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Exploring the Need for a Consensus Standards Development Program to Accredit Emerging Environmental Monitoring Technologies

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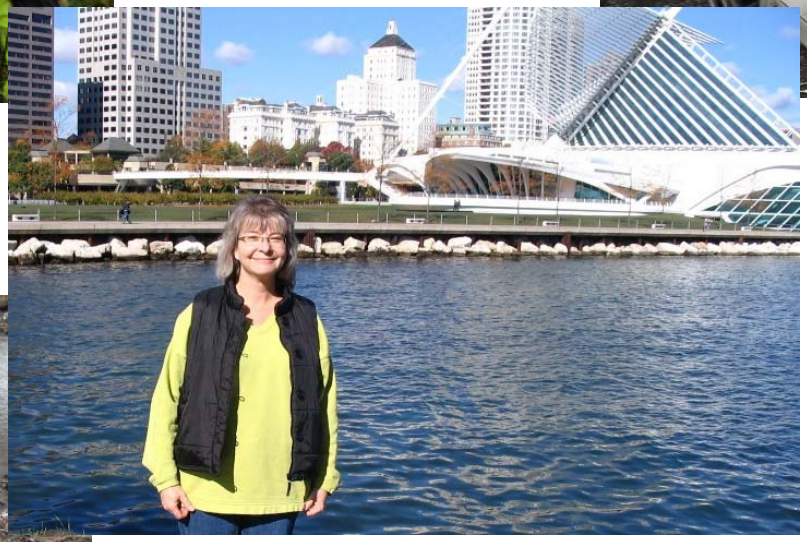
Overview

- Define the boundaries of today's topic
- The challenges of sensor technology
- What is the need?
- Recent efforts
- Conformity assessment programs
- Standards development programs
- Methods, performance specifications and limits development
- Consensus standards development program approach

Why am I talking to you?



What am I talking about today?

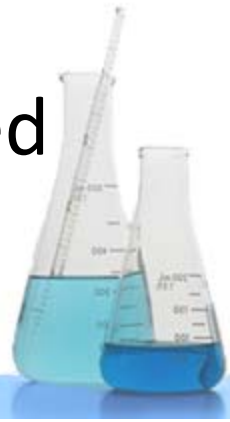
- Emerging monitoring technologies = sensor technologies
- Environmental monitoring
- Focus on characterization of data in terms of data quality
- A system that includes data specifications, methods, standards, conformity assessment and accreditation development

The challenges of sensor technologies

- Rapidly developing (changing) technologies
- Diverse data use – citizen monitoring, research, process control, regulatory, and more
- Largely uncharacterized quality
  - In many cases, specifications are non-existent
- Difficult to compare traditional quality indicators for continuous data monitoring

The challenges of sensor technologies

- How do we measure precision, accuracy and completeness on continuous data?
  - Matrix spikes, duplicates, 2nd source verification, calibration may be difficult to perform
- Data verification and validation needs to be defined and may be very different from traditional laboratory data
- Regulatory limits may need to be redefined



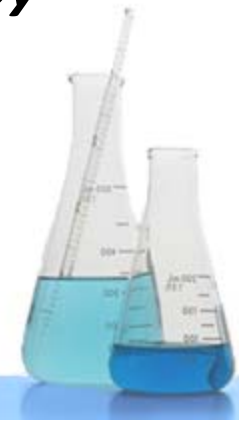
The challenges of sensor technologies

- While the focus tends to be on the device, conformity assessment programs must also address:
  - Training of device users (might include instructions provided by vendors)
  - “Sampling” considerations
  - Data manipulation and data management considerations

The challenges of sensor technologies

- When we start to collect real time data, the data itself may be better, but different, than more traditional monitoring approaches Regulatory limits and/or decision making rules may need to be revisited and revised

It may not be appropriate to verify real time data by comparing it to the same data generated using traditional laboratory methods.



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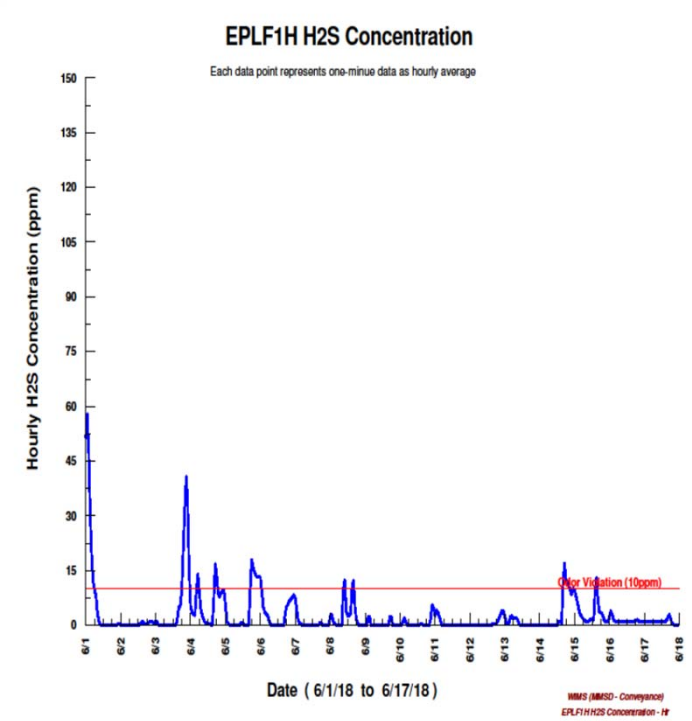
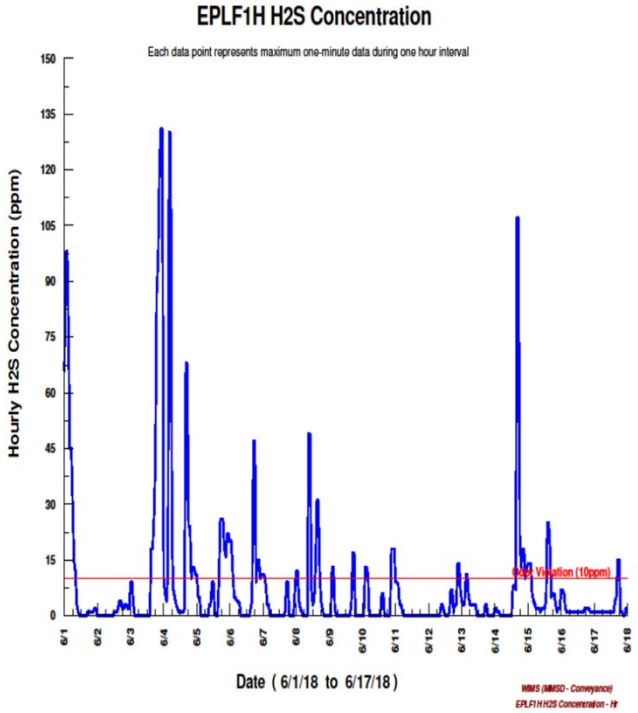
One example…





