

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

Virginian Suites

1500 Arlington Blvd.

Arlington, VA 22209

S.S. Virginian Conference Center

Wednesday – Friday, June 6-8, 2007

Draft Summary of Meeting #7

Decisions at Meeting #7

*Note: Highlighted votes are straw polls and not official votes taken by the Committee. All votes reflect the order they were considered and voted on during the meeting.

1. Meeting Summary #6

The FACDQ agrees to approve the summary from Meeting #6, with the following revisions: Correction of name spellings for Tim Fitzpatrick and David Piller and removal of “(except California)” from locations within the document.

Vote: 18 Agree, 0 Not Opposed, 0 Disagree (6/6/07 AM)

2. Pilot Study Results & Draft Pilot Study Report

The FACDQ agree to use the Pilot Study results and the May 24, 2007 Draft Pilot Study Report to inform decision-making on choosing a procedure(s).

Vote: 15 Agree, 1 Not Opposed, 2 Disagree (6/6/07 AM)

NOT APPROVED

3. DQOs Decision

The FACDQ recommends that EPA Office of Water use the *EPA Guidance on Systematic Planning Using the Data Quality Objectives Process* in all Clean Water Act (CWA) programs.

Straw Vote: 17 Agree, 1 Not Opposed, 0 Disagree (6/6/07 PM)

***Vote:* 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent (6/8/07 PM)**

4. Measurement Quality Objective (MQO) Decisions

A. False Positive Rate MQO

The FACDQ recommends that a $\leq 1\%$ False Positive rate be used for Detection.

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree (6/6/07 PM)

***Vote:* 17 Agree, 0 Not Opposes, 0 Disagree, 1 Absent (6/8/07 PM)**

B. Proposed additional language for MQOs – Future Methods

The FACDQ recommends that during the DQO process, EPA will give special attention to assuring the analytical method produces comparable results, at or near the QL_{nat} , on split samples, analyzed in different labs with the same method, and will specifically describe the steps taken in the proposed rule.

Straw Vote: 16 Agree, 1 Not Opposed, 1 Absent (6/8/07 PM)

***Vote:* 14 Agree, 3 Not Opposed, 0 Disagree, 1 Absent (6/8/07 PM)**

C. MQOs for Quantitation for Promulgated Methods

The FACDQ recommends that for promulgated methods in 40 CFR Part 136 without established MQOs, the initial MQO for Quantitation upon implementation of the new quantitation procedure is a specific False Negative rate ($\leq 5\%$) to be implemented through a multiplier of the Detection Limit (determined by the FACDQ recommended Single Lab Procedure for Detection). The Precision and Accuracy MQOs for individual analytes/methods would be generated and promulgated, as the data to

support those MQOs becomes available.

The FACDQ requests that the Technical Work Group establish or recommend a procedure to add MQOs to existing methods.

Straw Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent (6/7/07 PM)

***Vote:* 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent (6/8/07 PM)**

D. Limits for QL MQOs for Future Promulgation of New or Updated Methods

The FACDQ recommends the Technical Work Group develop recommendations for target MQO bounds for compliance and enforcement that define Quantitation. The TWG will bring these recommendations back to the FACDQ.

For example:

A. Precision \leq 30% RSD

2. Accuracy (measured as recovery for single determination) = 20-180%
3. False Negative rate \leq 10%
4. Ratio of Accuracy to Precision must be no less than 1.0

Example: 40% Recovery / 20% RSD = 2 O.K.,

Example: 20% Recovery / 30% RSD = .66 Not Acceptable

Straw Vote: 13 Agree, 5 Not Opposed, 0 Disagree (6/8/07 PM)

***Vote:* 12 Agree, 5 Not Opposed, 0 Disagree, 1 Absent (6/8/07 PM)**

E. MQO Bounds

The FACDQ recommends that EPA establish quantitative MQO bounds for relevant Data Quality Indicators (DQIs) that define Quantitation for intended CWA uses. These bounds would be offered for public comment by EPA.

Straw Vote: 13 Agree, 4 Not Opposed, 1 Disagree (6/8/07 PM)

Vote: 9 Agree, 7 Not Opposed, 1 Disagree, 1 Absent (6/8/07 PM)

NOT APPROVED

F. MQOs for Future Promulgation of Methods

The FACDQ recommends, for future method promulgation, that target MQOs for DQIs, such as Precision, Accuracy, Method Specified Qualitative Identification, and False Negative error rates derived from the DQO process, be established for Quantitation Limits in Part 136. If the target MQOs cannot be met, EPA may promulgate with rationale.

Straw Vote: 9 Agree, 9 Not Opposed, 0 Disagree (6/8/07 AM)

The FACDQ recommends, for future method promulgation, that target MQOs for Precision and Accuracy derived from the DQO process be established for QLs in Part 136. In addition, DQIs such as method specified quality identification and False Negative error rate would be considered. If the target MQOs cannot be met, EPA may promulgate with rationale.

Straw Vote: 9 Agree, 5 Not Opposed, 4 Disagree (6/8/07 AM)

5. Multi/Inter Lab Approaches

The FACDQ asks the Technical Work Group to develop a recommended process for determining a QL_{nat} .

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree (6/8/07 AM)

Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent (6/8/07 PM)

The FACDQ recommends that EPA promulgate how QL_{nat} is derived.

Straw Vote: 10 Agree, 6 Not Opposed, 2 Disagree (6/8/07 AM)

Straw Vote: 10 Agree, 7 Not Opposed, 1 Absent (6/8/07 AM)

Vote: 7 Agree, 10 Not Opposed, 0 Disagree, 1 Absent (6/8/07 PM)

The FACDQ recommends that EPA develop a procedure for establishing a QL_{nat} using the framework identified by the FACDQ. The Technical Work Group will develop this framework for FACDQ consideration.

Straw Vote: 6 Agree, 10 Not Opposed, 1 Disagree, 1 Abstained (6/8/07 AM)

The FACDQ asks the Technical Work Group to develop a recommended procedure(s) for determining QL_{nat} .

Straw Vote: 16 Agree, 1 Not Opposed, 1 Disagree (6/8/07 AM)

The FACDQ recommends that EPA establish after public comment how QL_{nat} is derived.

Straw Vote: 9 Agree, 4 Not Opposed, 5 Disagree (6/8/07 AM)

The FACDQ recommends that EPA develop a Multi Lab Procedure for establishing a QL_{nat} using the framework identified by the FACDQ. The Technical Work Group will develop this framework for FACDQ consideration.

Straw Vote: 0 Agree, 1 Not Opposed, 13 Disagree, 4 Abstained (6/8/07 AM)

The FACDQ asks the Technical Work Group to develop a recommendation for a process that considers both Multi and/or Inter Lab Procedures in developing a QL_{nat} .

Straw Vote: 13 Agree, 3 Not Opposed, 1 Disagree, 1 Absent (6/8/07 AM)

6. Recommendations on Procedures

A. The FACDQ recommends the Technical Work Group continue to develop the specifics for the following:

Single Laboratory Detection Limit Procedure

The ACIL Procedure, with modifications indicated by the Pilot Study results and informed by concepts from the Consensus Group and LabQC Procedures, is recommended for a Single Laboratory

Detection Limit Procedure.

Vote: 17 Agree, 1 Not Opposed, 0 Disagree (6/8/07 AM)

B. The FACDQ recommends the Technical Work Group continue to develop the specifics for the following:

Single Laboratory Quantitation Limit Procedure

The ACIL Procedure, with modifications indicated by the Pilot Study results and informed by concepts from the Consensus Group and Lab QC procedures, as well as decisions by the FACDQ at its June 2007 meeting.

Vote: 16 Agree, 2 Not Opposed, 0 Disagree (6/8/07 AM)

7. Uses Decisions

A. DL_{nat}

The FACDQ recommends the Policy Work Group explore the deletion of DL_{nat}, the possible policy changes to the document, and their implications for bringing back to the FACDQ. The Policy Work Group will also explore other policy issues not completed at the June 2007 meeting.

Straw Vote: 15 Agree, 3 Not Opposed, 0 Disagree (6/8/07 PM)

Vote: 16 Agree, 1 Not Opposed, 0 Disagree, 1 Absent (6/8/07 PM)

2. Uses Document

The FACDQ directs the FACDQ Work Groups to use the straw vote decisions as a starting point for writing the Uses portion of the Final Report and other activities subject to revisions based on a final vote to occur later.

Vote: 16 Agree, 0 Not Opposed, 0 Disagree, 2 Absent (6/8/07 PM)

- *A subscript “nat” is used to designate the nationally-promulgated DL or QL – DL_{nat} or QL_{nat}*
- *A subscript “lab” is used to designate the laboratory-specific DL or QL – DL_{lab} or QL_{lab}*

- A subscript “per” is used to designate the permit-specified $QL - QL_{per}$
- A subscript “st” is used to designate the state-optional DL or $QL - DL_{st}$ or QL

The FACDQ agreed to allow EPA come up with a new acronym for a situation where an analyte is detected below the QL_{per} . The acronym will replace “DNQ” and must fit into the conditions of the ICIS system. The facilitator used the acronym “DBQp” for purposes of completing this document. (6/7/07 PM)

1. Lab-Determined Detection Limits (DL_{lab} s) and Quantitation Limits (QL_{lab} s)

Recommendation: The FACDQ recommends that EPA promulgate the descriptive single-laboratory procedure(s) recommended by the FACDQ for individual laboratories to determine their Detection and Quantitation Limits. The procedure(s) should have the following two capabilities:

1. Demonstrate the lab’s performance at a specified level.
2. Determine the lowest possible value achievable by the lab.

The FACDQ further recommends that the descriptive procedure(s) replace the one currently in 40 CFR Part 136 Appendix B.

2. Method Promulgation

Recommendation: The FACDQ recommends that when the EPA promulgates future analytical methods in 40 CFR Part 136, Detection Limits (DL_{nat} s) and Quantitation Limits (QL_{nat} s) shall be included with the methods using the procedure(s) recommended by the FACDQ.

