5 said it would not want anything inconsistent with the Great Lakes Initiative (GLI).

The interagency group's discussion had focused on what really bothered people. Some offices were not ready to speak on behalf of their entire office. The message from meetings with senior managers from other Divisions in the Office of Water was that they are really engaged in the committee's efforts. On uses, Ms. Smith said what she brought to the table today was a lot of information of value, but she could not say that on most of the uses she could present an EPA position or, even, an Office of Water position.

These are extremely complicated issues, she said, with ten regional offices and a lot of history, but she committed to having a better perspective on the issues within the Office of Water by the July meeting. She said that at this committee meeting, she might vote that she could live with or not oppose an item, which meant she needed to go back to the agency and shop it around. She did think she came to the table with a sense of where the agency could go with respect to measurement quality objectives and what the committee needs a procedure to do.

Presentation and Discussion: Priority Characteristics and What does the FACDQ need procedures to do?

Alice Shorett introduced these topics and identified the documents relevant to the discussion. (See documents, "Priority characteristics of detection and quantitation procedures" and "What do we need a procedure to do?" on the EPA website.) She briefly explained how the list of priority characteristics had been developed, noted that the narrative document was not a consensus document, and said that Jim Pletl would explain the information in the narrative document.

Ms. Shorett said there was a need to have a good discussion today and to come to agreement on the list of characteristics that the committee believes a procedure needs to meet. She said the committee would look at the narrative and provide direction to either the Technical or Policy Work Group to make further refinements.

Jim Pletl described the basic concepts of a traditional data quality objective process. The first step was to describe the data quality objectives and then to set goals for what was to be achieved. He said that following a Policy Work Group discussion of measurement quality objectives for the pilot test, a few from the group had gotten together to talk about what was *needed* from a procedure.

Mr. Pletl said the point of the exercise today was for the committee to focus on what it absolutely needs from procedures. Once that was done, the committee would think about how the characteristics would be measured or evaluated so that the committee would know how to move forward when it receives the pilot study data. Mr. Pletl said the narrative document was prepared to think through how the pilot study would be evaluated, not necessarily potential final committee recommendations.

Mr. Pletl added that during the last subgroup conference call prior to the committee meeting, participants acknowledged the reality of how the pilot test could affect final recommendations.

After discussion, the committee generally agreed that the list of characteristics should be built with the final recommendations in mind and that those characteristics should drive the pilot study to test whether procedures met those characteristics. Committee members also generally agreed that the pilot test was an opportunity to inform the committee's final recommendation and that some of the characteristics might be refined as a result of the pilot study data.

In approving the list of priority characteristics for evaluating procedures, committee members agreed that the final characteristics would depend on the uses the committee agreed to, that it was important to understand the specifics of the characteristics, and that characteristics for the procedures needed on-going verification. Members agreed to add one characteristic to the proposed list – a consideration of multi-lab vs. inter-lab procedures.

Therefore, the committee agreed to the following list of characteristics.

1. Is bias explicitly derived by the procedure?
2. Is precision explicitly derived by the procedure?
3. Does the procedure provide for selection of a Type I error tolerance limit (false positive)?
4. Does the procedure provide for selection of a Type II error tolerance limit (false negative)?
5. Does the procedure require that qualitative identification take place at the determined detection and quantitation limit?
6. Does the procedure adequately represent variability in lab performance?
7. Does the procedure describe how to modify a detection or quantitation limit for applicability to real world samples?
8. Does the procedure evaluate the entire test method, including sample preparation and clean-up steps?
9. Does the procedure explicitly adjust or account for situations where method blanks always return a non-zero result/response (e.g., defects in calibration or consistent or chronic blank contamination of laboratory blanks)?
10. Does the procedure explicitly adjust or account for situations where method blanks are intermittently contaminated?
11. Is the procedure clearly written with enough detail so most users can understand and implement it?
12. Is the procedure cost-effective?
13. Is the procedure applicable to all users and test methods?
14. Does the procedure consider the differences between multi- and inter-lab approaches?

Action: The committee approved, by consensus, the above list of priority characteristics (not in priority order) for evaluating procedures.

