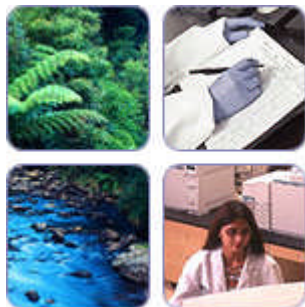




# Managing the Impact of New and Revised Regulatory Method Implementation on the Laboratory Community

NEMC - 2009

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## Managing the Impact of New and Revised Regulatory Method Implementation on the Laboratory Community

- \* Focus on Regulatory Implementation Not Individual Method Mechanics
- \* The Background & The Issue
- \* USEPA/States Roles, Global National Accreditation Impact & Coordination Needs
- \* A Case Study
- \* The SW-846 Issue, Update IV, Accreditation Impacts & Examples
- \* What The Future Holds





## The Issue & The Background

### \* EPA Role

- Clarify the Use Application
  - How, When & What About Previous Versions?

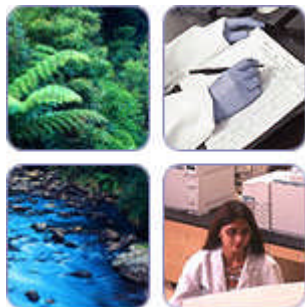
### \* States Role

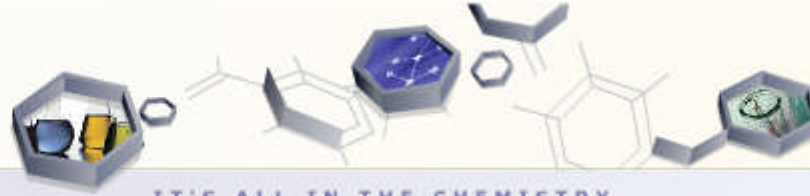
- Local Program Application to USEPA Requirements
- Coordinate Accreditation for Uniform Implementation

### \* Global Impacts for National Accreditation

- States Can No Longer Act Unilaterally
- Secondary Accreditation Impacts Multiple States
- Coordinated Approach Between States Required

### \* Lack of Accreditation Coordination (Unilateral Implementation) Causes Interstate Accreditation Difficulties for National Accreditation Programs

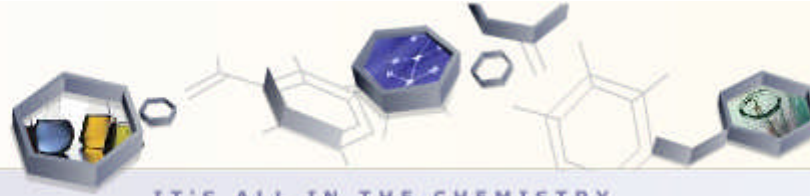




## A Case Study – The Method Update Rule

- \* **New Federal Rule Changes Clean Water Act Method References**
  - EPA Provides Significant Advanced Notice on Implementation Date
  
- \* **State Implementation Process**
  - NELAP Board Requested to Coordinate Implementation
  - Unilateral Implementation Occurs Instead
  - Interstate Accreditation Recognition Difficulties Immediately Occur





## **MUR Implementation Gone Bad** **New Jersey Strategy vs. Pennsylvania Strategy**

- \* **PA Implements 4/1/07, NJ Implements 7/1/07**
  - MUR Method Accreditation Required for PA CWA Analysis
  - NJ Labs With Secondary Accreditation in PA Can't obtain Recognition Until 7/1/07
    - NJ Labs Must Sub PA CWA Analysis
- \* **Alternative: Seek Primary Accreditation in PA**
  - Expensive
  - Lengthy process
- \* **The Situation Self Resolves Over Time**



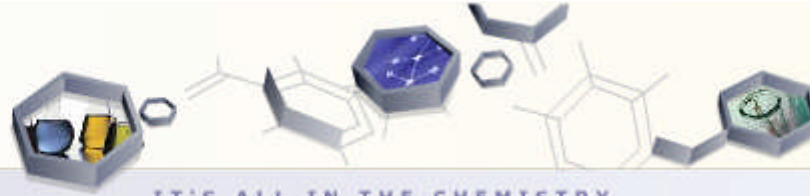


## SW-846, Update IV

### EPA Objectives vs. State Application

- \* **North & South Carolina Strategy Forces Issue**
  - Both Require Update IV Methods Exclusively
  - Other States Require III But Accredit Both
  - Labs Must Obtain Primary Accreditation for Update IV for Recognition in Carolinas
  - Can Updates III & IV Co-exist In the Laboratory?
    - Multiple Accreditations
    - Multiple SOPs
    - Batching, Instrument Efficiency
    - Data Processing Confusion
    - Cost vs. Data Quality Improvement
  
- \* **Interstate SW-846 Accreditation Difficulties Will Never Self-Resolve**





## Implementation (EPA) Accreditation (States)

### \* Implementation

- Method Use Status Language Not in Updates and Not Provided By ORCR (Formerly OSW)
- No Timeline For Moving to UPDATE IV or Discontinuation Of Update III
  - All Versions Are Valid.



