

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

Hilton Alexandria Old Town, Salons A & B
1767 King Street
Alexandria, VA
Tuesday – Wednesday, June 21-22, 2005

Final Meeting Summary

DAY 1 – Tuesday, June 21, 2005, 9:00 AM – 5:00 PM

Dick Reding, US Environmental Protection Agency (EPA) Designated Federal Officer, opened the meeting of the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs (committee) at 9:00 a.m. and welcomed committee members and other attendees. He noted that the name of the committee, although long, captured the essence of its scope: detection and quantitation approaches and uses in Clean Water Act programs. Mr. Reding then introduced Mike Shapiro, EPA's Deputy Assistant Administrator for the Office of Water.

EPA Welcome, Purpose, Hopes for the Process

Mr. Shapiro welcomed everyone and briefly described his background in environmental engineering and his career at EPA. He stated that one of the lessons of this experience is that some issues of long term consequence have to do with the nuts and bolts of monitoring and measurement. He emphasized that proper measurement is the starting point for decision-making, setting rules and procedures, and enforcement. He said that detection and quantitation have enormous consequences for the way EPA does its business. He said the purpose of the committee was to examine the current procedures and to make consensus recommendations on approaches for the development of detection and quantitation procedures and uses of these procedures in Clean Water Act programs.

Mr. Shapiro noted that he co-chairs the Forum on Environmental Measurements, which is charged with addressing issues associated with environmental measurement across EPA programs. He said he considers this federal advisory committee to be the proper forum for addressing issues related to detection and quantitation.

Mr. Shapiro said he was delighted that the committee included such a diverse group of people and interests. He also said that EPA would make its resources available to the committee throughout the process and could provide access to additional resources from outside the agency as needed.

Mr. Shapiro said he had participated in a number of federal advisory committees in the past, both representing the agency at the table and in other roles. In all cases, his experience with federal advisory committees was positive. They greatly improved his understanding of the issues under discussion. Mr. Shapiro noted that when a federal advisory committee achieves consensus, this consensus is powerful, and he has seen EPA

act on consensus recommendations. He said that moving an agency's process forward could be frustrating at times, but he urged committee members to keep at it, because the power of consensus was worth the effort. Mr. Shapiro said he hoped this committee would provide consensus recommendations on detection and quantitation. He said he also understood that this committee's recommendations could set precedent for what the agency could do across other programs in EPA.

Mr. Shapiro said that he intended to attend subsequent committee meetings to check on progress because detection and quantitation are among the most important issues in the Office of Water. He identified Mary Smith as EPA's lead negotiator at the table and said that he would stay in close contact with her. He again thanked committee members for their commitment to the process and said he looked forward to hearing from the committee as its work unfolded.

Mary Smith, EPA Engineering and Analysis Division Director and EPA designee on the committee, also thanked committee members for their commitment. She said more than 50 people had been nominated or self-nominated to be on the committee. EPA was able to select only 20 people to serve on the committee, in addition to herself as EPA's representative.

Ms. Smith briefly described her previous successful collaborative experiences and said she was very committed to this process and to achieving consensus recommendations. She emphasized the need for Committee members to listen to one another and to understand each others interests. She said that EPA had committed significant resources to the committee, including her staff. She then introduced her staff – Marion Kelly, Meghan Hessenauer, Upton Siddons and Bill Telliard – as well as Joanne Dea from the EPA Conflict Prevention and Resolution Center. She also noted that EPA had formed an internal working group to keep up with committee progress and to facilitate broad understanding within the agency of the implications of the committee's recommendations.

Introductions

Alice Shorett, facilitator, welcomed members of the committee and introduced the other members of the Triangle Associates team: Bob Wheeler, Derek Van Marter, and Vicki King whom many committee members had met by telephone. She said the role of the facilitation team in the process was to serve the committee as a whole, to keep conversation balanced, to make sure everyone participated, and to keep an eye on overall process from this day to the final product. Ms. Shorett acknowledged that while some committee members had been engaged in this topic for many years, the federal advisory committee approach would have a different feel. The federal advisory committee approach allows the parties at the table who represent a balance of interests to work together to develop and provide consensus policy recommendations to the agency.

Ms. Shorett noted that as facilitators, one of the team's jobs would be to ensure that we were having the right discussions in the right places – policy level discussions in

committee meetings and technical discussions in the Technical Work Group. She invited committee members to help with this task.

She asked those who had worked on these issues for a long time to put on a new hat even as they continued to work on the familiar topic. She added that relative newcomers would learn a lot and would have valuable perspectives to contribute. She urged everyone to listen to one another carefully.

Ms. Shorett said that a number of people were listening to the meeting via telephone and asked those participating by telephone to put their phones on mute and those in the room to turn off all cell phones and digital devices.

She then asked committee members to introduce themselves, giving their names and their affiliations. (Please see the attendance list at the end of this summary.)

Federal Advisory Committee Act – An Overview

Marilyn Kuray of the EPA Office of General Counsel gave a brief overview of the Federal Advisory Committee Act. (Please see Attachment A for her presentation.) Committee members had no comments or questions.

Agenda Review, Review and Approval of Ground Rules

Ms. Shorett reviewed the agenda for the two-day meeting, noting that the first day was focused on getting organized and hearing statements of interest from individual committee members and from the interest groups represented on the committee.

Review and Approval of Ground Rules

Ms. Shorett said that the first committee action would be to discuss and approve its ground rules. She referred committee members to the draft ground rules, dated May 20, 2005, in their packets and explained that discussion would focus initially on issues and questions about the ground rules that were raised during the facilitators' pre-meeting calls with committee members. The committee would then have an opportunity to discuss other issues or propose amendments before approving final ground rules.