With respect to these characteristics, the committee also agreed to the following stipulations:

1. The characteristics depend on the uses the committee agrees to.
2. It is important to understand the specifics of the characteristics.
3. The characteristics for the procedures need on-going verification.

Vote: 20 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

Ms. Shorett then asked committee members for comments on the draft narrative. Each caucus presented comments for consideration. Ms. Shorett asked each caucus to provide its marked-up version of the narrative document to the facilitation team. She said the facilitation team would integrate those comments into one document that showed changes. The committee further agreed that a representative from each caucus would work together to reconcile those comments for presentation to the committee at its meeting in July.

Action: The committee tasked a subgroup consisting of Richard Burrows, Tim Fitzpatrick, Michael Murray, John Phillips and Jim Pletl with incorporating comments from the five caucus groups into the narrative of what the committee needs procedures to do. The revised narrative is to be presented to the committee in July.

Vote: 20 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

Overview of Uses of Detection and Quantitation

Ms. Shorett presented the results of a straw poll from the committee's December meeting on the following uses: permit limits, compliance and enforcement, and regulatory reporting. She asked the committee to break into inter-caucus groups over lunch and to develop suggestions/responses in three areas:

1. Review the summary of the "straw poll" from the December 2005 FACDQ meeting and find the commonalities.
2. For each use, identify ways to "close the gap" to reach consensus.
3. For compliance/enforcement reporting, how do you deal with decisions on daily maximum limit and decisions on average limits?

After lunch, Ms. Shorett introduced a panel of committee members who had developed the framework document in the committee's packet: Larry LaFleur, Tom Mugan and Mary Smith. (See the "Clean Water Act Uses Framework" document on the EPA website.) David Kimbrough presented information regarding a prescriptive approach while Richard Reding presented information regarding a descriptive approach. (See the "Prescriptive and Descriptive Approaches Comparison Chart" document on the EPA website.)

Reports from Inter-caucus Group Discussions

Alice Shorett asked for reports from the four small groups that had met over lunch to address three issues.

Permit Limits

The four groups reported the following discussion regarding permit limits.

Group 1

- When values are at or below L_Q , it is difficult to demonstrate compliance.
- Methods are not sensitive enough for really low numbers. The real core of the issue is having the necessary analytical methods to be able to reach those kinds of permit limits. One of the ways to address this is to insert specific language in permits when the WQBEL is less than L_Q .
- Limits need to protect human health and aquatic life, from the state's perspective. How data below L_Q is reported is the make or break point.
- There is concern about using flags because they can get lost in the shuffle.
- Our group had concerns about the current reporting system (Permit Compliance System, PCS).
- There were concerns about whether limits were instantaneous or maximums.
- Our group talked about the magnitude of difference between L_C and L_Q and suggested that it might be helpful to better characterize those points and to understand how close together they really are.

Group 2

- Users need to know what needs to be complied with. It becomes an issue of due process.
- Public perception issues were raised in terms of non-compliance or perceived non-compliance.
- Movement on this one may depend upon resolution of some of the other issues.

Group 3

- One caucus is focused on promoting a package deal.
- Most of our discussions were exactly the same as previously stated.
- Our group also talked about perception issues.

Group 4

- Our group had some of the same conversations as already noted.
- EPA should review the limits used in permits.
- One caucus offered suggestions on ways to move forward, but our group did not make any headway.

Compliance/Enforcement

The four groups reported the following discussions regarding compliance and enforcement.

Group 1

- There seems to be some confusion about what a compliance/enforcement level is as opposed to a permit limit. Are there two different examples for the same parameter of each of these? Are these actual limits or are we talking about how data is censored? The group talked about the difference between a limit and a level (as indicated in the 1991 guidance) and the regulatory impact of those two terms.
- Some of the things the group discussed could be beneficial in a guidance document but may not actually be in a procedure. From the standpoint of laboratories, a defensible procedure is needed.