### \* Regulatory Authorities Use Status Confusion

- Varying State Accreditation Strategies
  - Many Required To Use The Latest Version
- Looking to ORCR for the “*Accreditation Solution*”

### \* Interstate Implementation/Accreditation Strategy Absent.



# Method Version Uncertainty Creates Laboratory Difficulties

## \* Accreditation

- Differing State Agendas
- States Must Employ Similar Accreditation Mechanisms to Resolve Interstate Accreditation Issues

## \* Identification of Intended Use

- Revised Methods Contain New, Different and Often Conflicting Requirements vs. Old Methods

## \* Maintaining Multiple Method Version Accreditation is Logistically Unmanageable

- Differing QC
- Differing Calibration
- Requires Separate Batching/Separate Instrumentation
- Execution Confusion Leading to Misreporting of Analytical Data
- Sophisticated Management of Analysis & QC Difference

## \* The Bottom Line: Increased Cost and Unnecessary Waste





# Difficulties for Laboratories

- \* **Example: Method 8270C vs. 8270D**
  - 8270C SPCC and CCC
    - Positive, Negative Or Neutral Impact?
  - 8270D -has minimum response factors for 67 analytes.
    - Positive, Negative Or Neutral Impact?
  - 8270D-Minimum RF applies to all levels of the curve, not just the Average RF.
    - Positive, Negative Or Neutral Impact?
  - 8270D- Has different calibration criteria
    - Positive, Negative Or Neutral Impact?
- \* **All Versions are Capable of Producing Good Quality Data – USEPA ORCR**





## What are EPA's Method Use Objectives?

- \* ORCR Must Provide Clarity on Use Objectives
- \* What is the Relationship of a New or Revised Methods to Previous Versions?
- \* Do New Methods Supersede Previously Existing Versions?
- \* When Does The Previously Published Version Become Obsolete?
- \* Can ORCR Issue Clarifying Position Statements On All Existing and Future Revisions Of SW846 Methods Explaining Their Status and Eliminating Difficulties that are Occurring Without Such a Statement?





## Accreditation vs. USEPA Method Use Objectives

- \* **Accreditation is a State Issue**
  - USEPA is not Involved with Laboratory Accreditation
- \* **USEPA Has a Use Agenda for SW-846**
  - Flexibility to Meet Hazardous Waste Analysis Complexity
  - Continued Support of the Performance Approach
- \* **ORCR Will Not Withdraw Previous Method Versions**
  - Consent Decrees, RODs & Permits
  - Guidance Must Remain in Place
- \* **State Program Offices Lack Methodology Expertise**
- \* **States Must Develop SW-846 Accreditation Strategy Without USEPA's Support.**
  - New ORCR Policy & Definitions will Assist in Decision Process





## Progress Towards Resolution - I

- \* **ELAB (Federal Advisory Committee – FACA) Provides Suggestions To ORCR**
- \* **Meetings Conducted Between ORCR & ELAB**
- \* **Firm Policy & Clear Definitions Proposed**
  - Working Within USEPA Legal Framework
- \* **Target Policy & Definition Refinement By August. Federal Register Notice – Unknown.**

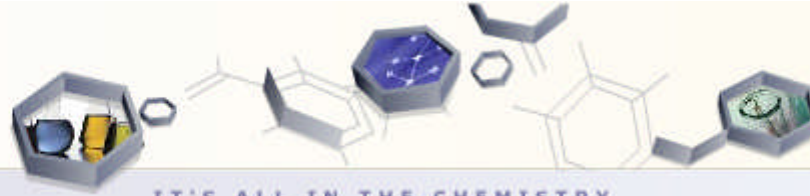




## Progress Towards Resolution - II

- \* **TNI Works With NELAP Board to Develop Accreditation Solution**
- \* **Several Proposal Meet With Resistance**
  - Eliminate Letter Designation
    - Define Method Version Via Laboratory SOP
  - Offer Accreditation for all Versions
    - Laboratory Chooses Version to Satisfy Operational Need
- \* **NELAP Progress Towards Solution Not Evident**
  - Awaiting Packaged Solution From USEPA, Which Will Not Help The Accreditation Issue.
- \* **TNI Board Issues Resolution to NELAP Board**
  - Solution Deadline Required by August





## God, Motherhood & Apple Pie

- \* **The Landscape Has Changed**
- \* **Regulatory Agencies Can No Longer Modify Methods Without Considering Use Implications**
  - Considerations For Previous Versions
  - Procedural Changes
    - QC
    - Operational
- \* **State Agencies Must Coordinate Accreditation & Implementation**
- \* **State Programs Must Clearly Understand Method Application Objectives**