The FACDQ agreed to remove all language referring to a published table of limits in a promulgated rule in 40 CFR Part 136 as well as the pre-existing footnote. (6/7/07)

The FACDQ also agreed to remove the following language though it was agreed that the Final Report Work Group would keep it under consideration when drafting an introductory paragraph: “These limits will serve to define the minimum required performance of a laboratory and may assist in comparing performance of one method to another (facilitating selection of a method most suitable for a given use), and may define important thresholds for use in evaluating compliance. (See the section titled “NPDES Permits and Compliance Uses, Recommendation 5.A & B”).”
(6/7/07 AM)

3. Verification of Laboratory Proficiency of Detection and Quantitation Limits

Recommendation: The FACDQ recommends developing a process for initial and on-going verification of DL_{lab} s and QL_{lab} s by laboratories. This recommendation includes the following guidance:

- The FACDQ recommended procedure (e.g., what goes into 40 CFR Part 136 Appendix B) should include on-going verification of DL_{lab} and QL_{lab} (either explicitly within the procedure or as an “attachment” if the FACDQ chooses to recommend a consensus procedure)
- Meeting MQOs for use
- Separate initial vs. on-going verifications
- Strive for feasibility, practicality, representativeness, and cost-effectiveness

The FACDQ agreed to replace “demonstration” from this section with the word “verification” and to strike the pre-existing footnote and to add the bullet: “Meeting MQOs for use.” (6/7/07 AM)

4. Future Updates of Promulgated Analytical Method DL_{nat} s and QL_{nat} s

Recommendation: The FACDQ recommends that EPA periodically review current capabilities of promulgated analytical methods. The focus of this review should be on methods where there have been significant improvements in Detection or Quantitation Limits or on methods that do not contain DL_{nat} s or QL_{nat} s. This review would be particularly important for cases where Detection and Quantitation Limits are critical to the permit program (e.g., those required for very low WQBELs). EPA should focus on analytes for which current methods provide poor performance or do not meet program needs. Using best judgment and where resources are available, EPA shall update DL_{nat} and QL_{nat} limits on an on-going basis. EPA should also consider information submitted by states and/or other qualified third parties. EPA shall publish a Federal Register Notice announcing the DL_{nat} s and QL_{nat} s it proposes to update. Provisions later in this document are for the purpose of providing EPA with robust data sets for updating and or creating DL_{nat} s and QL_{nat} s.

The FACDQ agreed to leave "4." as it is with the understanding that "shall" (...EPA shall update DL_{nat} and QL_{nat} limits on an on-going basis.) will remain. (6/7/07 AM)

4. The FACDQ recognizes that the existence of WQBELs at concentrations less than quantitation limits presents a number of NPDES-related issues. These include appropriate approaches for:

- Calculating monthly averages
- Determining compliance with daily maximum limits and monthly average limits
- Reporting data, and
- Appropriate compliance response in light of data uncertainty and the need for the protection of public health and the environment.

To deal with these various issues, the FACDQ recommends a balanced response as outlined below.

States that have been delegated the NPDES program from EPA have the authority under the Clean Water Act to adopt regulatory provisions that are different, but no less stringent than, those required under federal regulations. Such provisions, if authorized or not prohibited by state law, would operate in lieu of the following recommendations and could include a QL_{st} value lower than the nationally promulgated QL_{nat} . In that case, the QL_{st} applicable under the state program would be used for determining compliance, reporting, and other applicable requirements.

A. Recommendations for NPDES Permits and Compliance Uses where a QL_{nat} exists and for WQBELs at concentrations less than QL_{nat} . If the permitting authority requires use of a method more sensitive than the method for which a QL_{nat} exists, go to section B:

The FACDQ agreed to include the following language: "If the permitting authority requires use of a method more sensitive than the method for which a QL_{nat} exists, go to section B."

Straw Poll: 14 Agree, 4 Not Opposed, 0 Disagree (6/7/07 PM)

1. The FACDQ recommends that a Part 136 DL_{nat} and QL_{nat} determined by the procedure recommended by the FACDQ be promulgated for each method/analyte combination which shall be the upper bound for lab performance. The regulator shall insert QL_{per} s in permit or in rule as appropriate. The default QL_{per} is the lowest Part 136 promulgated QL_{nat} . The regulator would then

consider whether the method associated with this QL_{nat} is the most appropriate method considering sensitivity, selectivity, and/or matrix effects and adjust the QL_{per} accordingly.

The FACDQ agreed not to include the following language: “All the following does not apply if the QL_{nat} is not the most sensitive method QL_{nat} .”
Straw Poll: 8 Agree, 8 Not Opposed, 2 Disagree

The FACDQ agreed to the following language: “...the method associated with this QL_{nat} is the most appropriate method considering sensitivity...”

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree (6/7/07 PM)

The FACDQ agreed to the following language: The regulator shall insert QL_{per} s in permit or in rule as appropriate.

Straw Vote: 15 Agree, 3 Not Opposed, 0 Disagree (6/7/07 PM)

The FACDQ agreed to remove the following language: “The QL_{per} shall be applicable for the term of the permit unless the regulator reopens and modifies the permit” as well as #3 with the two options regarding the life of the permit.

Straw Vote: 9 Agree, 9 Not Opposed, 0 Disagree (6/7/07 PM)

2. The permit shall also contain a

condition that the permittee’s QL_{lab} shall be at or below the QL_{per} . The permit shall require permittees to report DL_{lab} s and QL_{lab} s as determined by the procedure recommended by the FACDQ and maintain such information for a period of at least five years.

3. For a list of analytes as defined by EPA, the permittee shall ensure that the DL_{lab} s and QL_{lab} s are determined using the steps of the procedure to determine the lowest possible value by the lab for setting QL_{lab} s and DL_{lab} s.

The FACDQ agreed on the following language:

3) For a list of analytes as defined by EPA, the permittee shall ensure that the DL_{lab} s and QL_{lab} s are determined using the steps of the procedure to determine the lowest possible value by the lab for setting QL_{lab} s and DL_{lab} s.

Straw Vote: 10 Agree, 8 Not Opposed, 0 Disagree (6/7/07 PM)

4. The FACDQ further recommends, for purposes of updating Part 136 DL_{nat} s and QL_{nat} s, that EPA require the lab-specific information be reported in the Integrated Compliance Information System (ICIS).

The FACDQ agreed to return to the option of deleting the new **4)** if it is found to be duplicative in later sections of the document. *(6/7/07 PM)*

5. Implementation in NPDES Permits:

- a) Set average and daily maximum permit limits at the WQBEL.
- b) Assign zero for values less than the permit QL_{per} when determining average and daily maximum discharge levels.

The FACDQ agreed to rename the title of the new section 5 from:

“Recommendation for NPDES Permits and Compliance Uses for WQBELs when QL_{nat} s do exist” to ***“Implementation in NPDES Permits.”*** *(6/7/07 PM)*

Rationale: While the FACDQ recognizes that values between a given laboratory's DL_{lab} and QL_{lab} have a higher level of uncertainty, the science suggests they are unlikely to be zero. However, assigning a non-zero value where an analyte is detected below the QL_{per} (DBQp) would have significant compliance and enforcement implications. Therefore, the committee recommends assigning a zero in these cases.

The FACDQ agrees on the following language:

Note: The FACDQ agrees that this rationale concept is important and will be included in the Final Report.

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree (6/7/07 PM)

1. To

The FACDQ agreed to change “above” to “below.” (6/7/07 PM)

determine NPDES permit compliance, compare average and daily maximum discharge levels, calculated in accordance with item (d.ii.) below, to the respective WQBEL.

d) A permittee must report to the permitting authority all information in the following manner:

i. When reporting daily maximum sample results:

i. For values less than the DL_{lab} , report “ND” (not detected) on the DMR.

ii. For values greater or equal to the DL_{lab} and less than the QL_{per} , report “DBQp” (detected below QL_{per}) on the DMR.

iii. For values greater than or equal to the QL_{per} , report the actual values on the DMR.

i. When reporting averages:

1. Where all values used to calculate an average are less than DL_{lab} , report “ND” on the DMR.

2. Where all values used to calculate an average are greater than or equal to DL_{lab} but less than QL_{per} , report “DBQp” on the DMR.

3. When values used to calculate an average are a combination of ND and DBQp values, report “DBQp” on the DMR.

4. When any value used to calculate an average is greater than or equal to QL_{per} , report on the DMR the average as calculated in item (5.A.5.b) above.

The FACDQ agrees that DL_{lab} will remain in **i.** and **ii.** With the proviso that there will be consideration of this post the MQO discussion.

Straw Vote: 15 Agree, 3 Not Opposed, 0 Disagree (6/7/07 PM)

i. Additional reporting requirements:

1. The regulator shall require that the permittee report the DL_{lab} and QL_{lab} (for purposes of updating methods and to determine compliance with the conditions of the permit.) The permitting authority shall report the DL_{lab} , QL_{lab} , and QL_{per} for each analyte to EPA in ICIS.
2. The regulator may require the individual numeric result for any value that is greater than or equal to the DL_{lab} and less than the QL_{per} be reported in a supplemental report.

The FACDQ agreed to the remove the second sentence in **iii.b**: "Potential uses would be to determine reasonable potential and for public knowledge."
Straw Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent (6/7/07 PM)

3. The permittees shall maintain individual numeric results for a period of at least five years.
6. Permits shall include language that triggers additional steps when a "significant number of" (to be determined in the permitting process) DBQp values are reported. These steps may include additional or accelerated monitoring, analytical studies such as matrix studies, pollutant minimization programs, or other permit conditions outside of the determination of compliance with effluent limitations. Reports under such provisions will be done outside of the DMR reporting process, except that any additional effluent testing performed using approved analytical methods as part of the special studies must be reported according to the protocol in (5.A.5.d.iii).

B. Recommendations for NPDES Permits and Compliance Uses for WQBELs when no QL_{nat} exists:

- 1) In the absence of QL_{nat} , the permitting authority is free to establish it's method for determining compliance for analytes that have limits/water quality standards at a level lower than that which can be detected and/or quantified.

2) For a list of analytes as defined by EPA, the permittee shall ensure that the DL_{lab} s and QL_{lab} s are determined using the steps of the procedure to determine the lowest possible value by the lab for setting QL_{lab} s and DL_{lab} s.

The FACDQ agreed to 1) and 2)

Straw Vote: 17 Agree, 1 Not Opposed, 0 Disagree (6/7/07 PM)

3) The FACDQ further recommends, for purposes of developing Part 136 DL_{nat} s and QL_{nat} s, that EPA require the lab-specific information be reported in the Integrated Compliance Information System (ICIS).

Note: The FACDQ recommends that EPA reconsider the usefulness of this requirement after time.

The FACDQ agreed to the following language:

3) The FACDQ further recommends, for purposes of developing Part 136 DL_{nat} s and QL_{nat} s, that EPA require the lab-specific information be reported in the Integrated Compliance Information System (ICIS).

Note: The FACDQ recommends that EPA reconsider the usefulness of this requirement after time.

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree (6/7/07 PM)

7. Other Uses to Consider

Recommendation: The FACDQ tabled the discussion on recommendations regarding the use of Detection and Quantitation for other uses including but not limited to the following:

- ambient monitoring 305(b)
- pretreatment
- non-regulatory operational monitoring
- stormwater monitoring
- other studies, such as fish tissues or biosolids characterization

- reasonable potential analysis
- effluent guidelines development
- limit derivation
- development of water quality criteria

The FACDQ agreed to the language in the section "Other Uses to Consider."
Straw Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent (6/7/07 PM)

8. Alternative Test Procedures

Recommendation: The FACDQ tabled the option of developing recommendations to EPA on updating the Alternative Test Procedures (ATP) program. The FACDQ recommends that the ATP program be updated to be consistent with recommendations in this document.

The FACDQ agreed to the language in the section "Alternative Test Procedures."
Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree (6/7/07 PM)

9. Great Lakes Initiative (GLI)

Recommendation: The FACDQ recommends that FACDQ recommendations should not supersede the current GLI provisions. There is no significant conflict between the anticipated FACDQ recommendations and the GLI.