The committee approved the following sections with no changes:

- A. Purpose
- B. Roles and Responsibilities of EPA
- D. Roles and Responsibilities of the Facilitators (See note on meeting summaries below.)
- E. Roles and Responsibilities of the Designated Federal Officer
- F. Meeting Content
- G. Draft and Working Documents
- L. Schedule
- N. Products

Sections where language was revised, added or clarified included the following:

C. Roles and Responsibilities of Committee Members

Several committee members raised the issue of whether, and how, a committee member who could not attend a meeting due to extraordinary circumstances could

participate in decision-making. After discussion, the following sentence was added: “If extraordinary circumstances prohibit a committee member from attending a meeting, special arrangements can be made to accommodate that member’s participation in the meeting via phone.”

D. Role of the Facilitators – Meeting Summaries

Ms. Shorett noted that the facilitators were responsible for drafting an accurate summary of each meeting and sending the draft summary to members for review in advance of the next meeting. At that meeting, members would have an opportunity to comment and propose changes, if needed, to the draft. Members would then approve the summary, after which it would be considered final. Once the summary was approved, EPA would post it to the docket.

H. Communication during Process

While there was no change to this section, committee members discussed how to keep their constituencies informed. They agreed to encourage interested parties to send ideas and comments to the committee members who represent the respective party’s interest.

I. Internal Decision-making

After discussion, committee members suggested that the following language be added to the first bulleted item: “Members will vote using one of three options: ‘agree’, ‘disagree’ or ‘not opposed.’ Consensus will be defined as all members ‘agreeing’ or ‘not opposed to’ the decision. Votes will be tallied.”

J. Membership

A suggestion was made to change the number of committee members and total categories in the first sentence to read: “The committee will consist of about 20 members appointed by the EPA Administrator to represent the following six categories.” In the fifth bullet, the word “and” was inserted, and a sixth bullet was added to read: “US Environmental Protection Agency.”

K. Technical Work Group

A sentence was added in the fifth bullet after the first sentence, to read: “At a minimum, each of the interest groups will be represented on the Technical Work Group.”

M. Observers and Informational Material

A new bullet was added: “The committee may allow public comment prior to making a decision on a particular subject.”

Ms. Shorett summarized the proposed changes to the draft ground rules and said the facilitation team would prepare revised language for committee review and approval over the lunch break.

Approval of Ground Rules

After a break for lunch, the facilitation team projected the proposed changes to the draft ground rules. After brief discussion, Ms. Shorett asked whether members were prepared to vote on adopting the ground rules as revised (Attachment B).

Action: Committee members approved by consensus the revised ground rules for the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs (20 Agree; 1 Absent).

Statements of Interest by Advisory Committee Members and Hopes for the Process

At Ms. Shorett's invitation, committee members read their individual statements of interest, which they had prepared in advance of the meeting. (Copies were available as handouts for committee members and observers. These statements are available at the EPA website: <http://epa.gov/waterscience/methods/det/>)

After all of the statements had been read, committee members discussed the commonalities in their statements of interest. Ms. Shorett commented that committee members were likely, over the course of the meeting, to refer back to these individual statements and to the joint interest group statements of interest that would be presented later in the day.

Process Design and Schedule

Ms. Shorett briefly described the proposed process design (Attachment C) and said that it was based on comments from situation assessment interviews and from pre-meeting calls with members. The process called for a two-tiered approach. Policy discussions would occur in the committee which was expected to meet quarterly in two-day meetings over approximately a year's time. A Technical Work Group would carry out technical assignments from the committee between committee meetings and would present the Technical Work Group's results at the next committee meeting. Like the committee, representation on the Technical Work Group would reflect a balance of the interests at the committee table.

The committee discussed the proposed process design and agreed, in general, with the proposal. Many committee members supported the idea of pilot testing procedures before finalizing recommendations. Others commented that the process might need to last longer than one year to get a successful, long-lasting result. Committee members then discussed and approved proposed meeting dates for the next two meetings (September 29-30 and December 8-9). They also requested exploring the possibility of holding one or more committee meetings outside of Washington, D.C. in cities where EPA has facilities. The committee agreed that it would be an advantage to meet in Washington, D.C. when the committee was finalizing recommendations, to facilitate having Mike Shapiro and other senior EPA staff at the meeting.

Ms. Shorett said that the facilitation team would propose agenda topics for future meetings at the end of day two of the meeting for committee members to consider and approve.

Common Base of Information

Ms. Shorett described the approach to developing a common base of information in this first meeting. Dick Reding of EPA would give a brief history of detection and quantitation procedures. After his presentation, the five other interests represented at the

table – states, industrial dischargers, publicly-owned wastewater treatment plant operators, environmental laboratories, and environmentalists – would present joint statements that responded to three questions:

- What are your primary responsibilities that are related to or impacted by detection and quantitation procedures?
- How do you use the results of these procedures in carrying out your responsibilities?
- What issues or concerns do you have about the current procedures to establish detection and quantitation limits?

Mr. Reding's presentation on the history of detection and quantitation procedures is available on the EPA website (<http://epa.gov/waterscience/methods/det/>).

The presentations by the remaining interest groups follow. Questions and responses that followed several of the presentations are included.

