THE NELAC INSTITUTE

Changes to TNI Standard Module 6 Quality Systems for Radiochemical Testing

Presented at the
2015 RRMC

Iowa City, Iowa
25 September 2015

Radiochemistry Expert Committee

Committee Members

David Fauth
C. Martin Johnson, Jr.
Sreenivas Komanduri
Nile Ludtke
Keith McCroan
Larry Penfold
Bob Shannon
Tom Semkow
Richard Sheibley
Carolyn Wong

Associate Members

Ariana Mankerian
Bill Ray
Bryan Miller
Carl Kircher
Jim Chambers
Reed Jeffery
Joe Pardue
Ron Houck
Terry Romanko
Tom Patten
Virgene Mulligan
Yoon Cha

TNI Staff

Ilona Taunton

Background

- Environmental testing for inorganic and organic, and for radiochemical parameters, have evolved separately
- Protocols and concepts used for “stable” chemistry may not always be applicable to radiochemistry, although they often have been used as basis for quality requirements

Regulatory Background

- EPA Office of Water Certification
  - Safe Drinking Water Act (and to a lesser extent also Clean Water Act)
    - Narrow, specific set of tests
    - Promulgated methods based largely on EPA procedures from 1950s through the 1970s
    - Quality requirements sparse
    - Little or no reliable method performance / validation data

What are Key Differences?

- Lab-developed and lab-modified methods are the rule
  - Not “pre-validated” reference methods (i.e., from EPA or consensus standards bodies)
- Results are not censored rather they are reported “as measured”
  - Positive, zero or negative
- Measurement uncertainty reported with each result

TNI Radiochemistry Expert Committee

- Formed in 2012
  - Ten radiochemists (plus associate members) updated Module 6 of the *TNI Standard*
  - Balloted and unanimously approved in September 2015
- Schedule for implementation will be set by TNI and State Accrediting Bodies over the next several months

Terms and Definitions

Added definitions specific to Module 6 to add clarity

- Examples include:
  - **Detection concepts** (e.g., Critical Value, MDA/MDC, Detection Limit (DL) for Safe Drinking Water Act (SDWA) compliance)
  - **Uncertainty Concepts** (e.g., Measurement Uncertainty, Standard Uncertainty, Expanded Uncertainty, Counting Uncertainty, Total Uncertainty)
  - **And a new concept:** Radiation Measurements Batch

Exclusions and Exceptions

- Module 6 is once again applicable to non-radiometric measurements of radionuclide parameters (e.g., KPA, ICP-MS)
  - Previously excluded from Module 6 - some methods were not covered anywhere
  - Labs may fall back on *Module 4* (*Chemistry)* for technique-specific requirements or QA/QC that is not addressed in Module 6

“Detection Capability”

- Requirements similar to current requirements.
- Expressly precludes use of MDA/MDC for detection decisions

Validation of Methods

- Method performance must be known and documented for <u>all methods</u>
  - Performance data must address key performance indicators *(consistent with published guidelines e.g., MARLAP, FEM, EUROCHEM)*
  - Performance data may be taken from published validation data, historical QC results, or method validation performed by the laboratory
- The concentration range includes zero activity (since results are reported at background)

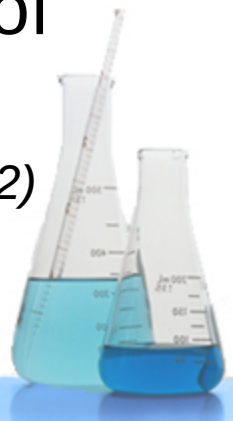
Demonstrations of Capability (DOC)

- Analyze four samples **and four blanks**
  - Blanks added since results are not censored
    - "Absolute bias" can compromise low-activity results
  - There are several options for obtaining this data including use of ongoing QC measurements!

Technical Requirements

- Reorganized to parallel the “calibration life-cycle” commonly used at rad labs
  1) Set-up of instrumentation
  2) Establish QC limits and perform ongoing instrument QC
  3) Initial method-specific calibration
  4) Calibration verification - true verification of method-specific calibration

(see ASTM D7282)



Calibration by Mathematical Modeling

- The section on calibration
  - Reiterates the need for physical (empirical) calibration of instruments against traceable reference materials
  - Allows application of mathematical or statistical corrections to empirical calibrations
  - Modeled calibrations must be validated across the range of modeled parameters

Background Measurements

- Previous requirements were vague and implementation / assessment inconsistent
  - The update differentiates between
    - subtraction backgrounds
    - short-term background checks, and
    - contamination controls
- Recognizes different approaches for determining background to minimize prescription, such as:
  - Paired measurements
  - Historical compositing of backgrounds
  - Blank populations, etc.

NEW CONCEPT !
"Radiation Measurements Batch"

- Applies to non-destructive measurements where prep has no effect on measurements
  - For example:
    - Direct counting alpha/beta swipes
    - Gamma spectrometry of air filters
- Batch size ≤ 20 samples
  - Must share common physical / chemical parameters and analytical configurations
  - May add samples to batch for 14 days
  - One LCS (can reuse), blank, and duplicate per batch

Sample Specific QC Measures

- Matrix Spikes
  - Not required for methods with yield correction using tracers / carriers
  - Not required for non-destructive methods (e.g., gamma spec)
- Duplicates (sample or matrix spike dups)
  - When multiple detectors used, the duplicate is counted on a second detector

No Special Handling of QC Samples

- Systematic preference of detectors, equipment, or glassware for QC samples is not permitted
  - For example, always counting blank in same detector, or dedicating equipment or glassware for QC samples, would be considered a systematic preference.
- Labs may dedicate/segregate glassware or instrumentation for different activity level samples as long as QC samples are not given preferential treatment

Reporting

- Results must be reported as measured (i.e., uncensored) with measurement uncertainty
- Uncertainty must be clearly defined
- Activity reference date must be reported
- Allows project- or client-specified requirements to supersede requirements of the standard.

Our Next Steps?

- Assessment checklist
- Training for assessors
- Training for laboratories

THE NELAC INSTITUTE

Thank you!!!

Questions?

For questions or more information on TNI:

BobShannon@boreal.org