What is needed to ensure that the data generated is of known and documented quality that can be used for its intended purpose?

- What is being measured?
- How is it being measured?
- How is quality defined (specifications)?
- Who made the rules?
- Who made sure they were being followed?
- Who decided rules were needed?

Looking at this another way…

- Conformity assessment program/Accreditation body
- Standards development
- Conformity assessment
  - Performance specifications, methods, customer specifications, etc.

Recent Efforts

- E-Enterprise Advanced Monitoring meeting with ANSI stakeholders in November 2017
- White paper distributed in March – "E-Enterprise Advanced Monitoring: EPA and State Objectives and Principles for Standards Development and Conformity Assessment Organizations"
- Workshop – EPA Air Sensors 2018
- Several Standards Development Organizations have prepared mock ups of what a standard for sensor technology might look like

Conformity Assessment Programs

- Examples of Federal vary
  - Center for Devices and Radiological Health Standards Program
    - Medical devices – Works with SDOs to develop standards, manages the Standards Program, maintains database, coordinates recognition of standards publishes these in Federal Register
  - DOD Environmental Laboratory Accreditation Program
    - Requires certification and works with 3rd party ABs for assessment; specifications defined in Quality Systems Manual
  - Energy Star Program
    - Voluntary program, 3rd party certification of products
  - Nationally Recognized Testing Laboratories Program (NRTL)
    - OSHA uses this to recognize organizations that test and certify products

NELAP and NEFAP

- Not Federal conformity assessment programs
- Governed by accreditation councils (AC)
- Accreditation bodies may be states or non-governmental ABs, depending on the program
- Standards developed through a consensus standards development program
- Methods and customer specifications are independent of the program but may be specified by AB to comply with regulatory requirements

Conformity Assessment Program for Sensor Technology

- EPA and states seek organizations to design and manage a Conformity Assessment program
  - No funding commitment
- Suggested elements (partial list)
  - Consensus based standards against which new monitoring technologies can be evaluated
  - Testing and evaluation protocols
  - Accreditation procedures for organizations that will be testing products
  - Procedures for certifying organizations

Conformity Assessment Program for Sensor Technology

- Is there a regulatory driver for an accreditation program for sensor technology?
  - CWA, CAA, SDA regulations?
  - Permits, limits generally not written for continuous monitoring measurements
  - Who would have regulatory authority to approve?
- EPA may need to address this before too long

Standards Development Program

- "Consensus-based performance standards and evaluation methods should be developed and maintained by technical working groups representing a wide range of stakeholders, including EPA and states. This helps ensure that the protocols developed both meet the needs of the program and are technically achievable"
- "For endorsement of standards and certification of products, EPA and states would need to review and approve processes used to develop standards, protocols and procedures for the program"
  - E-Enterprise March 2018 white paper

Existing Standards

- Various standards may have applicability in developing standards for sensor technologies
  - ISO/IEC 17065 – Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services
    - Not written specifically for environmental measurements but is a recognized management system approach that can be applied to sensor technology
  - TNI Standards (REFERENCE)
    - Not written for product or sensor technology but applicable to environmental measurements systems for laboratory and field measurements

Standards Development for Sensor Technology

- Must be consistent with Federal law and policies
  - OMB Circular A-119
  - Section 12(d) of the NTTAA
  - Guidance on Federal Conformity Assessment
    - Consensus based
    - Representative of involved stakeholders
- Ensure that these can be communicated and transferred effectively to those implementing the technology, regulators and others involved
- Input must represent the expertise of the industry as well as the needs of data users and regulators

Standards Development for Sensor Technology

- Effort could be undertaken by existing SDOs, using existing standards and modifying them to meet the specific needs of environmental sensor data technologies.
- The scope of the initial effort must be well defined and narrow enough to be achievable.
- The standards development process should be flexible enough to be able to extend to other aspects in the future.

In summary….

- EPA and the States should continue the effort to develop a Conformity Assessment Program for Environmental Monitoring Sensor Technologies.
- The program should use existing models but recognize the technological and operational differences between sensor and traditional laboratory measurements.
- The process for developing standards should be open, transparent, and include input from all affected stakeholders.

In summary….

- EPA and other regulatory agencies may need to develop new limits or tolerances for parameters monitored using sensor data.
- There are many stakeholders who are ready and interested in supporting this effort.

Thank you for your time!

Questions??