Joint Statement of Interest – States

Prepared by:

- David Akers, Colorado Department of Public Health and Environment
- Bob Avery, Michigan Department of Environmental Quality
- Timothy Fitzpatrick, Florida Department of Environmental Protection
- Thomas Muga, Wisconsin Department of Natural Resources

Primary State Responsibilities related to or impacted by analytical testing methods

- States have the responsibility to:
 - Protect the Environment
 - Protect Water Quality
 - Protect Public Health

How results of methods are used to carry out the state responsibilities

- Analytical results, including detection and non-detection, are fundamental to the operation of environmental programs to:
 - Identify pollutant, source and potential health risk
 - Determine extent of contamination
 - Monitor efficacy of remediation
 - Determine permit limits
 - Determine TMDL assessments and the development of BMP's and surface water management plans
 - Determine regulatory compliance

States Issues and Concerns on current procedures to establish detection and quantitation limits:

- Must be scientifically acceptable and legally defensible
- Should be understandable, useful and practical
 - Cost effective
 - Compatible with routine laboratory operations

- Easy to determine
- Achievable on a daily basis
 - To insure accuracy and precision at the lowest level under normal laboratory operating conditions
- Must be uniform and consistent in:
 - Nomenclature
 - Terminology
 - Concept
 - Reporting of D/Q by all laboratories at lowest levels
- Should be flexible to account for matrix variability/interferences
 - CWA includes biosolids
 - We see benefits if, in the future, other environmental programs borrow from or adapt our approaches
- Should be determined at the lowest level possible to insure public health safety
 - Minimize false positives
 - Be laboratory specific
 - Toxicological studies often identify chronic or acute toxic substance exposure limits far below achievable laboratory analytical capabilities. These default to either the detection or quantitation limits in permits.
 - Flexible to utilize new technology

In response to a question on how the states use detection and quantitation numbers and whether there was a majority approach, Mr. Avery said that there was not a majority approach. He said states often have an interest to monitor ambient levels of pollution down to detection limits.

Ms. Shorett said the desirability of asking all states how they use detection and quantitation numbers had been raised during the situation assessment interviews. Mr. Avery said that the caucus had discussed the possibility of surveying states to find out how detection and quantitation numbers are used across all states. He said that data sets with this information might be available.

A committee member asked if it would be feasible to develop a procedure that resulted in consistency across all states. In response, Timothy Fitzpatrick said that states adopt rules in various ways, with different drivers, such as tourism or industry. David Akers added that, in many cases, his state (Colorado) addresses these issues on a permit-by-permit basis, which is very resource intensive. He said there was a desire among states for the committee's work to result in more consistent approaches across the country.

Joint Statement of Interest – Industrial Members

Prepared by:

- Roger E. Claff, American Petroleum Institute
- Larry LaFleur, National Council for Air and Steam Improvement, Inc
- John H. Phillips, Ford Motor Company
- David J. Piller, Excelon Power

Primary Impacts:

- NPDES Permits
- Stormwater monitoring
- Wastewater monitoring
- Drinking Water monitoring
- Ambient water quality monitoring
- Effluent Guideline development

How the results are used:

- NPDES compliance testing
 - 40 CFR Part 136
 - Alternate testing programs approved by EPA
- NPDES permit applications
- Agency Enforcement
- Determine water impairments

Issues or Concerns:

- Current MDL and ML:
 - dependent on spike levels
 - limited data sets
 - not based on inter-laboratory data
 - Unsound statistical procedure
- Permit Limits
 - WQBEL should be set based on reliable sampling results
 - Consistent data quality between labs for decision making
 - Limits could be set causing compliance uncertainty
- The current procedures for addressing matrix effects do not serve stakeholders

John Phillips added that the current method requires different detection limits under different circumstances, which makes decision-making difficult. Mr. Piller said that industries needed to be confident that they were meeting standards.

Joint statement of interest – Publicly Owned Treatment Works (POTWs)

Prepared by:

- Zonette English, Louisville and Jefferson County MSD
- Chris Hornback, National Council of Clean Water Agencies
- James Pletl, Hampton Roads Sanitation District
- David E. Kimbrough, Association of California Water Agencies

What are your primary responsibilities that are related to or impacted by analytical test methods?

- Protecting the environment, human health, plant and service area operations, and plant personnel
- Providing true and accurate data
- Characterization/troubleshooting plant performance

- Collecting revenue based on wastewater quality received
- Planning/designing/constructing wastewater plants and service lines

How do you use the results of these methods in carrying out your responsibilities?

- Regulatory Reporting
- Permit Applications and Limit Derivation
- TMDL basis and research
- TREs/TIEs
- Regulate Industrial Discharges
- Biosolids Management
- Special Studies
- Define Quality Charge Testing Programs
- Develop Local Limits
- Influent/Effluent information for plant upgrades

What issues or concerns do you have about the current procedures to establish detection and quantitation limits?

- We don't have a promulgated procedure for defining detection and quantitation limits for methods
- The current procedures are not scientifically sound within the context of their use
- The procedures do not incorporate and apply Data Quality Objectives for bias, precision, representativeness, and comparability for lab and method performance at the detection and quantitation limits used in CWA programs, at all levels and frequencies of operations that can influence data use and interpretation relative to detection and quantitation limits.
- EPA does not use the uncertainty of data, defined by detection and quantitation limits and their DQOs, to determine how data is used and reported in CWA programs, and whether it should be used in these programs.
- EPA does not qualify analytical method performance relative to DQOs defined for CWA programs and does not have promulgated procedures to determine whether methods are appropriate for these programs.
- The procedures do not allow labs to qualify analytical results relative to analytical interferences.

Bottom Line: Our top priority is compliance with the Clean Water Act

- In terms of detection and quantitation, what is the lowest concentration that can be measured using methods approved in 40 CFR 136 that can determine if a discharge is in compliance with the CWA?
- For reasons of enforcement, equity, accreditation, and practicality, this lowest reportable concentration should be the same for all dischargers and receiving bodies.