Group 2

- Somewhere between 30-40% of states regulate at the detection limit. Above L_Q , regulation occurs at the value in the permit. Below L_Q , there is a lack of confidence in the value. Between L_C and L_Q , and when the WQBEL is less than L_Q , there is a delta that could trigger additional actions. Perhaps a stepwise approach would make sense, such as no enforcement by the agency but a requirement for additional monitoring. If more data were collected and no improvement was seen, enforcement might then be an option. There could also be incentives to push for better, more sensitive analytical methods. (Wisconsin has an approach similar to this. Tom Mugan could supply a document, if the committee wishes.)

Group 3

- The group agreed that L_Q was the right place to be for compliance/enforcement. The states have the ability to be more restrictive no matter what EPA issues as guidance. There are some states that currently regulate down to L_C and have said that is how they want to do it.

Group 4

- The group emphasized the need to know where states are coming from and a hope that momentum will develop for consistency.
- With respect to compliance and enforcement, the group discussed the opportunity to focus on chemicals of emerging concern and to set up a system that effectively addresses those types of parameters. The focus of the conversation was the delta between L_C and L_Q , what gets reported, and how that data is used. Some committee members urged development of more sensitive analytical methods, instead of focusing too much on any one number.

Regulatory Reporting

The four groups reported the following discussions regarding regulatory reporting.

Group 1

- How do you carry a regulatory flag through a process? The idea of addressing the uncertainty of data is a good one.

- The gap between L_C and L_Q is very small. There is no question about reporting data below L_C and no question above L_Q , so the focus is on a very small gap.

Group 2

- The idea of creating incentives for more sensitive analytical methods to move L_C and L_Q is a significant one that has implications for reporting, too.

Group 3

- A new EPA reporting database is currently being developed. The bottom line is that there is reporting of the analysis, but there are also other uses for that data other than Discharge Monitoring Reports (DMR) and National Pollutant Discharge Elimination System (NPDES) permits. Maybe there is a way to report that data on the DMR and then in another format for the states if they need to use it for other programs.

Group 4

- Flags have been handled for years. Starting with toxicity in the 1980s, a permit was violated not when fish were killed or habitat destroyed but when the permittee did not conduct additional analysis.

Mary Smith said that it was clear everyone in her lunch group had engaged with their constituents. Although her group did not reach any agreements that they could forward to the whole committee today, a lot of good ideas came out of all of the discussions.

She suggested that a small drafting subgroup be formed to review the information and to work on a straw proposal for committee members to shop around with their constituencies and bring back to the committee at the July meeting. Committee members agreed and encouraged the small group to identify a few attractive options for committee members to shop around to individual constituencies.

Action: The committee tasked a subgroup consisting of Chris Hornback, Larry LaFleur, Tom Muga, Michael Murray and Mary Smith to develop a straw proposal on the uses of detection and quantitation approaches in Clean Water Act programs, including permit limits, compliance enforcement, data reporting, and data reporting for reasonable potential determinations. In particular, the group will develop options to address the “delta” between L_C and L_Q and other uses taking into consideration the committee’s discussion of these topics.

Vote: 20 Agree, 0 Not Opposed, 0 Opposed, 1 Absent

Public Comment

No public comments were offered during Day 1.

Measurement Quality Objectives

Bob Wheeler introduced the topic of measurement quality objectives and reviewed a worksheet with questions for use in caucus work over the evening and for discussion during Day 2. He asked committee members to refer to the documents in their packets

that relate to the discussion of MQOs. (See the following documents at the EPA website: “Technical Work Group Discussion Summary,” “Framework for FACDQ Discussion on MQOs,” and “MQO Straw Proposal.”)

Richard Burrows said it was important for the committee to come to a consensus on the measurement quality objectives to move forward with the pilot. If the committee could not reach consensus on the measurement quality objectives, Mr. Burrows said it could mean that the pilot study could not be finished before the committee charter expired.

Ken Miller, EPA consultant, briefly presented background information on measurement quality objectives. (See PowerPoint presentation “methodperf_pres_withnotes” on the EPA website.)

Summary and Closing

Richard Reding, DFO, adjourned the meeting at 5:30 p.m.

DAY 2 – Thursday, March 30, 2006, 8:00 AM – 4:00 PM

Richard Reding, EPA Designated Federal Officer, opened the meeting at 8:00 a.m., welcomed participants to the second day, and turned the meeting over to Alice Shorett, facilitator.