The FACDQ agreed to the language in the section "GLI."
Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree (6/8/07 PM)

8. Matrix Effects (Use 6.)

The FACDQ recommends that EPA consider how Matrix Effects impact Detection and Quantitation. The FACDQ requests that the Policy Work Group bring back a conceptual recommendation including details to be considered.

Vote: 17 Agree, 1 Not Opposed, 0 Disagree (6/8/07 PM)

9. Implementation of the FACDQ Recommendation

The FACDQ recommends “9. Implementation of the FACDQ Recommendation” be removed from the Uses Document for consideration by a work group. However, the importance of these issues related to Uses should not be separated. A work group of the FACDQ is tasked with bringing recommendations on the implementation issues back to the FACDQ.

Vote: 18 Agree, 0 Not Opposed, 0 Disagree (6/8/07 PM)

Day 1 – Wednesday, June 6, 2007, 9:00 AM – 8:00 PM

*Note: All perspectives offered at the meeting are not reflected in this summary. However, audio tapes of the entire meeting are available.

Opening and Introductions

Richard Reding, EPA Designated Federal Officer (DFO), opened the meeting at 9:00 AM and welcomed the participants. Alice Shorett, facilitator, then introduced the facilitation team from Triangle Associates and initiated a round of introductions of the advisory committee members. Ms. Shorett and Mr. Reding noted the absence of Committee members Steve Bonde and David Kimbrough.

Ms. Shorett observed that the committee had made significant progress over the past two years toward achieving the objectives in the Committee's charter, which were to "provide advice and recommendations on approaches for the development of detection and quantitation procedures and uses of these procedures in Clean Water Act (CWA) programs." For example, at the committee's December meeting, the Committee had agreed to a document describing the Uses the Committee wants a recommended procedure to fulfill. The Committee had also concluded that it needed more time to fully complete the objectives of the charter and had requested that the Committee's charter be extended to allow further progress.

She reported significant Committee work that had occurred since the December meeting, including

- A meeting of the *Pilot Study Analysis Team* in Seattle in January to discuss the findings of the Pilot Study and outline the Pilot Study Report and Procedures Report.
- Eighteen *Technical Work Group* meetings focused on the Pilot Study Report and Procedures Report; additional work on Measurement Quality Objectives (MQOs); and recommendations related to procedures, including recommending a modified Single Lab Procedure for Detection.
- Seven *Policy Work Group* meetings, including an in-person meeting in Seattle, to further refine the Uses document and to make progress on issues regarding Data Quality Objectives (DQOs), implementation, and verification.

Ms. Shorett recalled advice at the July 2006 meeting from Ephraim King, EPA's Director of the Office of Water, who had urged the Committee to "find the issues you can get close to resolution on." Using this approach, he said, the Committee had "a wonderful opportunity to find middle ground and set the future in

terms of CWA method decision-making for the next 20-30 years.” Where the Committee could not reach agreement, Mr. King had urged the members to identify the divergent opinions and move on.

Ms. Shorett encouraged members to listen carefully and to search for ways to develop a package that would meet the needs of all the interests around the table. This would require give and take, she said.

Ms. Shorett then turned the microphone over to Mary Smith of EPA.

Welcome from EPA

Mary Smith thanked the Committee members for their hard work. She said that the Committee’s charter had been extended because of the progress made. Ms. Smith said she hoped the Committee would reach a consensus on Uses at this meeting and continue to push as far as they could on other issues so that the FACDQ could wrap up successfully in December.

Agenda Overview and Grounding

Ms. Shorett then briefly reviewed the agenda for the three-day meeting and the Committee’s ground rules for consensus decision-making. She pointed to the Final Report Outline on the wall and encouraged Committee members to focus on the “gaps” that needed to be filled so that the Final Report Work Group could begin its task.

The goals for the meeting, she said, were to:

- Approve December 2006 FACDQ Meeting #6 Summary
- Agree to use the Pilot Study results and Pilot Study Report to inform decision-making on choosing a procedure/s
- Make fundamental decisions on Method Quality Objectives (MQOs)
- Recommend procedure(s) or, at a minimum, an approach for making final decisions on recommended procedure/s
- Agree on the Uses document

- Discuss and provide direction on implementation, Data Quality Objectives (DQOs), and verification
- Make assignments to the Policy Work Group, the Technical Work Group and the Final Report Work Group

Review and Approval of Draft Meeting Summary #6 (December 6-8, 2006)

Ms. Shorett asked the committee for comments on the summary of Meeting #6. After agreeing to the changes described in the box below, the Committee approved the summary of Meeting #6.

Action: The FACDQ agrees to approve the summary from Meeting #6, with the following revisions: Correction of name spellings for Tim Fitzpatrick and David Piller and removal of “(except California)” from locations within the document.
Vote: 18 Agree, 0 Not Opposed, 0 Disagree

Caucus Reports on Outreach, Approaches, and Expectations for the Meeting

Ms. Shorett asked each caucus to report any outreach it had conducted.

Caucus

- The *State caucus* expressed optimism on reaching agreement at this meeting and a willingness to agree to disagree if a consensus could not be reached.
- The *Public Utilities caucus* said its approach was to be forward thinking, especially in terms of a final recommendation to EPA. It encouraged the Committee to step back from the details of the issues in dispute and to search for agreement on general concepts and to remember that the recommendations the Committee came to needed to be understandable, in lay-person’s terms, to all of their constituents.
- The *Industry caucus* echoed many of the previously-stated sentiments and said that a measure of the meeting’s success would be EPA’s decision to continue the Committee’s work.
- The *Environmental Community caucus* echoed the need to avoid getting caught up in the details and to lose sight of the progress made over the past two years.

Rick Rediske reported that he had recently attended the 50th Great Lakes Conference and had heard quite a bit of agreement from researchers on the need to have uniform standards for Detection and

Quantitation as well as MQOs. He said there was real interest among scientists on the issues the Committee was addressing.

- Richard Burrows of the *Environmental Laboratory caucus* told the Committee he has discussed the American Council of Independent Laboratories (ACIL) procedure with constituents and that he would consider this meeting a success if the Committee made the decisions necessary to complete a recommendation for a Single Lab procedure. He mentioned that a national environmental conference would be held at the end of August which the National Environmental Laboratory Accreditation Conference (NELAC) and EPA would attend and that members of the FACDQ would present in a "Detection and Quantitation" section. He emphasized that the meeting would be a great opportunity to spread the word about the FACDQ's recommendations. Cary Jackson added that he would like to invite two of his constituents, who might be impacted by FACDQ recommendations, to the September FACDQ meeting.

Mary Smith thanked the caucuses for their statements. She asked the Committee to be efficient in reaching consensus at this meeting and encouraged clarity in its recommendations.

Pilot Study Report

Robert Wheeler introduced the Pilot Study Report as a summary that was intended for those who were not on the Technical Work Group. He then introduced Ken Miller, an independent consultant from CSC Inc., who gave a brief PowerPoint presentation on the Pilot Study.

Mr. Wheeler then invited Technical Work Group members to comment on the Report and to answer questions from the FACDQ. Technical Work Group members offered the following comments and responses to Committee questions:

Information about the Pilot Study and the Pilot Study Report

- Because of resource and time constraints the Technical Work Group had selected specific analytes for testing. The success and failure rates of Detection reflected a mixture of 'well behaved' analytes and 'tough' ones. If the entire list of known analytes had been analyzed, the success rate would have been much higher.
- The data spread was similar for all analytes tested.
- Not all labs volunteered to do all of the analytes in method 300.

- Some of the procedures assumed that labs were at similar performance capabilities; but that may not have been the case. The non-normally distributed data may have had an affect.
- All data units were in micrograms per liter. MQOs were quantified by % recovery or Relative Standard Deviations (RSD).
- The Pilot Study Report attempted to sort out the cause of failures, whether it was a procedure failure, a method failure, a lab failure, or some combination.

Pilot Study Results

- The Pilot Study produced a considerable amount of data that are well suited for decision-making.
- There were significant differences in values among labs for both Detection and Quantitation determinations, on the order of several orders of magnitude for some test values.
- Generally speaking, the ACIL Procedure met the Pilot Study MQOs more frequently than the other procedures tested. The Lowest Concentration-Minimum Reporting Level (LC-MRL) did quite well but its targets were more stringent than the Pilot Study MQOs; thus, for some methods, a limit could not be estimated. The American Society for Testing and Materials Standards (ASTM)'s Interlaboratory Detection Estimate (IDE) did better on an Inter-Lab basis and the Interlaboratory Quantitation Estimate (IQE) came close to target RSDs.

After discussion, the Committee considered whether or not to agree to use the Pilot Study results to inform decision-making on choosing a procedure. Some Committee members indicated a concern that the results in the Pilot Study Report had not been thoroughly considered and evaluated. After discussion, the Committee was not able to reach consensus on a motion in favor of using the Pilot Study results to inform decision-making on choosing a procedure.

Action: The FACDQ agree to use the Pilot Study results and the May 24, 2007 Draft Pilot Study Report to inform decision-making on choosing a procedure(s).

Vote: 15 Agree, 1 Not Opposed, 2 Disagree (6/6/07 AM)

NOT APPROVED

Procedures Report

Mr. Wheeler introduced the Procedures Report as a product that the Technical Work Group had put a lot of time and energy into and introduced Brian Englert, Environmental Scientist, U.S. EPA, who gave a brief PowerPoint presentation on the report. Mr. Wheeler then opened the discussion and asked Technical Work

Group members to answer questions from the Committee. Technical Work Group members offered the following comments and responses to Committee questions:

- The report has a lot of useful information, but it is not complete and, therefore, should be considered a work in progress.
- It is a summary of how the procedures the Committee is considering compared against the criteria in the document, “What Do We Need A Procedure To Do?”
- The report did not reflect Technical Work Group consensus.
- A thorough discussion of procedures had to be limited until the Committee agreed on MQOs.

Technical Work Group Procedures Recommendations

Richard Burrows summarized the modifications he and a subgroup of the Technical Work Group had made to the ACIL Single Lab Procedure, the procedure the Technical Work Group was recommending to the FACDQ as a Single Lab Procedure for Detection. The modifications were designed to address the conditions where the ACIL Procedure had not worked well in the Pilot Study and to incorporate some of the advantages of some of the other procedures under consideration. These included strengthening the requirement for the 2x multiplier (which all labs had not followed reliably in the Pilot Study) and better addressing intermittent blank contamination.

Technical Work Group members commented that they had considered making modifications to other procedures but favored a modified ACIL Procedure as the Single Lab Detection Procedure for the following reasons: it had the highest probability of success, given time and resource constraints; it was fairly well-developed; and it met 14 of 15 criteria in the document, “What Do We Need A Procedure to Do?”

The Technical Work Group indicated that a modified ACIL Procedure was likely also a good choice for the Single Lab Quantitation Procedure, but said that the Group had not reached consensus on eliminating the LCMRL procedure for Quantitation.

