Ensuring Reliable Data Across All EPA Programs

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THE NELAC INSTITUTE

Overview and Focus

Briefly discuss:

1. Various EPA Programs for air, drinking water, hazardous wastes, and wastewater
    a. Various monitoring requirements
    b. Different analyte lists, quality control requirements, and slight differences in test methods that use the same technology.
2. Additional requirements through specifiers: The NELAC Institute, Federal Agencies, States, Local Authorities, Department of Defense, Department of Energy, and various customers.
3. How commercial laboratories support many EPA programs for a variety of customers.
4. Environmental laboratory industry, current trends, and outlook for the future.
5. Current challenges faced by the industry: breadth and magnitude of the problems.
6. How laboratory management can overcome the challenges by creating and supporting a quality culture where all employees are committed to generating and delivering reliable data for sound decision making.

EPA Programs

Drinking Water (SDWA)	Wastewater (CWA)	RCRA (Waste – solid & liquid)	Air (CAA)	CERCLA/ Superfund
• 40CFR Part 141 - Specific methods Example: VOCs 524.2/4 - 21 Primary Regulated	• 40CFR Part 136 - Specific methods • Example: VOCs 624.1 - 33 listed	• 40CFR Part 257 - 278 (ID and Eval) • Example: VOCs • 8260 – 47 (App 1 part 258)	• 40CFR Part 50 - 58 (particulates and pollutants) • 189 Total HAPs • Example: VOCs • TO-15 – 82 of 97 listed VOCs	• CLP Methods in SFAM01.1 and HRSM02.1 • Example: VOCs • SFAM01.0 Trace • 55 VOCs
Subchapter D	**Subchapter D**	**Subchapter I**	**Subchapter C**	**Subchapter B & J**

Example Method Summary – VOCs by GCMS

- **Sample Collection:** Collected in a 40mL VOC vial, preserved with HCl, stored at 6°C for up to 14 days.
- **Purging:** Sample loaded into an instrument sparger and purged with inert gas.
- **Phase Transfer:** Target analytes transferred from aqueous to vapor phase.
- **Sorbent Trap:** Vapor enters, purgeables trapped.
- **Desorption:** Trap heated & backflushed to desorb purgeables onto a GC column.
- **Separation & Detection:** Column temperature programmed to separate purgeables, detected by mass spectrometer.

Strategy for working with all QC requirements:

Option 1

Establishing a laboratory quality system that is robust enough to accommodate all the various QC requirements in order not to have to change the analytical process to accommodate varying client needs.

Option 2

Run each method by program and change analytical process based on specific matrix and/or client needs.

Consolidate Methods

Address the differences

Example - Differences

- Weighted? Not Weighted?
- 2nd Source? Primary Source?
- LFB? LCS?
- LOQ? CRDL? RL? MRL?
- RE, RSE, RSD? 15%, 20%, 30%
- RF? Linear? Options???
- Tune? There's more than 1 way?
- MDL? LOD? LOQ
- In-house limits? Method limits?
- Suggested? Recommended? Required?
- Qualify? Okay? Not Allowed?
- Recalc curve pts back to ICAL?
- % D, Recovery? Etc.
- Verify ICV, CCV, LCS, MS/MSD
- 12 hour? 24 Hour?

Consolidate criteria and terminology

- Standardized terms
- One set of criteria
- Performance Appropriate
- Holding time..3,7,14
- Cal Points - 5
- Cal Conc – Range established for use
- Internal Stds
- Surrogates
- Batch Criteria – set
- Time (12 or 24 hr) - set
- QC Frequency – set
- Sensitivity Ck - set

Comparison and Options: One Method?

1. **Program-Specific Methods:** Developed to cater to the unique needs of each program.
2. **Common Target Compounds:** Numerous compounds are shared across all programs.
3. **Basis for Unification:** Similarities sufficient to establish a single method.
4. **Best Practice Development:** Collection and handling requirements comparison reveals potential to combine for best practices.
5. **Addressing Differences:** Variations can be managed within the method by categorizing sample types.
6. **Method Application Discretion:** Advisable to avoid using the same method for trace or DW samples and known contaminated samples in the same run.

Other Requirements

Laboratories

Navigating relationship between specifiers

NELAP

Quality Systems

Section Requirements

DOD

QSM, ISO Version

Safety Aspects

Consistent Quality System

States

NELAP vs Non-NELAP Interpretations

Dual programs

Local Authorities

Individual programs

Federal

DW Cert Req's

Method Requirements by program and by organization (Std. Methods)

Certification, Qualifier Use

Additional Requirements

Customers

Contract requirements

Data storage & Sample retention

Data Deliverables

End User Expectations

Why do we need to look for new ways to improve & advance?

Advancements in Technology #1

The Industry is Changing

The digital world is forcing us to think differently

AI gives new options (and new concerns)

Sustainability (preserve the future) and Regulations (newfound contamination of the past) will continue to drive change.

The Future

There are many trends, advancements, and changes

Growth of the Industry

%2.6(analytical) to 7.8 (overall) per year on average

Market size >2.5B

Technical Staff Turnover

>%25 *(Down from COVID Era)*

Loss of experts–not enough protégé's staying in field

Possible anecdote - Automation & Better technology

Digital Communication

Electronic Documents such as eCOC, Digital messaging & dashboards via facility monitors. Electronic data, reports, etc.