Joint Statement of Interest – Environmental Laboratories

Prepared by:

- Richard Burrows, Severn Trent Laboratories and American Council of Independent Laboratories
- Nan Thomey, Environmental Chemistry, Inc.
- Steve Bonde, North Creek Analytical
- Cary Jackson, Hach Company

Primary Responsibilities of Environmental Laboratories

- The commercial laboratories are the primary generators data on the levels of contaminants in the environment.
- We perform the detection and quantitation level determinations.
- We are the group that will be tasked with implementation of whatever new procedures arise from the FACA process

Use of Results

- We are required to generate detection and quantitation limits for virtually every analytical method that we perform.
- A large laboratory will routinely perform several hundred method detection limit studies every year.
- Although the procedures at 40CFR Part 136 Appendix B in theory apply only to analysis performed under the clean Water Act, in fact the states have required that they be performed across the board.
- The detection and quantitation limits generated form the foundation of our ability to provide data of high quality.

Concerns with the Current Procedure

- We do not believe that the current procedures at 40CFR Part 136 Appendix B allow for reliable determination of detection and quantitation limits.
- This is due to technical limitations such as failure to consider long term variability, method blank results and qualitative identification.

Generation of quality data

- Our primary interest in the work of this committee is the hope that the resulting policies and procedures will allow us to generate higher quality data.

Use of Data

- The lowest limit of reporting for normal data uses, and certainly for regulatory compliance, should be the quantitation limit.
- This is because it represents, or should represent, the lowest level at which the accuracy and precision of the data is sufficient to generate a reliable number.

Generation of Quality Data

- If a method quantitation limit is not low enough for the intended use of the data, the first choice should be an alternative method or method modification that will allow for a lower quantitation limit, not use of results between the detection limit and quantitation limit.

- Quantitation and detection limit procedures must consider factors such as long term variability, method blank levels and compound identification criteria in order to be reliable.
- In the absence of these requirements both false positives and false negatives may be routinely generated, leading to erroneous decisions.

Consistency

- Procedures for determination of the quantitation limit (and detection limit if needed) must be clear, consistent, technically valid and well documented.
- They must be adopted consistently by all EPA offices that are engaged in development and publication of analytical methods.
- To ensure consistency and technical validity, the new procedures for identifying quantitation and detection limits should be applied to current methods and supersede the MDL procedure currently used.
- EPA should also work to ensure that state regulatory agencies and accrediting organizations such as NELAC adopt the new procedures.

Ease of Adoption

- Within the constraints of technical validity, the new procedures should be as simple and straightforward to implement as possible, in order to ensure quick and complete adoption by testing laboratories.
- We must recognize that the procedures will need to be adopted not only by large laboratories with IT staff resources and sophisticated LIMS systems, but also by small laboratories.
- The procedures need to be clear and well documented, so that the scope for different interpretations by regulators and data users is limited.

In response to a question on how laboratories determined the Minimum Level (ML), Mr. Burrows said that laboratories did not have a single approach.

Mr. Burrows said industries were also interested in seeing EPA adopt consistent procedures across all EPA programs, not just Clean Water Act programs. He urged that whatever recommendations the committee developed should be used to replace current regulatory language.

Joint Statement of Interest – Environmental Community

Prepared by:

- Robert Moore, Environmental Advocates of New York
- Michael Murray, National Wildlife Federation
- Richard Rediske, Grand Valley State University
- Barry Sulkin, Environmental Consultant

Issues of Concern

- In some cases, evolution of federally-approved analytical methods have not kept pace with developments in environmental analysis

- While environmental levels of some persistent bioaccumulative and toxic (PBT) chemicals have decreased over past 2-3 decades, many remain at levels of concern
 - PCBs often seen at levels exceeding 0.1 ng/l in Great Lakes water, compared to GLI criterion of 0.026 ng/l
 - PCB quantitation level of 200 ng/l (in the range of value commonly used) exceeds GLI criterion by 7700x
- Statistical approaches may not always be considered in the context of all elements of the analytical procedures

What We Would Like to See

- Consideration of both sampling and analytical issues in developing detection limits (DLs) and quantitation limits (QLs)
- Incorporation of current sampling and analytical capabilities into relevant EPA water program method guidelines
 - This should include requiring use of congener-specific analysis for complex mixtures, and moving away from pattern recognition approaches for quantitation
- Move away from current procedure involving spiking at artificial level, and toward more rigorous approach for identifying DLs and QLs
- Matrix interferences should be addressed in guidelines, but need not be a reason for high limits – simple steps can in many cases be taken to address interferences
- Methods for DLs and QLs should be scientifically sound
- But, methods need to be able to be practically implemented by industrial and municipal dischargers, as well as states and tribes in monitoring programs
- Inappropriately elevated analytical detection/quantitation limits and matrix interferences should not be used as a justification to allow more toxic chemicals to be discharged into the environment
- In addition to having sound DLs and QLs for meeting risk-based targets, we need to keep in mind broader policy goals, including virtual elimination in the Great Lakes

Mr. Murray said that a concern that had not been brought up among committee members was that there may not be a single process that identifies detection and quantitation for every analyte. He said detection and quantitation levels were directly related to the methods used. Committee members agreed that the purpose of the committee was to look at and evaluate all potential methods.

Joint Statement of Interest – EPA

Mary Smith spoke on behalf of EPA. She repeated Mike Shapiro's statement in his opening remarks that the scope of the committee was Clean Water Act programs. She said that committee members would review statistical approaches and data to develop recommendations. She noted that there were 21 members on the committee who represented a balance of interests. She said that technical experts were available to supplement the work of the Technical Work Group or the committee. She explained that US EPA's desire was to complete the process within a year or so. She said the pilot

testing process would take some time and resources but that it was an important aspect of evaluating any method.

Identification of Key Policy Questions/Issues

Ms. Shorett asked Bob Wheeler, co-facilitator, to lead the committee in a discussion on key policy questions.