Committee Discussion on Procedures Recommendations

A member asked whether the ACIL Single Lab or the modified ACIL Single Lab Procedure addressed what a lab would do when a test value was below what a lab could positively identify. After discussion, the Committee requested that the ACIL authors include guidance on how labs should evaluate data near or above the Detection Limit and how verification should be addressed within the procedure.

In the discussion, it was noted that while modifications could be made to the procedure, it was still necessary to know what the target was. For that to happen, MQOs had to be established; therefore, the MQO issue needed to be resolved first.

The Committee, therefore, moved to a discussion of Data Quality Objectives/Method Quality Objectives (DQO/MQOs) before making decisions on procedure recommendations.

DQOs/MQOs

Mr. Wheeler invited Committee member Jim Pletl to start this session by presenting his proposal to focus and reach agreement on broad DQO concepts before addressing specific MQO issues. Mr. Pletl said that the DQO process could be developed in the same way that the Committee had developed the document, "What Do We Need A Procedure To Do?" He said that the DQO process could be an iterative one for matching needs with tools and helping one decide if the performance of a method was adequate to make a decision. The process could have the following steps: first, decide what the uses are; second, determine the informational needs, and, third, decide what tools would meet those uses and needs.

Mr. Wheeler then distributed a Technical Work Group document entitled, "Role of MQOs in Implementation of FACDQ Candidate Detection and Quantitation Procedures" (Document# FACDQ7-05). The intent of the document, he said, was to facilitate Committee discussions and decision-making related to MQOs. The FACDQ reviewed and discussed the content of the handout and agreed to discuss both DQOs and certain aspects of MQOs, such as applying a multiplier to the Detection Limit and considering minimum bounds.

After discussion, the Committee recommended that EPA follow the DQO process, a process that presently exists in EPA guidance.

The Committee assignment over lunch was to work in caucuses to review and discuss the handout and to

consider their caucus' positions related to DQOs and MQOs.

Lunch Break

DQOs/MQOs Discussion (continued)

The FACDQ reconvened after lunch to discuss DQOs and MQOs. (The MQO document was projected on a screen before the Committee.) Mr. Wheeler facilitated the Committee's extended discussion of MQOs for different uses and appropriate recommendations to EPA. Several caucuses offered additional options and revised language that were added to the MQO document.

The Committee then met in caucuses to discuss the MQO document and proposed language.

After the Committee reconvened, the Committee took a straw poll on two of the items in the revised MQO document: a recommendation related to using the EPA Guidance on Systematic Planning using the Data Quality Objectives Process and a recommendation on a False Positive rate. The results were as follows:

Action: The FACDQ recommends that EPA Office of Water use the *EPA Guidance on Systematic Planning Using the Data Quality Objectives Process* in all Clean Water Act programs.

Straw Vote: 17 Agree, 1 Not Opposed, 0 Disagree

Action: The FACDQ recommends that a $\leq 1\%$ False Positive rate be used for detection.

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree

After the straw votes, the Committee had another extended discussion of MQO options for different uses, such as future promulgation of methods and Quantitation for promulgated methods.

At the end of the discussion, it was agreed that the facilitators would prepare a brief summary of the issues and options for a subgroup to develop a proposal to present to the Committee on Day 2.

Public Comment

There was no public comment.

Wrap-up and Adjourn for the Day

Robert Wheeler asked designated subgroup members to arrive at 8:00 AM the following morning, an hour before the meeting was to convene, to discuss the revised MQO language recommendation.

Mr. Wheeler briefly reviewed the agenda for the next day and noted that its focus would be on the Uses document.

Richard Reding, DFO, adjourned the meeting at 8:00 PM.

Day 2 – Thursday, June 7, 2007, 9:00 AM – 6:30 PM

Welcome and Agenda Review

Richard Reding, DFO, opened the meeting at 9:00 AM and turned the meeting over to the facilitator, Alice Shorett.

Ms. Shorett reported that the subgroup formed late on Day 1 had met at 8:00 AM to work on a “hybrid” MQO/DQO concept and would present its proposal later in the day. The first agenda item would be a discussion of the Uses document.

Revised Uses Document

Ms. Shorett recalled that the Policy Work Group had met in Seattle to further refine the Uses document, focusing specifically on items that had been presented in gray-scale in the summary of the December 2006 FACDQ meeting. She said that the document reflected a package that included a balance of elements that were essential to every caucus. She asked the Committee to keep that balance in mind while working through the document. She then asked Tom Mugan to review the changes the Policy Work Group proposed.

Mr. Mugan gave the Committee an overview of the Policy Work Group’s revised Uses document (Document # FACDQ7-08). He explained the nomenclature the Group used to define various Detection and Quantitation Limits, as follows:

- *A subscript “nat” denoted a nationally-promulgated DL or QL – DL_{nat} or QL_{nat}*
- *A subscript “lab” denoted a laboratory-specific DL or QL – DL_{lab} or QL_{lab}*

- *A subscript “per” denoted a permit-specified $QL - QL_{per}$*
- *A subscript “st” denoted a state-optional DL or $QL - DL_{st}$ or QL_{st}*

Mr. Wheeler then led the Committee through the document, use by use. Member questions, responses, and comments are presented in the discussion below each recommendation. In the few cases where the Committee proposed revised language to a recommendation, those proposals are shown.

Note: *While the Committee reached tentative agreements and conducted several “Straw Votes” for portions of the Uses document, it did not have time to finalize agreements on the Uses document. The Committee requested that the Policy Work Group consider certain modifications to the document and report to the Committee during a teleconference Committee meeting at some future date. Therefore, agreements on Uses shown below are tentative and straw votes will need to be finalized at a future Committee meeting.*

1. Lab-Determined Detection Limits (DL_{lab} s) and Quantitation Limits (QL_{lab} s)

Comment (Larry LaFleur): The intent of the following language: “Demonstrate the lab’s performance at a specified level or at its reporting level for QL_{lab} and DL_{lab} ” is to use a procedure that demonstrates one had met or exceeded QL_{lab} .

Comment (Richard Burrows): I think this procedure is not necessarily to verify the lab’s ability to meet a certain limit. It is to demonstrate what the lab’s capability is.

Comment (Jim Pletl): The language should be changed to reflect that.

Comment (Larry LaFleur): It is to do both. It is to demonstrate the capability of the laboratory or to demonstrate that it can meet or exceed specified performance criteria like a QL_{nat} .

A note was made to the Final Report Work Group that clarity was needed surrounding the language in, “at a specified level.” The FACDQ tentatively agreed to move forward with the following language.

Action: The FACDQ agreed to move forward with the following language.

1. Lab-Determined Detection Limits (DL_{lab}s) and Quantitation Limits (QL_{lab}s)

Recommendation: The FACDQ recommends that EPA promulgate the descriptive single-laboratory procedure(s) recommended by the FACDQ for individual laboratories to determine their Detection and Quantitation Limits. The procedure(s) should have the following two capabilities:

- a. Demonstrate the lab's performance at a specified level.
- b. Determine the lowest possible value achievable by the lab.

The FACDQ further recommends that the descriptive procedure(s) replace the one currently in 40 CFR Part 136 Appendix B.

2. Method Promulgation

Question (Nan Thomey): Have we decided how QL_{nat} will be determined?

Response (Tom Mugan): It will be method-performance based.

Question (Larry LaFleur): Is the QL_{nat} health-based or performance-based?

Response (Tom Mugan): When EPA nationally promulgates something, they use a DQO process. Once EPA selects a method, it's what that method can perform.

Comment (Zonetta English): I am not comfortable with a QL_{nat} without a specific implementation process.

Question (Jim Pletl): Should the FACDQ recommend to EPA that it promulgate how it will calculate national values or derive national limits?

Response (Chris Hornback): We don't want to dictate necessarily how it's done, but, ultimately, I think people will want to see the rationale or the process that EPA went through so there's some sort of common methodology or understanding of the process.

Response (Larry LaFleur): I think, at the bare minimum, we ought to say that they ought to be promulgated so that they go through rule making. If the FACDQ can get to guidance to EPA on how that ought to be done, I think that would be very desirable.

Question (Nan Thomey): Are the QL_{nat}s just for new methods or for existing methods?

Response (Tom Mugan): It is for new and updated methods.

Comment (Richard Burrows): I think there are serious problems with the concept of DL_{nat} and I'd

like to suggest we remove DL_{nat} entirely.

After further discussion, Tom Mugan asked the Committee to trust the work of the Policy Work Group which had gone through similar discussions and to see that the Policy Work Group had tried to make everything fit together throughout the document. In other words, the Committee needed to consider the Uses document as a package and not as separate sections.

The Committee also discussed the advisability of including a Table of Detection Limit and Quantitation Limit values, as discussed at the December 2006 Committee meeting, and concluded that it did not want to proceed with that recommendation. A key consideration was the difficulties of populating such a table. The Committee then agreed to remove from the Uses document all language referring to a published table of limits in a promulgated rule in 40 CFR Part 136.

The FACDQ also agreed to remove the following language from the Uses recommendations but authorized the Final Report Work Group to consider it when drafting an introductory paragraph: “These limits will serve to define the minimum required performance of a laboratory and may assist in comparing performance of one method to another (facilitating selection of a method most suitable for a given use), and may define important thresholds for use in evaluating compliance. (See the section titled “NPDES Permits and Compliance Uses, Recommendation 5.A & B”).”

Action: The FACDQ agreed to move forward with the following language.

2. Method Promulgation

Recommendation: The FACDQ recommends that when the EPA promulgates future analytical methods in 40 CFR Part 136, detection limits (DL_{nat} s) and quantitation limits (QL_{nat} s) shall be included with the methods using the procedure(s) recommended by the FACDQ.

3. Demonstration of Laboratory Proficiency of Detection and Quantitation Limits¹

After discussion, the FACDQ agreed to the following changes in this recommendation: replace “demonstration” with the word “verification;” replace DL_{nat} s and QL_{nat} s with DL_{lab} s and QL_{lab} s; strike the associated footnote; and add the bullet: “Meeting MQOs for use.”

¹ *This is for a situation where a laboratory needs to demonstrate its performance at a specified level or at its reporting level for QL_{lab} and DL_{lab}*

Action: The FACDQ agreed to move forward with the following language.

3. Verification of Laboratory Proficiency of Detection and Quantitation Limits

Recommendation: The FACDQ recommends developing a process for initial and on-going verification of DL_{lab} s and QL_{lab} s by laboratories. This recommendation includes the following guidance:

- The FACDQ recommended procedure (e.g., what goes into 40 CFR Part 136 Appendix B) should include on-going verification of DL_{lab} and QL_{lab} (either explicitly within the procedure or as an “attachment” if the FACDQ chooses to recommend a consensus procedure)
- Meeting MQOs for use
- Separate initial vs. on-going verification
- Strive for feasibility, practicality, representativeness, and cost-effectiveness

4. Future Updates of Promulgated Analytical Method DL_{nat} s and QL_{nat} s

The FACDQ agreed to leave this recommendation unchanged with the understanding that “shall” (...EPA *shall* update DL_{nat} and QL_{nat} limits on an on-going basis.) would remain.

Action: The FACDQ agreed to move forward with the following language.

