

ELAB

Environmental Laboratory Advisory Board

“ELAB”

Semi-Annual Face-to-Face Meeting

Savannah, Georgia

January 31, 2011

Environmental Laboratory Advisory Board

- **Solicits Consensus Advice From the Environmental Laboratory Community On the NELAC Process and Standards.**
- **Provides Advice, Information, and Recommendations to the EPA Administrator, the Office Of Research and Development and the Forum On Environmental Measurements**
 - Enhancing The Environmental Protection Agency's (EPA's) Measurement Programs
 - Facilitating The Operation And Expansion Of A National Environmental Laboratory Accreditation Program.
- **Sixteen Individuals Who Serve as Representative Members:**
 - Trade Associations For The Environmental Laboratory Industry,
 - Trade Associations From EPA's Regulated Community;
 - Environmental Public Interest Groups;
 - Academia;
 - Federal, Local, And Tribal Governments;
 - Laboratory Assessment Bodies.

Name & Affiliation *Members* *Represented Constituency*

Mr. David Speis (Chair)	ACIL
Ms. Judith Morgan (VC)	Commercial Environmental Laboratories
Dr. Richard Burrows	Commercial Laboratory Industry
Mr. Eddie Clemmons	Clients of Quality System Services
Mr. John (Jack) Farrell	The NELAC Institute (TNI)
Dr. Jeff Flowers	Elected Officials of Local Government
Dr. Reza Karimi	Nonprofit R&D Organizations
Dr. Skip Kingston	Native Americans and Academia
Ms. Sylvia (Silky) Labie	Third Party Assessors
Mr. Jeff Lowry	Proficiency Testing Providers
Mr. John Phillips	Alliance of Auto Manufacturers
Dr. Jim Pletl	Municipal Environmental Laboratories
Ms. Patsy Root	Laboratory Product Developers
Ms. Aurora Shields	Wastewater Laboratories
Ms. Michelle Wade	Laboratory Accreditation Bodies
Dr. Michael Wichman	Association of Public Health Laboratories

AGENDA
ENVIRONMENTAL LABORATORY ADVISORY BOARD

January 31, 2011; 1:30 – 5:00

1:30	Opening Remarks	Autry/Speis
1:35	ELAB Members & Guest Introduction	All
1:40	Review/Approval of November Minutes	All
1:45	Sufficiently Sensitive Methods	Phillips
1:55	Methods Update Rule (MUR)	Flowers
2:05	SW-846 Policy Update	Speis
2:15	Recreational Water Quality Criteria Development	Root
2:25	Workgroup Reports	
	- Monitoring Workgroup	Karimi
	- Measurement Technology Workgroup	Morgan
2:45	Office of Water, Quality System Update	Speis
3:00	BREAK	
3:30	Open Discussion - New or Old Topics	All
4:30	News/Updates from the DFO	Autry
4:45	Review Action Items	Speis/Autry
5:00	Adjourn	Speis

Sufficiently Sensitive Test Methods Rule

Task Group Report Out

Jim Pletl – Chairman

Jeff Flowers, Jeff Lowry, Patsy Root,
John Phillips and Michael Wichman

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122 and 136

[EPA–HQ–OW–2009–1019; FRL–9166-7]

RIN 2040–AC84

National Pollutant Discharge Elimination System (NPDES): Use of Sufficiently Sensitive Test Methods for Permit Applications and Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing minor amendments to its Clean Water Act (CWA) regulations to codify that under the National Pollutant Discharge Elimination System (NPDES) program, only “sufficiently sensitive” analytical test methods can be used when completing an NPDES permit application and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit.

This proposal is based on requirements in the CWA and existing EPA regulations. It also would codify existing EPA guidance on the use of “sufficiently sensitive” analytical methods with respect to measurement of mercury and extend the approach outlined in that guidance to the NPDES program more generally. Specifically, EPA is proposing to clarify the existing NPDES application, compliance monitoring, and analytical methods regulations. The amendments in this proposed rulemaking affect only chemical-specific methods; they do not apply to the Whole Effluent Toxicity (WET) methods or their use.

**Federal Register / Vol. 75, No. 120 /
Wednesday, June 23, 2010 / Proposed Rules**

1. 45 Day Comment Period – Ended August 9th 2010
2. ELAB submitted a letter of concern on 08/09/10 as a placeholder for later comments
3. ELAB submitted a comprehensive set of comments on October 18th based on Task Group recommendations
4. ELAB has requested a face to face meeting with the USEPA Office of Water to discuss our comments

Under the proposed rules, EPA would specify that a method is "sufficiently sensitive" if it meets one of three tests:

1. The method minimum level (ML) is "at or below the level of the applicable water quality criterion or permit limitation."
2. The ML is above the applicable criterion or permit limit, "but the amount of the pollutant or pollutant parameter in a facility's discharge is high enough that the method detects and quantifies the level of the pollutant or pollutant parameter in the discharge."
3. The method has the lowest ML of the methods approved by EPA under 40 CFR 136 for the pollutant or pollutant parameter.