Ms. Shorett thanked everyone for the tremendous amount of work completed the prior evening. She noted that members discussed measurement quality objectives and uses in caucus groups. Technical Work Group members had then worked until 11:00 p.m. to finalize details of the draft pilot study design to present to the full committee.

Discussion of Measurement Quality Objectives

After briefly reviewing the agenda for Day 2, Ms. Shorett distributed a summary of the prior evening's caucus discussions showing each caucus' preferences for measurement quality objectives for false positives, false negatives, precision and accuracy. In addition, she summarized responses from each caucus to the following questions:

1. Do you agree that there should be a single set of MQOs for all uses? If so, why? If not, why not? Should the MQO's be goals for the pilot study and/or goals for the final recommendation?

On this question, Ms. Shorett noted that there was general agreement that there should be a single set of measurement quality objectives for all uses, primarily for simplicity's sake, and that these goals should be set for both the pilot study and the committee's final recommendations.

- Labs: Yes. It is too complicated to use multiple sets of MQOs, which would result in different detection and quantitation limits depending on the use. They should be set for both.
 - Environmental Community: Yes for simplicity. Initially, they should be set for the pilot, but considered for the final recommendation.
 - EPA: Yes because of uniformity and simplicity. These goals would be for the pilot study.
 - States: Yes.
 - Industry: Yes for both.
 - Public Utilities: Yes for both. Certainty is just as important for permit limit determinations as it is for compliance determination. Verification is a key component for MQOs.
2. What use or uses do you want to consider in setting MQOs?
 - Industry: compliance/enforcement
 - Public Utilities: compliance/enforcement
 3. Which MQOs do you prefer for alpha, beta, accuracy and precision? Why (in each case)?

Each of the four measurement quality objectives are discussed below.

4. What flexibility do you have on your position on MQOs? Are there combinations of these four that you could live with?
- Labs: This is open for discussion.
 - Environmental Community: There is potentially some flexibility; the caucus recognizes the challenge in verifying small alphas and betas.
 - Industry: There is some flexibility on this option; want to demonstrate compliance so there cannot be too high an Alpha-False Positive error rate at L_C and Beta-False Negative Error Rate at L_C .
 - Public Utilities: Potentially some on everything except for verification, which is a “must-have” for the caucus.
 - EPA: The caucus has some flexibility.
 - States: Have flexibility on Beta-False Negative Error Rate at L_C . For compliance, that would not be an issue for the states. The caucus wants achievable detection and quantitation measurement quality objectives.
5. If there is time remaining, please answer: How do you verify that a procedure meets specific MQOs?

On this question, Ms. Shorett said that the general consensus of the six caucuses was that procedures would be verified by analyzing a substantial number of blanks and spikes at the appropriate levels.

- Labs: Analyze a substantial number of blanks and spikes at MQL over time. See if the MQOs are met.
- Environmental Community: Analyze blanks and spikes at appropriate levels.
- EPA: New rule should require this and what should be done if it is not met.
- Industry: Analyze spikes and blanks.
- Public Utilities: For detection, Alpha (% False Positive) error rate at L_C , use batch blanks; for Beta (% False Negative) error rate at L_C , use spike blanks; Accuracy – at what level you are interested in (L_Q and below).

The committee had a significant discussion on the issue of verification. Many committee members had questions of clarification or comments as to how verification would be conducted (e.g., batch-by-batch analysis) and the costs associated with verification.

There was clarification that the committee seems to be using the terms “confirmation” and “verification” interchangeably. In terms of the pilot, facilitator Bob Wheeler said the discussion had focused on how to confirm that procedures met the set measurement quality objectives. In terms of final recommendations, the committee said it wanted to verify that the procedure performed as intended.

Furthermore, the committee agreed to set measurement quality objectives for the pilot study with the understanding that the committee would make decisions at a later date regarding measurement quality objectives for Clean Water Act programs in its final recommendation.

Measurement Quality Objectives (Question #3)

The committee discussed each of the four measurement quality objectives. In beginning the discussion, the committee reviewed a summary chart that describes the caucus positions (refer to Attachment A) for four (4) parameters:

False Positive Rate

The committee started the discussion already near agreement on a false positive rate. The focus of the discussion was the difference between setting a false positive rate at some percentage and not setting one (i.e., 0%). After a brief discussion among the caucuses, the committee agreed to set the false positive rate at less than or equal to 1% for purposes of pilot testing.