4. Future Updates of Promulgated Analytical Method DL_{nat} s and QL_{nat} s

Recommendation: The FACDQ recommends that EPA periodically review current capabilities of promulgated analytical methods. The focus of this review should be on methods where there have been significant improvements in detection or quantitation limits or on methods that do not contain DL_{nat} s or QL_{nat} s. This review would be particularly important for cases where detection and quantitation limits are critical to the permit program (e.g., those required for very low Water Quality Based Effluent Limits (WQBELs). EPA should focus on analytes for which current methods provide poor performance or do not meet program needs. Using best judgment and where resources are available, EPA shall update DL_{nat} and QL_{nat} limits on an on-going basis. EPA should also consider information submitted by states and/or other qualified third parties. EPA shall publish a Federal Register Notice announcing the DL_{nat} s and QL_{nat} s it proposes to update. Provisions later in this document are for the purpose of providing EPA with robust data sets for updating and or creating DL_{nat} s and QL_{nat} s

At this point the Committee broke for lunch and to work in caucuses on three issues:

- Recommendation “5.” in the Uses document, where WQBELs are below Quantitation Limits,
- The subgroup’s proposal on DQOs/MQOs, and
- The Technical Work Group’s procedure recommendations, especially related to a Multi/Inter Lab Procedure(s).

Lunch Break and Caucus Time

After lunch, the Committee turned to Recommendation “5.” and reviewed it, section by section, with the following results.

5. The FACDQ recognizes that the existence of WQBELs at concentrations less than quantitation limits presents a number of National Pollution Discharge Elimination System (NPDES)-related issues. These include appropriate approaches for:

- Calculating monthly averages
- Determining compliance with daily maximum limits and monthly average limits
- Reporting data, and
- Appropriate compliance response in light of data uncertainty and the need for the protection of public health and the environment.

To deal with these various issues, the FACDQ recommends a balanced response as outlined below.

States that have been delegated the NPDES program from EPA have the authority under the Clean Water Act to adopt regulatory provisions that are different, but no less stringent than, those required under federal regulations. Such provisions, if authorized or not prohibited by state law, would operate in lieu of the following recommendations and could include a QL_{st} value lower than the nationally-promulgated QL_{nat} . In that case, the QL_{st} applicable under the state program would be used for determining compliance, reporting, and other applicable requirements.

A. Recommendations for NPDES Permits and Compliance Uses where a QL_{nat} exists and for WQBELs at concentrations less than QL_{nat} .

The Committee's discussion of this section centered on providing further detail if a permitting authority required the permittee to use a method that was more sensitive than the one for which there is a QL_{nat} . The Committee agreed to add a clarifying sentence.

Action: The FACDQ then agreed to include the following language.
 "If the permitting authority requires use of a method more sensitive than the method for which a QL_{nat} exists, go to section B."
Straw Vote: 14 Agree, 4 Not Opposed, 0 Disagree

1. The FACDQ recommends that a Part 136 DL_{nat} and QL_{nat} determined by the procedure recommended by the FACDQ be promulgated for each method/analyte combination which shall be the upper bound for lab performance. The regulator shall insert QL_{per} s in permits. The default QL_{per} is the lowest Part 136 promulgated QL_{nat} . The regulator would then consider whether this is the most appropriate method considering sensitivity, selectivity, and/or matrix effects and adjust the QL_{per} accordingly.¹

Comment (Tom Mугan): I'm concerned that there is no legal way to implement the QL_{per} .

Question (Tim Fitzpatrick): What value would a regulator pick? If we have a pollutant for which there is an existing sensitive method but no QL_{nat} established or no ML established and an instrument vendor or EPA promulgates a method; they're required to put a QL_{nat} in their newly promulgated method. It's well above the existing method. The regulator doesn't want to use the new method but how does he come up with a number to put in the permit? How does he justify that?

Response (Chris Hornback): A couple of meetings ago we built a lot of intentional flexibility in here for the states to do essentially what they wanted if this approach didn't work for them. Doesn't the language above "A" or elsewhere in the document give states the ability to do something different?

After discussion, it was agreed that there was a need to provide some flexibility to the states on where the QL_{per} would be shown, so an option of including it in a rule was agreed to for Committee decision-making. The Committee discussed providing flexibility to the regulator to consider if the QL_{nat} was the most appropriate method and agreed to include it in their recommendation.

¹ The revised language in this recommendation replaces Recommendation B from the December Uses document.

Action: The FACDQ agreed to the following language:

- 1) The FACDQ recommends that a Part 136 DL_{nat} and QL_{nat} determined by the procedure recommended by the FACDQ be promulgated for each method/analyte combination which shall be the upper bound for lab performance. The regulator shall insert QL_{per} s in permit or in rule as appropriate. The default QL_{per} is the lowest Part 136 promulgated QL_{nat} . The regulator would then consider whether ***the method associated with this QL_{nat} is the most appropriate method considering sensitivity***, selectivity, and/or matrix effects and adjust the QL_{per} accordingly.

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree

Action: The FACDQ did not agree to include the following language:

“All the following does not apply if the QL_{nat} is not the most sensitive method QL_{nat} .”

Straw Vote: 8 Agree, 8 Not Opposed, 2 Disagree

Action: The FACDQ agreed to the following language:

- 1) The FACDQ recommends that a Part 136 DL_{nat} and QL_{nat} determined by the procedure recommended by the FACDQ be promulgated for each method/analyte combination which shall be the upper bound for lab performance. ***The regulator shall insert QL_{per} s in permit or in rule as appropriate.*** The default QL_{per} is the lowest Part 136 promulgated QL_{nat} . The regulator would then consider whether the method associated with this QL_{nat} is the most appropriate method considering sensitivity, selectivity, and/or matrix effects and adjust the QL_{per} accordingly.

Straw Vote: 15 Agree, 3 Not Opposed, 0 Disagree

2) The QL_{per} shall be applicable for the term of the permit unless the regulator reopens and modifies the permit. The permit shall also contain a condition that the permittee's QL_{lab} shall be at or below the QL_{per} . The permit shall require permittees to report DL_{lab} s and QL_{lab} s as determined by the procedure recommended by the FACDQ and maintain such information for a period of at least five years.

Comment (Barry Sulkin): Permits can go on more than five years, even up to ten and twenty years. More than half of the permit challenges I work on are more than five years old, because they're problematic. If you're trying to get consistency across the board, you don't want the permits of competing industries to change at varying intervals: one, five, or twenty years apart.

Comment(Barry Sulkin): We're not directing how to interpret the data like we are for permits. When you take a sample above and below a pipe, sometimes it's a permit requirement and sometimes it's done by an environmental group. It is the same body of water, but for different uses. Do you want two different Detecion Limits and Quantitation Limits to apply? Or do you always even know which one you're doing when you fill up that bottle of water? What I would like to see is that EPA set national standards with Detection Limits and Quantitation Limits and tell the states to get consistent.

There was considerable discussion regarding the appropriate recommendation given the variability in the life of permits. The Committee agreed to remove sections of this recommendation that relate to the life of the permit to resolve this issue.

Action: The FACDQ agreed to remove the following language from #2:
 "The QL_{per} shall be applicable for the term of the permit unless the regulator reopens and modifies the permit" as well as all of **3)**:

3) The FACDQ recognizes that permits may be extended beyond their normal five-year term during which time period modifications to DL_{nat} s and QL_{nat} s may occur. For these situations, the FACDQ recommends that regulatory authorities consider if changes are appropriate.

The Policy Work Group posed two other options for the committee to consider:

- If the QL_{nat} is lowered below the QL_{per} , the QL_{per} is automatically lowered to the QL_{nat} [number to be determined] years later.
- If a permit is more than five years old, then any new DL_{per} and/or QL_{per} take effect.

Straw Vote: 9 Agree, 9 Not Opposed, 0 Disagree

1. The permittee shall ensure that the DL_{lab} s and QL_{lab} s are determined using the steps of the procedure to determine the lowest possible value by the lab for setting QL_{lab} s and DL_{lab} s.

The Committee agreed to re-number 4) to 3) and include the language below. The Committee additionally

had a substantial discussion related to whether or not the lab would need to test for the lowest DL_{lab} and QL_{lab} s. Some of that discussion was as follows:

Comment (Tom Muga): We need to protect the environment. I feel pretty strongly that we should be pushing the technology for these nasty pollutants.

Response (Richard Burrows): The permit ought to be what drives how protective we are with the environment.

Response (Nan Thomey): My understanding of the intent of this was for the lab to make some attempt to be measuring as low as it can.

Comment (Tim Fitzpatrick): I think we envisioned a double-tiered procedure or set of procedures: one that allows you, if you need to, to determine your lowest Detection and Quantitation Limit and another one to verify or demonstrate that you can hit a particular targeted Detection Limit or Quantitation Limit. Which one you follow depends on your needs.

After discussion, the Committee agreed that for situations where QL_{nat} does exist and for situations where the WQBEL is below the QL_{nat} , it would be important to determine the lowest possible value.

Action: The FACDQ agreed on the following language:

3) For a list of analytes as defined by EPA, the permittee shall ensure that the DL_{lab} s and QL_{lab} s are determined using the steps of the procedure to determine the lowest possible value by the lab for setting QL_{lab} s and DL_{lab} s.

Straw Vote: 10 Agree, 8 Not Opposed, 0 Disagree

The Committee then discussed reporting results to the Integrated Compliance Information System (ICIS) in “5.A.5.”

2. The FACDQ further recommends, for purposes of updating Part 136 DL_{nat} s and QL_{nat} s, that EPA require that lab-specific information be reported in the Integrated Compliance Information System (ICIS).

The Committee readily agreed to this language, determined a new numbering as shown in the Action below

with the proviso that it be considered in light of the whole document.

Action: The FACDQ agreed to make the old **5)** the new **4)** and to return to the option of deleting the new **4)** if it is found to be duplicative of later sections in the document.

The Committee then discussed its recommendations for NPDES permits and compliance uses for WQBELs when QL_{nat} s do exist.

6) Recommendation for NPDES Permits and Compliance Uses for WQBELs when QL_{nat} s do exist:

The Committee determined that the title did not appropriately identify what was intended in this section. The Committee therefore agreed to rename the section, "Implementation in NPDES Permits" to more appropriately identify the purpose of this section."

Action: The FACDQ agreed to turn the previous 6) into 5) and rename it: "Implementation in NPDES Permits."

The Committee then reviewed the remaining sections of the Uses document; the specific actions associated with each section are indicated below.

1. Set average and daily maximum permit limits at the WQBEL.
2. Assign zero for values less than the permit QL_{per} when determining average and daily maximum discharge levels.

Rationale: While the FACDQ recognizes that values between a given laboratory's DL_{lab} and QL_{lab} have a higher level of uncertainty, the science suggests they are unlikely to be zero. However, assigning a non-zero value where an analyte is detected below the QL_{per} (DBQp) would have significant compliance and enforcement implications. Therefore, the committee recommends assigning a zero in these cases.

The Committee agreed that the rationale was important but that it might more appropriately be located in the Final Report.