ELAB Voiced Concerns in the Following Areas

- * NPDES Data Quality Objectives
- * Method Validation
- * Method Accuracy, Precision & Sensitivity
- * Method Selectivity
- * MDL and ML Definitions
- * Rule Impact on Data Cost

See Handout for Summary of Comments

Conclusions

- * ELAB does not recommend the implementation of the Sufficiently Sensitive Test Methods Rule as written, because of the specified concerns.
- * We believe that EPA is moving forward with the implementation of this rule.
- * ELAB has requested a meeting with the Office of Water to discuss our concerns.

Laboratory Management Group

* Task Assigned:

- Review and make draft Comments for the boards use of:
- *40 CFR Parts 136, 260, 423, et al. Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Analysis and Sampling Procedures; Proposed Rule (Method Update Rule [MUR])*
- The time to complete on assignment was brief due to short notice
- LMG scheduled two work sessions in Nov to form and review draft comments for the ELAB

Laboratory Management Group

- * **LMG invited technical assistance for several affect interest groups**
 - Comments were accepted and incorporated into the draft response from:
 - Commercial Lab Industry
 - The NELCA Institute (TNI)
 - Lab Accreditation Bodies
 - Standard Methods Publishers
 - Lab. Product Developers
 - Wastewater Laboratories

Laboratory Management Group

* Key Topics Addressed

- General Agreement with MUR
- LMG prepared Comments on
 - *Table **IB** (and footnotes)*
 - Need to make clear what QA would apply to SM
 - Make clear distillation requirements
 - Clean up elements referenced to include method referenced metals
 - *Table **IC** (and footnotes)*
 - Use of limits
 - *Table **ID** (and footnotes)*
 - Suggest update of 600 methods
 - *Table **II** (and footnotes)*
 - Add methods to HT for micro on sludge
 - *Section I **Quality Assurance***
 - Recommend TNI references to replace NELAC 2003
 - Recommend the quality assurance and quality control requirements listed in the appropriate sections in the consensus body compendium be adopted

Laboratory Management Group

- * All meetings were open to the public and minutes were prepared and submitted to the ELAB for review and consideration
- * The Draft submittal was prepared within the original time frame and provided to the full ELAB for its review and discussion
- * Subsequently; the time frame was extended by EPA
 - (thank you EPA)
- * ELAB completed its review and submitted consensus comments to EPA

ELAB

USEPA Policy for the Development & Use of SW-846 Methods

Environmental Laboratory Advisory Board
Federal Advisory Committee to EPA

Savannah Georgia
January 31, 2011

Issue Summary & ELAB Objective

- * **Stakeholders Express SW-846 Update IV Use Status Concerns**
 - Clear Language on Status Not Provided by EPA - ORCR.
 - Stakeholder Assume Updates are Improvements & Previous Versions Obsolete.
 - Regulatory Authorities Apply Changes Piecemeal for Monitoring Uses
 - Diverse AB Accreditation Policy Causing Interstate Recognition Difficulties
 - Revised QC Specifications Conflict With Previous Versions Causing Confusion

- * **ELAB Recommendation for USEPA ORCR SW-846 Policy**
 - Specify Termination Dates for Replaced Methods
 - Implement Policy Specifying Rigorous Criteria for Method Revision
 - Define Criteria for Initiating Revisions Including Clear Distinctions From Previous Versions
 - Define How Editorial Changes Are Differentiated From More Substantial Technical or Procedural Changes
 - Provide Strong Statement Indicating Latest Method Version is Preferred
 - Substantive Changes Should Be a New Version or a New Method

Issue Summary & ELAB Objective

- * **ELAB Recommendation for USEPA ORCR SW-846 Policy (cont'd)**
 - Establish Notification Provisions of The Agency's Intent to Withdraw/Replace Methods With a Target Date for Withdrawal
 - Provide Change Summaries in Revised Methods with Impact Statements
 - Reconfigure SW-846 Web Page Methods Table Indicating Most Recent Versions Only.
 - Provide Clear Definitions and Intended Use for Terms Such as Draft Method, Obsolete, Withdrawn, Final, Preferred Use, Etc.
 - Assign New Method Numbers When New/Revised Methods are Issued That Include a Technology Change or Significant Chemistry Change.
 - Caucus With States, NELAP Board & Interested Stakeholders to Develop Strategies Promoting The Performance Approach, Streamlining The Assimilation And Accreditation Of New Method Versions.