Action: The committee agreed, for purposes of pilot testing, and by consensus, to set the false positive rate equal to or less than 1%.

Vote: 18 Agree, 1 Not Opposed, 0 Opposed, 2 Absent

False Negative Rate

The discussion regarding setting a false negative rate included:

- Consideration of whether or not the absence of L_D in the single-laboratory pilot study impacted this decision,
- How data would be reported between L_C and L_Q for purposes of pilot testing,
- How that data would be used, and
- How to verify that the measurement quality objective was met.

The committee had considerable discussion on reporting data between L_C and L_Q .

Some caucuses added caveats and comments to the proposed action.

- The state caucus noted that “DNQ” was only one of many conventions for reporting results between L_C and L_Q , and the caucus was not recommending any specific reporting convention.
- The public utility caucus supported reporting data with its uncertainty, but said that implementation of this approach was still an issue.
- The industry caucus expressed concern with reporting any data below L_Q .
- The laboratory caucus proposed that reporting numbers below L_Q could be avoided so that some level of accuracy is not implied for a relatively meaningless number by reporting DNQ for values in the range between L_C and L_Q . Flags associated with numbers can be lost and reported results used in a way not originally intended. Knowing that results were detected but not quantified informs the user that those results would likely fall in a relatively narrow range between L_C and L_Q , which for informational purposes, was as good as an actual value.
- EPA said that by voting in favor of the proposal, committee members were committing to circulating the decision among their constituencies for comment.

Additionally, for purposes of pilot testing, the committee suggested that numerical data could be used in the calculations. Associated with that value would be a lower bound of

L_C and an upper bound of L_Q with some probability. A number with a flag would not be reported.

The committee voted on and agreed by consensus to the following action.

Action: The committee agreed, by consensus, that if or when data is reported below L_Q , then the data points that fall between L_C and L_Q would be reported, for example, as detected but not quantified (e.g. DNQ).

Vote: 19 Agree, 0 Not Opposed, 0 Opposed, 2 Absent

After this decision, the committee discussed whether or not to include L_D for purposes of the single-laboratory pilot testing. Many caucuses agreed that eliminating L_D for purposes of single-laboratory pilot testing would have little effect. Some committee members made it clear that some procedures would need to be modified to be evaluated in the single-laboratory pilot test.

Action: The committee agreed, by consensus, that determination of L_D was not a requirement for purposes of pilot testing, so long as data between L_C and L_Q is reported, for example, as detected but not quantified.

Vote: 19 Agree, 0 Not Opposed, 0 Opposed, 2 Absent

Finally, the committee addressed setting a measurement quality objective for the false negative rate. The committee clarified in its discussion the need to set measurement quality objectives for purposes of pilot testing with the understanding that once the committee received the data, it might need to re-evaluate where each of the objectives was set. The committee agreed that policy discussions of uses and what each caucus needed in procedures should continue in parallel with the pilot study.

The committee also discussed and agreed to set fixed targets rather than general goals for laboratories to meet. After further discussion, a target for a false negative rate was proposed and voted on.

Action: The committee agreed, by consensus, to set the false negative rate equal to or less than 1% measured at L_C for the true value at L_Q or L_D for purposes of pilot testing.

Straw vote: 12 Agree, 8 Not Opposed, 0 Opposed, 1 Absent

Precision

Committee members discussed the practicality of having numbers for precision *and* accuracy versus precision *or* accuracy. Some committee members expressed concern at setting a limit for precision that could potentially make previously-set WQBELs unattainable.

After noting that the committee may re-evaluate limits for its final recommendations based on the pilot test results, the committee agreed to set the precision limit at 20% for the pilot test.