Action: The FACDQ agrees on the following language:

Note: The FACDQ agrees that this rationale is important and will be included in the Final Report.

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree

3. To determine NPDES permit compliance, compare average and daily maximum discharge levels, calculated in accordance with item (ii.) above, to the respective WQBEL.

The Committee agreed to determine NPDES permit compliance, compare average and daily maximum discharge levels, calculated in accordance with item (ii.) above, to the respective WQBEL, but changing the wording to accurately reflect the location of the section referred to.

Action: The FACDQ agreed to change “above” to “below” in the following:

- c) To determine NPDES permit compliance, compare average and daily maximum discharge levels, calculated in accordance with item (d.ii.) below, to the respective WQBEL.

1. A permittee must report to the permitting authority all information in the following manner:
 - i. When reporting daily maximum sample results:
 1. For values less than the DL_{lab} , report “ND” (not detected) on the Daily Monitoring Report (DMR).
 2. For values greater or equal to the DL_{lab} and less than the QL_{per} , report “DBQp” (Detected Below QL_{per}) on the DMR.

The Committee agreed that Detected Not Quantified (DNQ) might not be the appropriate term for results below QL_{per} , and agreed to indicate a need for EPA to develop some term that would indicate it was detected.

Action: The FACDQ agreed to allow EPA to come up with a new acronym for a situation where an analyte is detected below the QL_{per} . The acronym will replace “DNQ” and must fit into the conditions of the ICIS system. The facilitator used the acronym “DBQp” (Detected Below QL_{per}) for purposes of completing this document.

3. For values greater than or equal to the QL_{per} , report the actual values on the DMR.
 - i. When reporting averages:
 1. Where all values used to calculate an average are less than DL_{lab} , report “ND” on the DMR.
 2. Where all values used to calculate an average are greater than or equal to DL_{lab} but less than QL_{per} , report “DBQp” on the DMR.
 3. When values used to calculate an average are a combination of ND and DBQp values, report “DBQp” on the DMR.
 4. When any value used to calculate an average is greater than or equal to QL_{per} , report on the DMR the average as calculated in item (5.A.5.b) above.

The Committee discussed whether or not there was a need to include recommendations for requiring a DL_{nat} and, if not, was there still a need to include reference to DL_{lab} . After discussion, the Committee agreed to retain DL_{lab} until other decisions were made.

Action: The FACDQ agrees that DL_{lab} will remain in **i.** and **ii.** with the proviso that there will be consideration of this after the MQO discussion
Straw Vote: 15 Agree, 3 Not Opposed, 0 Disagree

i. Additional reporting requirements:

1. The regulator shall require that the permittee report the DL_{lab} and QL_{lab} (for purposes of updating methods and to determine compliance with the conditions of the permit.). The permitting authority shall report the DL_{lab} , QL_{lab} , and QL_{per} for each analyte to EPA in ICIS.
2. The regulator may require the individual numeric result for any value that is greater than or equal to the DL_{lab} and less than the QL_{per} be reported in a supplemental report. Potential uses would be to determine reasonable potential and for public knowledge.

The Committee agreed that “shall” was the appropriate verb in iii.a., which would require the permittee to report the DL_{lab} and QL_{lab} (for purposes of updating methods and to determine compliance with the conditions of the permit). The permitting authority would additionally be required to report the DL_{lab} , QL_{lab} , and QL_{per} for each analyte to EPA in ICIS.

The Committee also agreed that there was no need to specify what numeric results reported in a supplemental report would be used for; therefore the Committee agreed to remove the sentence that specified the uses of such information

Action: The FACDQ agreed to remove the second sentence in **iii.b** which read: “Potential uses would be to determine reasonable potential and for public knowledge.”

3. The permittees shall maintain individual numeric results for a period of at least five years.

There were no changes to this part of the recommendation.

The Committee moved to Section 5.A.5 (formerly, Section 5.A.7) which remained essentially the same: Permits shall include language that triggers additional steps when a “significant number of DBQp values” (to be determined in permitting process) are reported. These steps may include additional or accelerated monitoring, analytical studies such as matrix studies, pollutant minimization programs, or other permit conditions outside of the determination of compliance with effluent limitations. Reports under such provisions will be done outside of the DMR reporting process, except that any additional effluent testing performed using approved analytical methods as part of the special studies must be reported according to the

protocol in (5.A.5.d.iii).

The Committee then moved to Section 5.B, recommendations when no QL_{nat} exists.

B. Recommendations for NPDES Permits and Compliance Uses for WQBELs when no QL_{nat} exists:

- 1) In the absence of QL_{nat} , the permitting authority is free to establish its method for determining compliance for analytes that have limits/water quality standards at a level lower than can be detected and/or quantified.

- 2) For a list of analytes as defined by EPA, the permittee shall ensure that the DL_{lab} s and QL_{lab} s are determined using the steps of the procedure to determine the lowest possible value by the lab for setting QL_{lab} s and DL_{lab} s.

After discussion of 5.B.2, the Committee agreed that “shall” required was preferable to “could” require, in part because EPA strongly supported requiring such reporting. (In the Action below, the approval of the B.2) refers to the “shall” language.

<p>Action: The FACDQ agreed to B.1) and B.2). <i>Straw Vote:</i> 17 Agree, 1 Not Opposed, 0 Disagree</p>

- 3) The FACDQ further recommends, for purposes of developing Part 136 DL_{nat} s and QL_{nat} s, that EPA require the lab-specific information be reported in the Integrated Compliance Information System (ICIS).

Note: The FACDQ recommends that EPA reconsider the usefulness of this requirement over time.

The Committee discussed concerns about setting up a system without the ability to discontinue a practice if it

no longer generated useful information. The Committee agreed to include an evaluation of the value of collecting this information in the future.

Action: The FACDQ agreed to the following language:

3) The FACDQ further recommends, for purposes of developing Part 136 DL_{nat}s and QL_{nat}s, that EPA require the lab-specific information be reported in the Integrated Compliance Information System (ICIS).

Note: The FACDQ recommends that EPA reconsider the usefulness of this requirement after time.

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree

4. **Matrix Effects**

The Committee felt that including a

recommendation on Matrix Effects would be important but decided to postpone specific recommendations until the next day.

Action: The FACDQ agreed to table the topic of Matrix Effects until the Day 3 of the meeting.

7. **Other Uses to Consider**

Recommendation: The FACDQ tabled its discussion of recommendations regarding the use of Detection and Quantitation for other uses including but not limited to the following:

- ambient monitoring 305(b)
- pretreatment
- non-regulatory operational monitoring
- stormwater monitoring
- other studies, such as fish tissues or biosolids characterization
- reasonable potential analysis
- effluent guidelines development

Jim Pletl proposed the following additional items:

- limit derivation
- development of water quality criteria

The Committee agreed to these additions.

Action: The FACDQ agreed to the proposed list of items in the section “Other Uses to Consider” with the addition of:

- limit derivation
- development of water quality criteria

Straw Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent

8. Alternative Test Procedures

Recommendation: The FACDQ tabled the option of developing recommendations to EPA on updating the Alternative Test Procedures (ATP) Program. The FACDQ recommends that the ATP Program be updated to be consistent with recommendations in this document.

Comment (Cary Jackson): I recommend that we make the recommendation that the ATP Program needs to be updated to reflect any changes that are promulgated.

The Committee agreed that it could not address this issue in more detail because of time constraints, but it also agreed that the Committee should provide direction to EPA on making the ATP process consistent with other Committee recommendations.

Action: The FACDQ agreed to the language in the section “Alternative Test Procedures.”

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree

The Committee agreed to table discussion of the need for DL_{nat} in the document until the next day.

DQO/MQOs Continued

Mr. Wheeler then reopened the discussion of MQOs from the previous day, referring members to the subgroup's draft MQO document.

The first related to MQOs for Quantitation for Promulgated Methods. Issues discussed included the needs of the procedure development work group for a defined False Negative rate and a multiplier for initial implementation of the procedure. After further discussion and edits, the FACDQ took a straw vote on the following MQO decision.

Action: MQOs for Quantitation for Promulgated Methods

The FACDQ recommends that for promulgated methods in 40 CFR Part 136 without established MQOs, the initial MQO for Quantitation upon implementation of the new quantitation procedure is a specific False Negative rate ($\leq 5\%$) to be implemented through a multiplier of the Detection Limit (determined by the FACDQ recommended Single Lab Procedure for Detection). The Precision and Accuracy MQOs for individual analytes/methods would be generated and promulgated as the data to support those MQOs becomes available.

The FACDQ requests that the Technical Work Group establish or recommend a procedure for adding MQOs to existing methods.

Straw Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent

Mr. Wheeler then called on Richard Burrows who reported the progress he and his subgroup had made on developing a Single-Lab Procedure and their need for Committee decisions on MQOs to enable them to develop a procedure.

Richard Burrows then suggested that a group of people meet face-to-face to develop and finalize the Single Lab Procedure that would meet the needs of the Committee.

Question (Tim Fitzpatrick): Do you anticipate developing a procedure that would take other MQOs into account as they become available?

Response (Richard Burrows): Yes.

Question (John Phillips): Do you need to know the floor for the MQOs?

Response (Richard Burrows): Probably; we could use guidance from the group on that.

Comment (Tim Fitzpatrick): I think the Technical Work Group could go away and develop a proposal for a detection and quantitation procedure that would include some constraints that make sense in the realm of what constitutes Quantitation and bring it to the FACDQ in order to find out if it is acceptable or not.

Question (Cary Jackson): Did we agree on what the elements of the multiplier are or are we asking the Technical Work Group to identify what those elements are?

Response (Richard Burrows): A multiplier will be based upon the 5% False Negative rate that we've identified as desirable.

Comment (John Phillips): You need to know what the Detection Limit is, as a start, for the multiplier. You need to know what the precision and accuracy are, too. You need to know those three elements and that you're targeting a 5% False Negative rate.

Public Comment

There was no public comment.

Wrap-up and Adjourn for the Day

Robert Wheeler congratulated the Committee on the significant progress it had made. He then briefly reviewed the agenda for the next day, noting the decisions the Committee needed to make. He also reported that Ephraim King, Director of the Office of Water, and Michael Shapiro, Deputy Assistant Administrator for the Office of Water, would join the Committee over lunch.

Alice Shorett asked the Final Report Work Group to meet at 7:15 AM the following morning for a check-in discussion prior to the FACDQ meeting.

Richard Reding, DFO, adjourned the meeting at 6:30 PM.

Day 3 – Friday, June 8, 2007, 8:00 AM – 3:00 PM

Welcome and Agenda Review

Richard Reding, DFO, opened the meeting at 8:00 AM and turned the meeting over to the facilitator, Robert Wheeler.

Mr. Wheeler welcomed the Committee to the final day of the meeting and highlighted what the Committee needed to accomplish during the day. To assist decision-making, he pointed to three new documents had been distributed at their seats: a revised agenda for the day, a proposed agreement on MQOs (drafted by a subgroup and refined to reflect discussions on Day 2), and a document that addressed Matrix Effects.