Comments from the committee included the following. The problem is that the current procedures do not allow for an unambiguous determination of compliance under the Clean Water Act. The characteristics for evaluating the procedures (i.e. criteria) and for determining the best procedure is a key policy issue. Assuming US EPA promulgated a new rule, there would be broad transitional implications for state regulations and permits. Committee members suggested it may be possible to use standard benchmarks for terminology (e.g. ISO/IUPAC: L_c , L_d , L_q).

Other members identified the issue of controlling externalities, such as sampling and analysis, in detection and quantitation. Once something was adopted, US EPA would need to consider what would happen to the hundreds of test procedures in current regulations. Committee members identified the importance of understanding the appropriate uses for detection and quantitation in order to determine the most effective approach in a particular situation.

Committee members discussed the importance of US EPA deciding whether it would determine new quantitation limits for new procedures or whether the laboratories would implement the new procedures over a period of time.

Another key policy issue identified by the committee was whether to take into account cost and science, and whether it was important to spend time early in the process on how cost might influence what could be selected for a detection or quantitation procedure. The point was made that the corollary to cost was supply. If all laboratories were moving to more advanced technology and achieving low numbers, the result would be a small number of laboratories available to do the work. Therefore, capacity as well cost must be addressed. Committee members acknowledged that laboratories were interested in knowing whether a new approach was more costly than what was currently required under existing regulation, and whether there was available technology to facilitate implementation of a new procedure.

Committee members also discussed the difficulty in separating the uses from the procedures. Members identified the issue of deciding what data quality objectives were needed to make decisions.

Ms. Shorett explained that during the evening break the facilitators would transcribe the flip charts of the discussion on key policy issues for the opening discussion for presentation at the opening session on Day 2. She asked committee members to review packets of resumes for potential Technical Work Group members to prepare for a discussion on the second day's agenda.

Public Comment

Alice Shorett asked for those who signed up to make public comment to step up to the microphone and state their name. She reminded those making public comment that each had three minutes to address the committee members.

David Friedman

Mr. Friedman addressed the committee as EPA's staff to the Forum for Environmental Measurements. He said there were at least five different users of methods that need to be considered in identifying what someone had to do in determining or demonstrating the applicability of a new method or technology (e.g., matrices to which the method is applicable, sensitivity in different media: bias, precision, selectivity as a function of concentration).

Regulatory agency needs must also be considered, particularly in identifying appropriate procedures for a regulatory agency to use when determining the general usability of a method or measurement technology. This includes determining the lowest levels at which the analyte could be detected with confidence; the lowest levels at which the analyte could be measured with a specified level of quality; and the lowest concentration at which there is confidence in reporting that the pollutant was found.

There are also laboratory requirements. A laboratory would need to demonstrate that its measurement system was achieving the sensitivity required for the particular application (e.g., permit or regulatory requirement).

Finally, the enforcement community has certain needs. He said the enforcement community needs to be able to determine who was in compliance and whether an analytical system achieved the level of sensitivity that was required of a particular application.

Wrap-up and Agenda Review

Alice Shorett reviewed the agenda topics for the second day of the meeting (Wednesday) and noted that the start time would be 8:00 a.m.

Dick Reding, the Designated Federal Officer, adjourned the meeting at 4:25 p.m.

DAY 2 – Wednesday, June 22, 2005, 8:00 AM – 4:00 PM

Richard Reding, EPA's Designated Federal Officer, opened the meeting at 8:05 AM. Alice Shorett, facilitator, reviewed the agenda for the day.

Key Policy Issues

Ms. Shorett noted that the first topic on the agenda was carried forward from the previous day. She noted that committee members had at their places a list of key policy issues,

generated in a brainstorming session the previous day. The purpose of the issues list was to identify topics for future committee agenda items. She called on Bob Wheeler of the facilitation team to lead the discussion of key policy issues.

Mr. Wheeler began by explaining how the facilitation team had taken the policy issues identified on the first day and had grouped them into issue categories. After discussion, the issue categories were revised and issues were distributed among them as follows:

Broad Policy (Tier I) – throughout

- What is the problem we are trying to fix? The current procedure gives ambiguous results.
- Don't create new problems trying to fix detection and quantitation.
- Describe the situation of detection and quantitation uses across all 50 states and how they are using them in Clean Water Act programs.
- Should detection be used as a permit limit?
- Properties of detection and quantitation procedures and how they are used.
- Transition times for implementation (existing NPDES, EPA and state guidance development)

Broad Policy (Tier II) – throughout

- What is an acceptable range of risk (qualitative and quantitative)?
- Understanding uses between detection and quantitation.
- Decide what quality of data we need to make decisions for different uses.

Definitions

- Standard benchmarks for detection and quantitation limit
- Critical level and others

Balance – throughout

- Complexity → simplicity
- Available resources (lab capacity system wide and individually, and skill set) → data quality needs
- Policy/science → statistics

Criteria

- Used for evaluation and comparison of procedures.
- Focus on what is important to you and others.

Will one size (procedure) fit all?

- One detection/quantitation procedures for every class of pollutant or technologies, or pollutant/technology-specific detection/quantitation procedures
- By user groups (laboratories, regulators, method developers, enforcers and permittees)
 - Laboratories get accredited and show that they are meeting the specifications routinely

- Regulators use them to write NPDES permits (stormwater/wastewater), ambient water quality monitoring quality, effluent guideline development
- Method developers use them to show that their methods are equivalent
- Enforcers use them for compliance decisions
- Permittees use them to show compliance with Clean Water Act programs

Procedures

- Sampling
- Analytical issues
- Is the committee recommendation an overall approach or a set number?
- Are there appropriate tools (e.g. software) for detection and quantitation procedures and if so, under what conditions? Transparency is important.