ESG

Driving attention towards conservation, sustainable practices, and a need for better technology

Regulations

PFAS/PFOS testing,

Listing of PFAS & PFOS as Hazardous substances, microplastics and a few more…..

Cyber Security

Ransomware

Artificial Intelligence

New methods for system breach

Impacts to the future

REGULATIONS – Effects on products, processes, and operations

Forever Chemicals

PFAS/PFOS testing

Listing of PFAS & PFOS as Hazardous substances

And….Microplastics

HON (Hazardous Organic NESHAP)

Reduce emissions of EtO by 63% & Chloroprene by 74%

Require fenceline monitoring for 6 key air toxics (EtO, Chloroprene, Benz, 1,3-butadiene, Ethylene Dichloride,

Methylene Chloride

Removed by EPA Toxic Substances Control Act (TSCA).

New exposure limits that are >10X lower than current OSHA 1910 Standards

OTHER Considerations

- Climate related regulations are also surfacing in several states.
- More strict requirements on cybersecurity
- AI

Navigating QUALITY – Is it a system or a culture?

System/Program

- Structured and formal system
- Documents the processes, procedures, and responsibilities for achieving quality policies & objectives.

Driven by compliance with known and applicable standards. (“Checklist” driven)

Strong foundation

Culture (defined)

- Attitude and active set of values employed by an entity to support and improve the levels of quality to the customer.
- Also a set or group of values that guide how improvements are made to everyday working practices and resulting outputs.

Support at all levels

=

Both

The two must work together to realize success. One without the other does not sustain success as a long-term model.

“ Compliance does not guarantee high quality…… High quality does indicate greater compliance”

Educate & train the people to the program

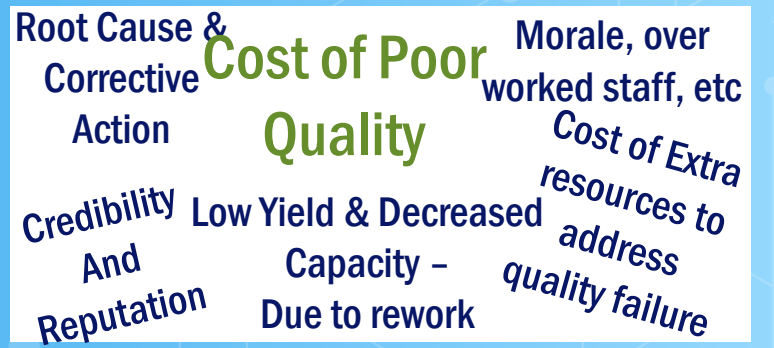
So, what can we do to ensure that we continue to provide reliable data for environmental and public health?

Emphasize and Strengthen Quality Culture

The Framework

Clearly define the program and train all levels on each aspect

QUALITY is everyone's responsibility



Educate

1. Teach problem solving
2. Use Assessments to learn
3. Encourage staff to talk about concerns and bring ideas
4. Refresh training

Root Cause (be an expert) & Corrective Action

Providing expert knowledge

Be the solution….follow up ensure success

Measure/Understand the Right Things (Metrics):

"Not everything that counts can be counted; not everything that can be counted counts."

Opportunities to Improve – Involve, Empower, Inspire

(find and create passionate professionals)

Empower the staff to learn & Grow your own SME's for:

Regulations, Standards, Auditing, Compliance

Have them teach and provide updates to the staff

Encourage Collaboration

Breakdown silos and open the communication lines

Create a "think tank" of problem solvers

Ethics & Integrity

Always the foundation

Accountability

Clear lines of responsibility

Innovation

Share challenges and empower staff to find and pitch solutions

Inform……often

Share information, upside, downside, near future focus, recent rear-view performance, etc.

FACT or MYTH?

- Corrective Action and Root Cause Analysis consistently appear in the TOP 10 deficiencies of agencies and organizations performing external audits.
- The cost of poor quality in any business is estimated at 5-30% of Gross Sales
- Most executives believe that their company's Cost of Poor Quality is less than 5%
- US environmental laboratories support 14000+ people (not including support businesses, suppliers, etc)
- There are >1200 laboratories accredited to the TNI standard
- Greater than 50% of businesses have suffered a security breach in 2024 and the types of threats are becoming more sophisticated.

Bringing it All Together

- **Consolidate Methods –** Develop a deep understanding of the method differences and regulatory program and specifier influences. Find ways to use technology to reduce the need to have redundant methods. Current option is run “as is” or to combine methods and eval all samples to the most stringent method criteria.
- **Quality Culture** – Understand if you have a culture or if the focus solely on compliance. Know the difference and build what’s missing.
- **The “Cost” of quality** – Understand your costs, both the investment in quality and the cost of failure.
- **Accountability** – Set expectations, make them known, bring up leaders who are excited about teaching and supporting quality as a key cultural ingredient in a successful future.
- **WHY WHY WHY WHY WHY** – Get good at root cause analysis. Use root cause to get to the crux of any problem or issue.
- **Continue to collaborate in the industry. Stay engaged!** Work with regulators, suppliers, competitors, to refine, innovate, reduce and combine methods. Better methods, less confusion.
- **Knowledge isn’t just for managers**…..EMPOWER the staff to learn how things work correctly and the consequences of when they don’t.

THANK YOU

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