MQO Agreements

Mr. Wheeler reviewed the proposed MQO agreement and reviewed the results of the straw poll on MQOs the previous day. The Committee reviewed the options in the document, made edits to some of them, and took straw votes on the revised options.

Note: Brief summaries of Committee discussions precede the Actions reported below.

In the following two Actions, the Committee developed language that addressed “target” MQOs for Precision and Accuracy that would be derived from the DQO process. The group was also considered other DQIs and a proposal to allow EPA to promulgate a method even if that method could not meet the target MQOs. While the first proposal was not approved, subsequent modifications allowed the Committee to reach agreement.

Action: The FACDQ recommends, for future method promulgation, that target MQOs for Precision and Accuracy derived from the DQO process be established for QLs in Part 136. In addition, Data Quality Indicators (DQIs) such as method specified quality identification and false negative error rate would be considered. If the target MQOs cannot be met, EPA may promulgate with rationale.

Straw Vote: 9 Agree, 5 Not Opposed, 4 Disagree

Action: MQOs for Future Promulgation of Methods

The FACDQ recommends, for future method promulgation, that target MQOs for DQIs, such as Precision, Accuracy, Method Specified Qualitative Identification, and False Negative error rates derived from the DQO process, be established for Quantitation Limits in Part 136. If the target MQOs cannot be met, EPA may promulgate with rationale.

Straw Vote: 9 Agree, 9 Not Opposed, 0 Disagree

The Committee then moved on to a consideration of setting limits or bounds for MQOs when considering quantitation.

Question (Jim Pletl): What are the reasons that we would *not* want a limit on MQOs in Clean Water Act programs?

Comment (Michael Murray): In Seattle we talked about the issue of new chemicals that may be developed and that may be of concern. We are just starting to look for new methods to be developed to address this issue. If you’ve got moderately tight MQOs, it may be difficult to meet those for this new method, yet, the chemical is still out there.

Response (Jim Pletl): I personally do not think the FACDQ should send a message that it is acceptable to use data of *any* quality in Clean Water Act programs. I'd be very concerned if we could not at least reach consensus on that. There still has to be, I would hope, some limit or bound on the quality of data that is used to make decisions in Clean Water Act programs.

After some discussion the Committee voted but did not reach consensus on the proposal.

Action: MQO Bounds

The FACDQ recommends that EPA establish quantitative MQO bounds for relevant DQIs that define Quantitation for intended CWA uses. These bounds would be offered for public comment by EPA.

Straw Vote: 13 Agree, 4 Not Opposed, 1 Disagree

Mary Smith told the Committee that she had disagreed with this proposal because it was an important issue that EPA needed to discuss internally. The Committee then considered and approved in a straw vote the following alternative approach:

Action: Limits for QL MQOs for Future Promulgation of New or Updated Methods

The FACDQ recommends that the Technical Work Group develop recommendations for target MQO bounds for compliance and enforcement that define Quantitation. The Technical Work Group will bring its recommendations back to the FACDQ.

For example:

- A. Precision \leq 30% RSD
- B. Accuracy (measured as recovery for = 20-180%)
- C. False Negative rate \leq 10%
- D. Ratio of Accuracy to Precision must be no less than 1.0
 - Example: 40% Recovery / 20% RSD = 2, Acceptable
 - Example: 20% Recovery / 30% RSD = .66 Not Acceptable

Straw Vote: 13 Agree, 5 Not Opposed, 0 Disagree

Mr. Wheeler reported that he had spoken with Richard Burrows briefly during the break and that Mr. Burrows had said the Committee's decisions were adequate for his Single Lab Procedure subgroup to proceed and finalize a procedure recommendation.

Multi/Inter Lab Procedure Discussion

Mr. Wheeler called on Larry LaFleur to begin the Committee's consideration of the Multi/Inter Lab Procedure issue. Mr. LaFleur indicated that the Industry caucus' concerns related to two aspects of data comparability: at the Quantitation level when two different labs run the same sample and on use of the same method for a specific analyte. He said if these issues were addressed in some way, the Industry caucus would endorse a Multi Lab Procedure over an Inter Lab Procedure. This made sense because an ACIL Modified Procedure was the likely choice for Single Lab Detection and Quantitation determinations, and it did not seem practical to have a totally separate Inter Lab Procedure. He then proposed a recommendation, to be added to the section on MQOs that was discussed, revised and then the subject of a straw vote, which is as follows:

Action: Proposed additional language for MQOs – Future Methods

The FACDQ recommends that during the DQO process, EPA will give special attention to assuring the analytical method produces comparable results, at or near the QL_{nat} , on split samples, analyzed in different labs with the same method, and will specifically describe the steps taken in the proposed rule.

Straw Vote: 16 Agree, 1 Not Opposed, 1 Absent

Given approval of the proposal, Mr. LaFleur said Industry would like for the Committee to reach agreement on a framework for a Multi Lab procedure that it could ask EPA or the Technical Work Group to flesh out. However, a few Committee members indicated that they did not want to jump to a Multi Lab approach. This led to Committee consideration of a series of proposals that progressed from a Multi Lab approach to a broader focus on how to determine the QL_{nat} .

Rather than recommending a specific approach for determining QL_{nat} , the Committee focused instead on developing a process for determining QL_{nat} and considering how the QL_{nat} would be implemented. After straw votes on several proposals that were not approved, Committee members reached agreement on requesting that the Technical Work Group recommend a process for determining a QL_{nat} and recommending that EPA promulgate how the QL_{nat} would be derived.

Action: The FACDQ recommends that EPA develop a Multi-lab Procedure for establishing a QL_{nat} using the framework identified by the FACDQ. The Technical Work Group will develop this framework for FACDQ consideration.

Straw Vote: 0 Agree, 1 Not Opposed, 13 Disagree, 4 Abstained

Action: The FACDQ recommends that EPA develop a procedure for establishing a QL_{nat} using the framework identified by the FACDQ. The TWG will develop this framework for FACDQ consideration.

Straw Vote: 6 Agree, 10 Not Opposed, 1 Disagree, 1 Abstained

Action: The FACDQ asks the Technical Work Group to develop a recommendation for a process that considers both Multi and/or Inter Lab procedures in developing a QL_{nat} .

Straw Vote: 13 Agree, 3 Not Opposed, 1 Disagree, 1 Absent

Action: The FACDQ asks the TWG to develop a recommended procedure(s) for determining QL_{nat} .

Straw Vote: 16 Agree, 1 Not Opposed, 1 Disagree

Action: The FACDQ asks the Technical Work Group to develop a recommended process for determining a QL_{nat} .

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree

Action: The FACDQ recommends that EPA promulgate how QL_{nat} is derived.

Straw Vote: 10 Agree, 6 Not Opposed, 2 Disagree

Action: The FACDQ recommends that EPA establish, after public comment, how QL_{nat} is derived.

Straw Vote: 9 Agree, 4 Not Opposed, 5 Disagree

Action: The FACDQ recommends that EPA promulgate how QL_{nat} is derived.

Straw Vote: 10 Agree, 7 Not Opposed, 0 Disagree, 1 Absent

Technical Work Group Recommendations on Procedures

Mr. Wheeler introduced the Technical Work Group's document, Recommendations on Procedures (Document# FACDQ 7-06), and pointed out the Group's qualification about the document:

“Agreement was reached on the following recommendations at a Technical Work Group Meeting. Not all members were present (although all caucuses were represented) and there was insufficient time to obtain further input and consensus from Technical Work Group members not at the meeting.”

Committee members asked questions and discussed the results, after which the Committee agreed it was premature to vote on a specific procedure. It voted, instead, to ask the Technical Work Group to continue to develop the ACIL modified procedure for Single Lab Detection and Quantitation.

Action: A. The FACDQ recommends the Technical Work Group continue to develop the specifics for the following:

Single Laboratory Detection Limit Procedure

The ACIL Procedure, with modifications indicated by the Pilot Study results and informed by concepts from the Consensus Group and LabQC procedures, is recommended for a Single Laboratory Detection Limit Procedure.

Vote: 17 Agree, 1 Not Opposed, 0 Disagree

Regarding a Single Lab Quantitation Limit Procedure, Larry LaFleur said he did not want a multiplier approach for future methods because Industry felt that was largely the problem with the current approach. He said he also thought the lab community would not welcome having different approaches for existing and future methods, that is, a multiplier approach for existing methods but not for future methods. Richard Burrows said he saw it not as two different procedures but as one procedure with additional steps.

Tim Fitzpatrick commented that he thought the procedure could be written in such a way that would allow other MQOs to be a consideration in determining the Quantitation Limit.

Action: B. The FACDQ recommends the TWG continue to develop the specifics for the following:

Single Laboratory Quantitation Limit Procedure

The ACIL Procedure, with modifications indicated by the Pilot Study results and informed by concepts from the Consensus Group and LabQC Procedures, as well as decisions by the FACDQ at its June 2007 meeting.

Vote: 16 Agree, 2 Not Opposed, 0 Disagree

Revised Uses Document

Mr. Wheeler led the Committee through a discussion of the Revised Uses document, beginning where the Committee had ended the previous day.

Mr. LaFleur repeated his recommendation to drop DL_{nat} and all references to it from the document because, if DL_{nat} were not going to be used, Industry should not be required to collect data for it. After discussion, Tom Mugan proposed that the Policy Work Group investigate the changes that would need to be made to the document to remove DL_{nat}. After more discussion the Committee reached agreement on the following motion:

Action: The FACDQ recommends the Policy Work Group explore the deletion of DL_{nat}, the possible policy changes to the document, and their implications, and bring them back to the FACDQ. The Policy Work Group will also explore other policy issues not completed at the June 2007 meeting.

Straw Vote: 15 Agree, 3 Not Opposed, 0 Disagree

Discussion with Michael Shapiro and Ephraim King

Mary Smith introduced Ephraim King, Director of the Office of Science and Technology, and Michael Shapiro, Deputy Assistant Administrator for the Office of Water and led a round of introductions of all the FACDQ members.

Mr. Shapiro and Mr. King both thanked the Committee for its hard work and emphasized the Agency's appreciation for the FACDQ's efforts and progress. Mr. King acknowledged how much "time and effort" it takes reach agreement on big principles and then to convert those agreements, through constructive give and take, into products that we can all be proud of and live by in the end.

Mr. King said that he, as well as others at the table, were in the business of trying to get things done. He committed that he and Mr. Shapiro would try their best to translate the balance, the advice, and the recommendations the Committee developed into a useful regulatory federal context."

Question (Tim Fitzpatrick): Based on the input we've had from the Drinking Water and the Solid Waste Programs, I think they are tagging along with this process and following it closely, but I wonder if you could give us some sense as to whether or not we might end up with laboratories having to use different procedures or where the Agency is heading, with the outcome of this process.

Response (Ephraim King): If we reach agreement here, we're certainly committed to see this through on the Clean Water Act side. We can do as much as we can to educate the rest of the Agency about the benefits of this approach. However, there are stakeholders in those other processes that aren't at this table. It may be a long while before the Agency finds itself in agreement that it would be better to have one set of procedures across the board. If we are successful in this area, we create a strong message and a signal to the rest of the Agency. And I think stakeholders who have the kinds of concerns and problems that brought us together to address will begin to create some external interest in moving those programs towards a review of their activity as well. I think you'll create an opportunity to create movement in that area across the Agency. However, I don't want to over promise because I know how hard it is to make progress.