Laboratory

- Should calculation of detection and quantitation limits be an interlaboratory procedure?
- It has to be feasible for labs (i.e. implementation, technology, costs, resources, training).

Costs

- How might cost influence detection and quantitation procedures and how might these procedures influence cost?
- How are technology costs and incentives considered?

Approaches: Laboratory Implementation

- What are the implications of change across the board?
 - What happens to existing analytical methods?
- What steps are taken to implement consensus recommendations on detection and quantitation procedures?
- What tools may facilitate implementation of new procedures?
- What form does a final procedure take? Is it guidance or regulation?

Uses: Implementation in Clean Water Act Programs

- Implementation into permits and 303 (d) listings
- Guidance on how to use limits in Clean Water Act programs

Ms. Shorett explained that the facilitation team would use the key policy issues to design agenda items for future meetings.

Initial Discussion of Detection and Quantitation Methods

Richard Reding briefly described the existing procedures for detection and quantitation, as follows:

Detection

- EPA's method detection limit (MDL)

- ASTM's International Interlaboratory Detection Estimate (IDE)
- American Chemical Society (ACS) limit of detection (LOD)
- International Organization for Standardization/International Union of Pure and Applied Chemistry) – ISO/IUPAC critical value (CRV)
- ISO/IUPAC minimum detectable value (MDV)
- American Council of Independent Laboratories (ACILL) Critical Value
- USGS Long-term Detection Limit (USGS LT-MDL)
- Inter-industry Analytical Group Sensitivity Test and Full-Range Validation Study

Quantitation

- EPA minimum level (ML) of quantitation
- ASTM International interlaboratory quantitation estimate (IQE)
- ACS limit of quantitation (LOQ)
- ISO/IUPAC LOQ

Mr. Reding suggested that these procedures could be a “starter list” of procedures for the Technical Work Group to evaluate. The committee would supply the “desirable characteristics of a procedure” for the Technical Work Group to use in analyzing them.

Mr. Reding then invited members of the committee to identify additional procedures that should be added to the list to be evaluated.

Committee members identified the following additional procedures for *detection*:

- National Environmental Laboratory Accreditation Conference (NELAC) uncertainty limit calculations for detection;
- The Huvaux and Vos procedure;
- The “consensus group”¹ detection limit (developed from the ACIL procedure)

Committee members suggested adding the following procedures for *quantitation*:

- NELAC uncertainty limits for quantitation;
- EPA's Drinking Water Lowest Concentration Minimum Reporting Limit (LCMRL); and
- EPA's Office of Solid Waste quantitation procedure.

The committee members discussed the need to talk about the desirable characteristics of a procedure before deciding which of the existing procedures should be evaluated by the Technical Work Group.

¹ The “consensus group” is comprised of individuals from companies and organizations representing a broad cross-section of interests from municipal, industrial, scientific, and laboratory communities. They collectively commented to EPA in a letter dated August 15, 2003 (“National Consensus on Detection and Quantitation Levels, EPA's Rulemaking on MDL and ML Procedures, RIN 2040 – AO53. 68 FR 11,700, March 12, 2003).

Initial Discussion of What Parties Need from Detection and Quantitation Methodologies That Will Lead to Criteria

Ms. Shorett asked committee members to break into their respective interest groups and answer two questions:

1. What does your interest group need from a final package of procedures?
2. What do you need to know to be able to participate in policy discussions at future committee meetings?

Following an hour of discussion in groups, committee members reconvened to report their responses to the two questions, as follows:

States (Thomas Mugan)

Elements needed in a final package:

- Both detection and quantitation procedures
- Flexibility to implement use of detection and quantitation limits as public policy evolves
- Protocols for advancement of technologies/sensitivity
- Approach that rewards entities to attain lower detection and quantitation limits where necessary (e.g., water quality)

Information needs for policy discussions:

- Input from other states
- Clear road map and milestones for the committee
- Technical work group presentation and distillation of alternative detection and quantitation methodologies
- Understanding of the flaws in existing MDL procedure

The states' caucus committed to survey all the states to get a better understanding of how states use detection and quantitation numbers. The committee discussed possible questions to include in the survey and the logistics of sending a survey to states. It was suggested that useful information on this topic might also be found in an American Petroleum Institute publication entitled, "Analytical Detection and Quantification Limits: Survey of states and federal approaches."

Environmental Laboratories (Richard Burrows)

Elements needed in a final package:

- Clear, consistent, technically-valid procedures to replace existing procedure in 40 CFR part 136 appendix B
 - Implemented as widely as appendix B is now
 - Can appendix B be replaced?
- Guidance document (e.g., SW846 – method 5035A)
- Ease of use in a competitive environment
- Enticing "non-compliant" laboratories to comply

Information needs for policy discussions:

- Understanding of what the states and EPA need from procedures

- Intended uses (e.g., TMDL?)
- Level of confidence for detection and quantitation limits

Environmental Community (Barry Sulkin)

Elements needed in a final package:

- A procedure that reflects routine laboratory operation
- Confidence in detection and quantitation procedures at low enough levels to protect human health and the environment
 - Implementable
 - Approaches or is below criteria
- Procedures that encourage more sensitive methods and equipment
- Equal attention to false positives and negatives
- Addresses matrices (e.g., sample interference)

Information needs for policy discussions:

- How the recommendations from the committee will or will not be (directly/indirectly) used in Clean Water Act programs
- Consistency with other regulations
- An understanding of what environmental groups want

Industry (Larry LaFleur and John Phillips)

Elements needed in a final package:

- Explicit definitions for a detection limit and a quantitation limit
- Different procedures tailored for different regulatory uses
- Quantitation suitable for regulatory compliance:
 - Explicit measurement quality objectives including precision and bias
 - Appropriate quality control procedures
 - A quantitation limit reflective of routine performance
- Detection:
 - Must address false positives and false negatives
 - A detection limit reflective of routine performance
 - Define procedures for addressing matrix effects

Information needs for policy discussions:

- Literature references
- Specific discussions and opportunities for education
- Conference calls

POTWs (David Kimbrough)

Elements needed in a final package:

- Procedures that determine in an unambiguous and legally-defensible manner compliance with the Clean Water Act (e.g., NPDES monitoring, reasonable potential determinations, 303(d) listings); procedures should apply to labs and analytical methods
- Procedures shouldn't preclude a qualified lab from conducting them

- 40 CFR promulgated procedures that clearly define measurement quality objectives for different uses
- Measurement quality objectives for data quality indicators for both detection and quantitation
- Procedures that allow assessment of ability to meet the measurement quality objectives on an ongoing, batch-by-batch basis
 - Calibration check at the quantitation limit with predetermined recovery rates
 - Method blank with maximum acceptable concentration as a percentage of the quantitation limit
- Within reason, procedures should be driven by quality not cost

Information needs for policy discussions:

- Better understanding of various state and federal approaches
 - What are current uses for detection and quantitation limits?
- An evaluation of existing detection and quantitation limit procedures based on a set of criteria (to be determined by Committee)
- What are the implications of these procedures for regulatory reporting?

EPA (Mary Smith)

Elements needed in a final package:

- A complete, tested, understandable written procedure
- A sense of method performance (QA/QC)
- A procedure for validation and a procedure for laboratories
- A statement of uncertainty level around detection and quantitation levels

Information needs for policy discussions:

- Options clearly delineated
- Criteria for evaluation
- Application of criteria to options (e.g., Costs to labs, Costs to regulators, Scientific concerns, Variability and Bias)

Alice Shorett asked that committee members convene in their respective interest group caucuses during the lunch break to discuss the slate of nominees for the Technical Work Group. She indicated that the goal for the Technical Work Group was to have about two members from each interest group, to keep the total number to between 12 and 14. Ms. Shorett also asked one representative from each interest group to meet with the facilitators in a small group later during the lunch break to develop a draft list of desirable characteristics of a procedure for committee discussion in the afternoon.

Discussion of Desirable Characteristics

After lunch, Mr. Wheeler presented the initial list of desirable characteristics of detection and quantitation procedures that the small group working with the facilitators had drafted over the lunch break. He explained that the purpose of creating the list was to have evaluation measures to send to the Technical Work Group for use in their review and analysis of detection and quantitation procedures. The list is intended to be a beginning,

and will be modified over time. The proposed list of desirable characteristics included the following:

- Measurement Quality Objectives
 - Bias
 - Precision
 - Percentage of false positives/negatives
 - Quantitative signal
 - Uncertainty
- Evaluation of method performance
 - Ongoing vs. one time evaluation
- Prescriptive/descriptive
 - Specific number to meet
 - Common method
- Reflection of routine performance
- Addresses matrix issues
- Complication of procedures
 - Data processing
 - Lab procedures
- Relative cost (high, medium, low)
- Is it or could it be a clearly written procedure?
- Ability to communicate concepts (approach and outcomes)
- Is it an interlaboratory procedure?
- Relative implications of the procedure
 - How will existing CWA programs be impacted?
- Is the procedure:
 - Detection
 - Quantitation
 - Evaluated with existing data
 - A one-size-fits-all approach
 - Flexible
- Is the procedure affected by censored/uncensored data?

Following a brief discussion by the committee, Mr. Wheeler proposed and the committee agreed to have the Technical Work Group present the results of its evaluation of detection and quantitation procedures in matrix format.

Mr. Wheeler also proposed for committee discussion the following assignments to give to the Technical Work Group:

1. Definition of terms and glossary
2. Refinement and addition of criteria
3. Evaluation of procedures using agreed-upon criteria
4. Identification of concerns related to existing MDL detection and ML quantitation
5. List of uses for detection and quantitation (e.g. regulatory, CWA)

After discussion, the committee agreed to delete the fifth task because it would duplicate the survey of the states, which had already been decided.

Identification of Terms Needing Common Definitions

Richard Reding suggested the following terms as a “starter list” of terms for which a common definition was needed:

- Detection
- Quantitation
- Reporting limit
- False positive/negative rate

He distinguished this list of terms to be defined from a glossary of terms which are commonly used in discussions involving detection and quantitation and in laboratories. The Technical Work Group was asked to recommend definitions for terms and items for a glossary.

After discussion, members agreed to add “uncertainty” and the three points defined by Lloyd Currie in his first article on the subject in 1968² – L_c , L_d and L_q – to the list of terms needing an agreed-upon definition. Committee members agreed that the Technical Work Group should cite the sources of its proposed definitions.

Discussion of Pilot Testing Concept

Alice Shorett introduced for committee discussion the concept of pilot testing procedures, noting that pilot testing was a suggestion that had been made by a number of participants during the situation assessment interviews. She explained that pilot testing would occur following an evaluation of the procedures based on desirable characteristics, to ensure that promising procedures met expectations. She said it was important to discuss the concept of pilot testing early in the process. The first question was whether or not the committee thought the concept of pilot testing was a good one. If the answer was positive, the committee would need time to discuss how pilot testing would be done.

Committee members generally agreed that the concept of pilot testing was a good idea. Their discussion of the practical implications of developing and conducting a pilot test addressed timing, existence of available data, costs associated with pilot testing, and development of a study plan.

Ms. Shorett called for a brief break and suggested the committee hear public comment after the break.