Key Features of ORCR Draft Policy

- **Method Availability Through FR Notice of Data Availability - NODA**
 - Formal Rulemaking Discontinued
 - Majority of Methods are Guidance
- **ORCR Committed to Performance Based Methods**
 - Promotes Flexibility for Complex RCRA Wastes
- **ORCR *Strongly* Recommends the Use of the Latest SW-846 Method Especially in New Monitoring Situations**
 - Most Recent Methods Posted as Part of the SW-846 Compendium
 - Designed for Flexibility & User Optimization
 - Older Methods Allowed for Existing Permits, Consent Decrees, etc
 - No Agency Restrictions on use of Superseded Methods
 - Superseded Versions Will be Available Through Separate EPA Link

Key Features of ORCR Draft Policy

- **Methods Added Following Rigorous Tech Evaluation, Internal & External Review**
 - Appended to Compendium Upon Completion of Process
- **Specific Naming Convention Designed to Minimize User Confusion**
 - Method Number Retained if Revision Retains Underlying Technology
 - Insignificant: Data Precision & Accuracy Unaffected – Letter Suffix Unchanged
 - Clarifying Language, Additional Compounds, Formatting, Editorial, etc
 - Significant: Data Precision & Accuracy Affected – Letter Suffix Sequenced
 - Bias Reduction, Improved Precision & Accuracy, New Instrument Specifications, etc

Key Features of ORCR Draft Policy

• **Final Method:**

- Methods Formally Incorporated Into SW-846 Compendium

• **Draft Method:**

- Methods Completing Technical Review by EPA But Not Adopted Into SW-846 Compendium Via NODA

• **Revised Method:**

- Methods Included In SW-846 Compendium Which Incorporate Significant or Insignificant Changes
 - Significant Changes Impact Data as Defined – Letter Suffix Sequenced
 - Insignificant Changes – Number and Letter Suffix Remain Unchanged
 - Changes Detailed in Summary

• **Superseded Method:**

- Earlier Method Version Replaced by a Revised Version in Compendium
 - Term *Superseded* is Documented in Method Title

• **Withdrawn Method:**

- Methods EPA Strongly Recommends not be Used Because of Technical or Regulatory Inadequacies

ORCR SW-846 Method Policy - Next Steps

- **Current Version is Draft – Not for Release**
- **Final Management Review**
- **Posted for Comment as Part of Update V in the FR Using NODA**

Federal Water Quality Standards and Recreational Water Quality Criteria

Summary for ELAB

January 31, 2011

EPA Is Currently Undertaking Two Efforts

1. Revision of the Federal Water Quality Standards at [40 CFR 131](#)
2. Developing new or revised Recreational Water Quality Criteria recommendations (per the [BEACH Act](#))

1. Federal Water Quality Standards (WQSs)

- Located at 131.11
 - States create and adopt their own WQSs, which are reviewed and approved by EPA (per 303(c))

OR...

- WQSs are put in place by EPA in those States that have not adopted EPA-approved WQSs

2. Recreational Water Quality Criteria - The BEACH Act

- Oct 10, 2004 Congress signed the BEACH Act (Beaches Environmental Assessment and Coastal Health Act), amending the CWA and requiring EPA to:
 - conduct studies associated with pathogens and human health [by OCT 2003](#)
 - publish new or revised recreational water quality criteria based on those studies [by OCT 2005](#); these will replace the [1986 WQS](#)

Studies were completed DEC 2010 and new criteria will be published by OCT 2012, along with new/revised analytical methods

Why Should We Be Interested?

- * Water quality criteria play a critical role in the CWA; they are used in:
 - **Water Quality Assessments (CWA Sections 303(d) and 305(b))**
 - **Total Maximum Daily Load determinations**
 - **National Pollutant Discharge Elimination System (NPDES) (CWA section 402)**
 - **Non-point Source Programs (CWA section 319)**
- ❖ **Recreational Water Monitoring and Notification**

Why Should We Be Interested?

- * New water quality standards and criteria will be accompanied by new or revised analytical methods
- * Criteria will likely include: *E coli*, enterococci and/or bacteroidales
- * New criteria must include at least one rapid method (real time-PCR for enterococci and/or bacteroidales)
- * Rapid method(s) to be used at ‘some’ beaches, not likely all

Topics To Think About Prior To Criteria Publication

- * Which Beaches Will Require Rapid Methods Versus ‘Traditional’ Testing? (Designated Use)
 - When/Where Do Samples Have To Be Taken?
 - What Time To Results Is Expected From A Lab That Is Using RT-PCR? (Note: There Is A 6-hour Hold Time Already In Place)

Topics To Think About Prior To Criteria Publication

- * How will RT-PCR methods be adopted in labs?
 - Who will assess labs? (EPA RT-PCR methods are 100+ pages long)
 - When will EPA have assessment criteria?
 - When/How will assessor training occur?
- * PT providers
 - Has there been discussion with PT providers?
 - How they will be assessed for RT-PCR samples?

Summary

- * New water quality standards and criteria will be in place by OCT 2012; adoption in 2015
- * Labs will need guidance on how to adopt new rapid methods
- * Assessing Bodies will need guidance on how to assess labs that are using RT-PCR methods and PT providers