The Committee then adjourned for lunch and further discussion with Mr. King and Mr. Shapiro.

Lunch Break

Matrix Effects

After lunch, Mr. Wheeler called on Larry LaFleur to present his proposal on Matrix Effects, as follows:

The FACDQ recommends EPA develop and promulgate procedures for:

1. The level of validation of proposed part 136 procedures to document and assess applicability of the procedure to different matrix types.
2. Procedures for demonstrating a matrix effect.
3. Procedures for determining a matrix specific Detection and Quantitation Limits

EPA should strive for feasibility, practicality and cost-effectiveness.

Because of time constraints, the Committee agreed to assign this proposal to a work group to develop a

recommendation for the September meeting; the assignment was to identify the details that should be considered, but not to develop those details. After discussion, the committee reached agreement on the following recommendation:

Action: The FACDQ recommends that EPA consider how Matrix Effects impact Detection and Quantitation. The FACDQ requests that the Policy Work Group bring back a conceptual recommendation, including details to be considered.

Vote: 17 Agree, 1 Not Opposed, 0 Disagree

Great Lakes Initiative (GLI)

Mr. Wheeler then turned the Committee's attention to Use "10. GLI." After discussion, especially around the use of the word "significant," the Committee took a final vote, as follows:

Action: The FACDQ agreed to the following language in the section "GLI."

Recommendation: The FACDQ recommends that FACDQ recommendations should not supersede the current GLI provisions. There is no significant conflict between the anticipated FACDQ recommendations and the GLI.

Straw Vote: 18 Agree, 0 Not Opposed, 0 Disagree

Implementation of the FACDQ Recommendation

Nan Thomey suggested that the implementation portion of the Uses document be pulled because it did not characterize a Use of the procedure. The Committee reached agreement on a proposal for a subgroup of the Policy Work Group to bring recommendations on implementation to the FACDQ at its September meeting.

Action: The FACDQ recommends "9. Implementation of the FACDQ Recommendation" be removed from the Uses document for consideration by a work group. However, the importance of these issues related to Uses should not be separated. A work group of the FACDQ is tasked with bringing recommendations on the implementation issues back to the FACDQ.

Vote: 18 Agree, 0 Not Opposed, 0 Disagree

Final Votes on Actions

After a discussion of the appropriate approach for converting "straw votes" to "final votes," the Committee decided to go through the straw poll votes, one by one, to finalize its decisions. The Committee completed final votes in the following order:

Action: DQOs Decision

The FACDQ recommends that EPA Office of Water use the *EPA Guidance on Systematic Planning Using the Data Quality Objectives Process* in all Clean Water Act programs.

Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent

Action: A. False Positive Rate MQO

The FACDQ recommends that a $\leq 1\%$ False Positive rate be used for Detection.

Vote: 17 Agree, 0 Not Opposes, 0 Disagree, 1 Absent

Action: B. Proposed additional language for MQOs – Future Methods

The FACDQ recommends that during the DQO process, EPA will give special attention to assuring the analytical method produces comparable results, at or near the QL_{nat} , on split samples, analyzed in different labs with the same method, and will specifically describe the steps taken in the proposed rule.

Vote: 14 Agree, 3 Not Opposed, 0 Disagree, 1 Absent

Action: C. MQOs for Quantitation for Promulgated Methods

The FACDQ recommends that for promulgated methods in 40 CFR Part 136 without established MQOs, the initial MQO for Quantitation upon implementation of the new Quantitation Procedure is a specific False Negative rate ($\leq 5\%$) to be implemented through a multiplier of the Detection Limit (determined by the FACDQ recommended Single Lab Procedure for Detection). The Precision and Accuracy MQOs for individual analytes/methods would be generated and promulgated, as the data to support those MQOs becomes available.

The FACDQ requests that the Technical Work Group establish or recommend a procedure to add MQOs to existing methods.

Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent

Action: D. Limits for QL MQOs for Future Promulgation of New or Updated Methods

The FACDQ recommends the Technical Work Group develop recommendations for target MQO bounds for compliance and enforcement that define Quantitation. The Technical Work Group will bring these recommendations back to the FACDQ.

For example:

- A. Precision \leq 30% RSD
- B. Accuracy (measured as recovery for single determination) = 20-180%
- C. False Negative rate \leq 10%
- D. Ratio of Accuracy to Precision must be no less than 1.0
 Example: 40% Recovery / 20% RSD = 2 O.K.,
 Example: 20% Recovery / 30% RSD = .66 Not Acceptable

Vote: 12 Agree, 5 Not Opposed, 0 Disagree, 1 Absent

Action: E. MQO Bounds

The FACDQ recommends that EPA establish quantitative MQO bounds for relevant DQIs that define Quantitation for intended Clean Water Act uses. These bounds would be offered for public comment by EPA.

Vote: 9 Agree, 7 Not Opposed, 1 Disagree, 1 Absent

Action: The FACDQ asks the Technical Work Group to develop a recommended process for determining a QL_{nat} .

Vote: 17 Agree, 0 Not Opposed, 0 Disagree, 1 Absent

Action: The FACDQ recommends that EPA promulgate how QL_{nat} is derived.

Vote: 7 Agree, 10 Not Opposed, 0 Disagree, 1 Absent

Action: The FACDQ recommends the Policy Work Group explore the deletion of DL_{nat} , the possible policy changes to the document, and their implications and bring them back to the FACDQ. The Policy Work Group will also explore other policy issues not completed at the June 2007 meeting.

Vote: 16 Agree, 1 Not Opposed, 0 Disagree, 1 Absent

Mr. Wheeler then introduced the following proposal to the Committee:

“The FACDQ acknowledges that at the June, 2007 meeting, it reached the following consensus recommendations regarding the uses of detection and quantitation approaches in Clean Water Act programs with the understanding that the FACDQ will review a more complete Uses package after further work by the Policy Work Group.”

The Committee discussed the proposal. Because many Committee members wanted to evaluate the

implications of deleting DL_{nat} before taking a final vote on the Uses document, the Committee developed and reached agreement on the following alternative proposal:

Action: The FACDQ directs the FACDQ Work Groups to use the straw vote decisions as a starting point for writing the Uses portion of the Final Report and other activities, subject to revisions based on a final vote to occur later.
Vote: 16 Agree, 0 Not Opposed, 0 Disagree, 2 Absent

The Committee requested that a teleconference meeting be held before the September 2007 FACDQ meeting which would allow the Committee to make final recommendations on the Uses document, after the Policy Work Group had been able to make appropriate changes.

Public Comment

There was no public comment.

Wrap-up and Adjourn for the Day

Robert Wheeler briefly reviewed the following assignments for the Technical Work Group, Policy Work Group, and Final Report Work Group:

Technical Work Group Assignments

- Review and Make Recommendations on Definitions
- Further Develop Procedure(s)
 - Single Lab Detection Limit
 - Single Lab Quantitation Limit
 - Multi/Inter Lab
- Finalize an Intermittent Blank Contamination Recommendation
- Develop credentials for potential peer review of Pilot Study Report
- Establish or recommend a procedure for adding MQOs to existing methods
- Develop recommendations for target MQO bounds for compliance and enforcement that define Quantitation.

- Develop a recommended process for determining a QL_{nat}

Policy Work Group Assignments

- Address Implementation
- Address Verification
- Address DQOs
- Provide guidance on Matrix Effects
- Prepare introductory language in the Uses document for QL_{per}
- Explore the deletion of DL_{nat} and the possible policy changes and implications of removing it from the document, and bring this information back to the FACDQ
- Explore other policy issues not completed at the June 2007 meeting

Final Report Work Group

- Develop Final Report

Closing

Mr. Wheeler and Ms. Shorett thanked the Committee for its hard work. They noted that the next FACDQ meeting would be a teleconference meeting in late July or early August. They also confirmed the schedule of remaining Committee meetings in 2007:

- September 19-21
- December 5-7

11/21/2007

Draft for Discussion

Document # FACDQ11-02

Both meetings are to be held at the FDIC in Arlington, VA.

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

MEETING ATTENDANCE

Committee Member Affiliation

Environmental Community

Michael Murray National Wildlife Federation

Richard Rediske Grand Valley State University

Barry Sulkin Environmental Consultant

Environmental Laboratories

Richard Burrows Severn Trent Labs

Cary Jackson HACH Company

Nan Thomey Environmental Chemistry, Inc

Industries

Roger Claff American Petroleum Institute

Larry LaFleur National Council for Air and Stream Improvement

John Phillips Alliance of Auto Manufacturers (Ford Motor Co.)

David Piller Exelon Corp.

States

Dave Akers Colorado Dept of Public Health and Environment

Bob Avery Michigan Dept of Environmental Quality

Timothy Fitzpatrick Florida Dept of Environmental Protection

Thomas Mugan Wisconsin Dept of Natural Resources

Public Utilities

Zonetta English Louisville/Jefferson Co Metropolitan Sewer District

Chris Hornback National Association of Clean Water Agencies

Jim Pletl Hampton Roads Sanitation District

EPA

Mary Smith US Environmental Protection Agency

Designated Federal Officer

Richard Reding US Environmental Protection Agency

Invited Speakers/Participants

Brian Englert US Environmental Protection Agency

Ephraim King US Environmental Protection Agency

Michael Shapiro US Environmental Protection Agency

Kenneth Miller CSC, Inc.

Facilitators

Alice Shorett Triangle Associates, Inc.

Bob Wheeler Triangle Associates, Inc.

Cole Gainer Triangle Associates, Inc.

Observers

Joanne Dea US Environmental Protection Agency

Meghan Hessenauer US Environmental Protection Agency

11/21/2007

Draft for Discussion

Document # FACDQ11-02

Marion Kelly US Environmental Protection Agency

Nicole Shao US Environmental Protection Agency

Brad Venner US Environmental Protection Agency

Stephen Winslow US Environmental Protection Agency

Jim Christman Hunton & Williams

DISTRIBUTED MATERIALS

Committee's Packet of Materials

Agenda (June 6-8, 2007)

FACDQ #6 Draft Meeting Summary (December 6-8, 2006)

Draft Pilot Study Report

Draft Procedures Report

MQOs Approaches & Discussion

Technical Work Group Recommendations on Procedure

Multi/Interlab: Approaches and Discussion

Revised Uses Document

DQO Discussion

FACDQ Implementation Issues To Date

Verification

Final Report Work Group: Draft Schedule & Assignments

Distributed at Meeting

What do we need a procedure to do?

Revised Glossary of Terms

What The Pilot Does What The Post-Pilot Could Do

Proposed Language: Matrix Effects

Proposed Language: States MQO Compromise

11/21/2007

Draft for Discussion

Document # FACDQ11-02

Proposed Language: MQO Compromise

Proposed Language: MQO Agreement

MQO Continuum