Action: The committee agreed, by consensus, that the goal for the pilot test of 20% relative standard deviation (RSD) is based on the mean recovery, understanding that there will be instances where this %RSD may show conflicts with accuracy (that is, set precision targets may inherently define accuracy targets). This may not be applied universally after the pilot study is complete. The study design team will consider higher precision targets (higher %RSD) if the goal cannot be met.
Vote: 18 Agree, 1 Not Opposed, 0 Opposed, 2 Absent

Accuracy

Committee members discussed the different ways to define accuracy and decided on an approach for the pilot study.

Action: The committee agreed, by consensus, that, for the pilot, the study design team will ask participating laboratories to use accuracy based on mean accuracy and that the Technical Work Group study design team should make decisions on specific goals for accuracy based on an evaluation of existing data. The study design team will ensure that the batch-by-batch data is available for the FACDQ to have analyzed.
Vote: 16 Agree, 3 Not Opposed, 0 Opposed, 2 Absent

Pilot Testing Study Design

After lunch, the committee reconvened to discuss components of the pilot study design. Ms. Shorett said that the goal for this part of the meeting was to reach agreement on specific aspects of the study design to allow contracting and logistics agreements to get underway. She asked EPA to present the questions that had to be addressed. Richard Reding said there were three topics that needed agreement:

1. Resolution of the MQO's;
2. Testing particulars of how to test and verify, how many laboratories to include, how many analytical methods to test; and
3. Tasking a study design team with melding the single- and multi-lab designs into a final design for presentation to the committee in July.

The committee agreed that a study design team should be tasked with developing the particulars of a pilot study and presenting the study design to the committee in July.

Action: The committee agreed, by consensus, to task the Technical Work Group and a “Study Design Team” consisting of one person from each caucus on the Technical Work Group with scoping the details of the pilot study.

Vote: 19 Agree, 1 Not Opposed, 0 Opposed, 1 Absent

The committee then discussed the number of analytical methods that should be tested in the pilot study. Mr. Reding presented a list of five analytical methods that had previously been discussed for testing by both the single- and multi-lab subgroups. After a brief discussion, the committee agreed to task the Study Design Team with developing the pilot study design.

Action: The committee agreed, by consensus, to proceed with pilot testing the following five analytical methods:

- 200.7 (metals),
- 300.0 (ions),
- 625 (SOCs),
- 608 (PCBs, pesticides)
- 335.3 (cyanide)

Vote: 18 Agree, 1 Not Opposed, 0 Opposed, 2 Absent

Policy and Technical Work Group Assignments

The following general, technical and policy action items were identified during the course of the two-day meeting.

General Action Items

1. Develop uniform questions for all caucuses for discussions with constituents. (Policy Work Group)
2. Explore how EPA’s new data reporting system (ISIS) can accommodate the FACDQ recommendations. (EPA)
3. Provide examples to differentiate between permitting and compliance/enforcement. (EPA)

Technical Work Group Assignments

1. Complete pilot study design
 - a. Consider funding
 - b. Choose procedures (and consider modifications from procedure proponents)
 - c. Choose analytical methods
 - d. Reach agreement on other technical components
 - e. Continue to evaluate existing data
 - f. Interact with the Policy Work Group concerning
 - i. what we need procedures to do
 - ii. criteria for evaluating pilot procedures

2. Develop L_C for censored methods
3. Update the glossary of terms
4. Normalize the matrix, time permitting

Policy Work Group and Subgroup Assignments

1. Develop straw proposal on uses for discussion with constituents, including how to characterize data between L_C and L_Q .
 - a. Chris Hornback
 - b. Larry LaFleur
 - c. Mary Smith
 - d. Tom Mugan
 - e. Michael Murray
2. Complete the narrative of “What we need procedures to do”
 - a. Jim Pletl
 - b. Tim Fitzpatrick
 - c. Michael Murray
 - d. John Phillips
 - e. Richard Burrows
3. Develop a draft outline for a final report

Public Comment

No public comments were offered during Day 2.

Summary and Closing

Alice Shorett thanked committee members for their hard work and commitment over the two-day meeting. She reminded everyone that the next full committee meeting is scheduled for Thursday and Friday, July 13-14 at the FDIC.

Richard Reding, DFO, adjourned the meeting at 3:00 p.m.