Public Comment

Ken Osborn, East Bay Municipal Utility District (California)

Mr. Osborn said that he is the current Chair of the Standard Methods Joint Task Group but that he was addressing the committee as a Quality Assurance Officer from East Bay MUD. He briefly described quality control measures his utility had adopted several years

² L.A. Currie, Limits for Quantitative Detection and Quantitative Determination, *Analytical chemistry*, 1968, 40: 586-593.

ago, as a routine part of laboratory procedures. The system involves analyzing samples at 2 to 5 times the MDL with each batch of samples. This system requires no special scheduling. The results are entered into the Laboratory Information Management System (LIMS), and the long-term method accuracy is evaluated using control limits. He said that the results are used as an on-going, real-time measure of accuracy. They are also used as an on-going verification in the laboratories of non-detections. This quality control system allows for a long-term measure of detection capability. Daily LIMS quality control reports are generated, and the results are reported to the data user.

Shen-Yi Yang, US EPA Office of Solid Waste

Ms. Yang commented that the Office of Solid Waste in EPA had developed a quantitation limit procedure. The procedure was developed as an alternative approach for reporting limits to match real world matrices. She said she understands what was stated yesterday in committee discussions about its recommendations having implications across the board in the agency. As the committee moves forward with its process, she said it was important to consider that data generated by labs, and sometimes data generated by the program, cannot always be consistent with the regulation at 40 CFR part 136.

Composition of Technical Work Group and Assignments to the Group

Alice Shorett asked committee members for comments on the slate of nominees for the Technical Work Group that was distributed on Day 1 (Attachment D). Each interest group responded with their respective suggestions on the slate of nominees for their Technical Work Group positions. Committee members wanted to have at least one committee member per interest group serve on the Technical Work Group to provide continuity and facilitate communication between the committee and the Technical Work Group.

Several of the interest groups made the following suggested changes to their representation on the Technical Work Group:

- Environmental Laboratories: Richard Burrows replaced Gale Sutton.
- Environmental Community: David Rocke from University of California-Davis was added. (It was clarified that Dr. Rocke had agreed to participate if nominated.)
- States: Timothy Fitzpatrick replaced Robert Lippincott.
- EPA: Richard Reding said representatives from other federal agencies on the Technical Work Group would be Brad Venner from EPA and Bill Ingersoll of the US Navy.

Mr. Reding announced that the Technical Work Group would have a first call on Friday, June 24, 2005 at 1:00 PM (EDT) to get acquainted and discuss the assignments from the committee. He provided committee members with teleconference access information.

Bob Wheeler suggested a few edits to the ground rules for the Technical Work Group and said he would review them with the Technical Work Group during the first

teleconference. Mr. Wheeler then summarized the assignments from the committee to the Technical Work Group described above on page 21.

Wrap-up and Agenda Review

Alice Shorett then proposed the following agenda topics for the next meeting:

- Report from the Technical Work Group on draft definitions and a glossary
- Report from the States on how detection and quantitation approaches are used in state programs
- Matrix of existing detection and quantitation procedures
- Characteristics for existing detection and quantitation procedures
- Narrowing of procedures – which ones look promising?
- Pilot testing – how will it work?
- Policy Issues framing
- Criteria for an end product

Ms. Shorett explained that the facilitation team would distribute materials to committee members at least a week in advance of the next meeting for review.

She then read a very brief summary statement of the two-day meeting and explained that the facilitation team would draft a more detailed summary of the meeting and send it to committee members for review. The committee would finalize it at the September 29-30 meeting.

EPA's Mary Smith again thanked committee members for their participation and encouraged them to stay in touch with their respective constituencies.

Richard Reding adjourned the meeting at 3:45 p.m.

Certified As Accurate:

Mary Smith, Chair, EPA

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	North Creek Analytical Labs
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
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 Environmental Protection
<i>POTWs</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	
Marilyn Kuray	US Environmental Protection Agency
Michael Shapiro	US Environmental Protection Agency
Facilitators	
Alice Shorett	Triangle Associates, Inc.
Derek Van Marter	Triangle Associates, Inc.
Bob Wheeler	Triangle Associates, Inc.
Observers	
Joanne Dea	US Environmental Protection Agency
Vicki Ellis	
David Friedman	

Carla Hernandez
Meghan Hessenauer
Marion Kelly
Connie Oldhom
Beverly Randolph
Bruce Schillo
Upton Siddons
Bill Telliard
Danielle Tillman
Steve Wendelken
Richard Witt
Shen Yi-Yang
Susie Bruninga
Jim Christman
Ken Miller
Kenneth Osborn
Dale Rushneck
Jerry Schwartz
Tracy Siglin
Daniel Tremblay
Rock Vitale

Bureau of National Affairs
Hunton & Williams
CSC
East Bay MUD
Interface, Inc.
AF&PA
Exelon Corp.
Orange County Sanitation
Environmental Standards, Inc.

DISTRIBUTED MATERIALS

Committee's Packet of Materials

Agenda (June 21-22, 2005)

Charter of the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act (CWA) Programs (Filed May 31, 2005)

Draft Process Design (May 4, 2005)

Draft Committee Ground Rules (May 20, 2005)

Draft Technical Work Group Ground Rules (May 19, 2005)

Distributed at Meeting

Technical Work Group Potential Nominees by Category (June 21-22, 2005) and resumes

Presentation Handout on Common Base of Information (June 21, 2005)

Presentation Handout on Federal Advisory Committee Act Overview (June 21, 2005)

Individual Statements of Interest

Presentation Handout on Detection Limits: Controlling the Addiction with Lab QC
(public comment – June 22, 2005)

Final Committee Ground Rules (Approved June 21, 2005)

Key Policy Issues from June 21, 2005 FACDQ Meeting

Background Resources on Detection and Quantification