MEETING ATTENDANCE

Committee Member	Affiliation
<i>Environmental Community</i>	
Michael Murray	National Wildlife Federation
Richard Rediske	Grand Valley State University
Barry Sulkin	Environmental Consultant
<i>Environmental Laboratories</i>	
Steve Bonde	Battelle
Richard Burrows	Severn Trent Labs
Cary Jackson	HACH Company
Nan Thomey	Environmental Chemistry, Inc
<i>Industries</i>	
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.
<i>States</i>	
Dave Akers	Colorado Dept of Public Health and Environment
Bob Avery	Michigan Dept of Environmental Quality
Timothy Fitzpatrick	Florida Department of Environmental Protection
Thomas Mugan	Wisconsin Dept of Natural Resources
<i>Public Utilities</i>	
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
<i>EPA</i>	
Mary Smith	US Environmental Protection Agency
Designated Federal Officer	
Richard Reding	US Environmental Protection Agency
Invited Speakers/Participants	
Kenneth Miller	CSC, Inc.
Facilitators	
Alice Shorett	Triangle Associates, Inc.
Bob Wheeler	
Derek Van Marter	
Observers	
Meghan Hessenauer	US Environmental Protection Agency
Joanne Dea	
Marion Kelly	
Nicole Shao	

Brad Venner
Richard Witt
Marcus Zobrist

Jim Laity
Jim Christman
Raj Patel
Michelle Rodrigues
Jerry Schwartz
Robert Yokley

Office of Management and Budget
Hunton & Williams
Abbott
SRI
AF+PA
Syngenta

DISTRIBUTED MATERIALS

Committee's Packet of Materials

Agenda (March 29-30, 2006)
 Draft Meeting #3 Summary (December 8-9, 2005)
 Committee Process Chart
 Narrative: What does the committee need a procedure to do?
 Clean Water Act Uses Framework
 Caucus Positions on Uses
 Prescriptive and Descriptive Approaches Comparison Chart
 Background on Policy Issues
 Uses Decision Trees
 Technical Work Group Discussion Summary
 Framework for Committee Discussion on MQOs
 MQO Straw Proposal
 Technical Work Group Assignments, Products and Questions
 Proposed Analytical Methods to Pilot, Priorities and Costs
 Matrix of Procedures and Characteristics
 Interpretations of Detection and Quantitation Procedures Evaluation Characteristics
 Proposed Regression Design Pilot Study Evaluation of Existing Data
 Proposed Regression Pilot Study Design
 Regression-based Pilot Study Design: Questions it would address
 Single Lab Report on Existing Data (Episode 6000 Data Assessment)
 Revised Glossary of Terms

Distributed at Meeting

Laboratory Caucus Outreach Report Handout of Slides
 Lunch Work Group Assignment
 Caucus Responses to MQO Worksheet

ATTACHMENT A
Measurement Quality Objectives
Chart Describing Caucus Positions

Goals	Values	Perspectives and Initial Preferences for L_C					
		EPA	Labs	Public Utilities	Industry	Environmental Community	States
Alpha - False Positive error rate at L_C	0%			X			
	0.5%						
	1%	X	X (<1%)		X	X	X
	5%						
	Other Options						
Goals	Values	Perspectives and Initial Preferences for L_D					
		EPA	Labs	Public Utilities	Industry	Environmental Community	States
Beta-False Negative Error Rate at L_C	1%	X	X (<1%)		X		
	5%				X	X	X
	50%						
	No need to establish a false negative rate			X			

Goals	Values	Perspectives and Initial Preferences for L _Q					
		EPA	Labs	Public Utilities	Industry	Environmental Community	States
Accuracy at L_Q	<u>100</u> +/- 10%						
	<u>100</u> +/- 20%	X (as a goal for certain methods)		X (for inorganics)	X		
	<u>100</u> +/- 40% for inorganics & VOCs			X (for SOCs)			X (30-40%)
	<u>100</u> +/- 50% for SOCs	X	X			X	X
Goals	Values	Perspectives and Initial Preferences for L _Q					
		EPA	Labs	Public Utilities	Industry	Environmental Community	States
Precision	10%				X		
	20%	X (goal for certain methods)	X (and at least 3x MDL)	X	X		X
	40%					X	
	No need to establish						