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How to use the TNI standards to meet essential QC elements in the MUR

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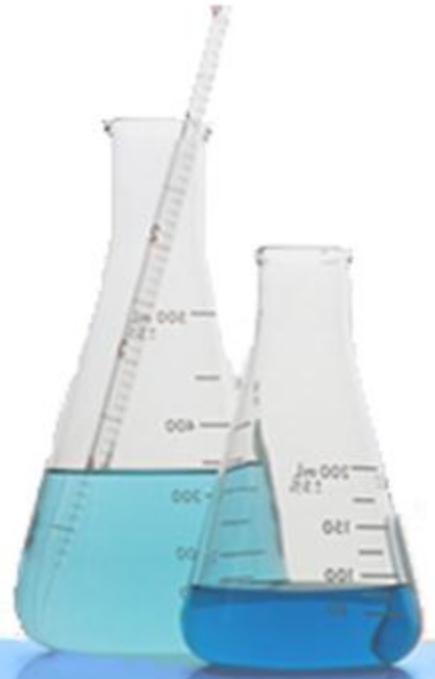


EPA Methods Update Rule

- Finalized on May 18, 2012 (Proposed 9/23/2010)
- Effective June 18, 2012
- New methods
- Updated versions of approved methods
- Revised method modification and analytical requirements
- Clarifications and corrections
- Changes to sample collection, preservation, and holding time requirements
- **Minimum QC requirements**
- “Technical Corrections”

New 136.7: Required Quality Control

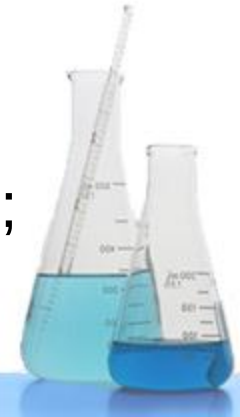
If the [chemical] method lacks QA/QC procedures

- Use the QC in an “equivalent” method
- Refer to QC section from a methods compendium
- Incorporate 12 Essential QC Checks

“In those cases where an approved method incorporates these QC procedures, the laboratory can follow the method as written without creating any duplication or conflict. “

Essential QC Checks

- (1) Demonstration of Capability (DOC);
- (2) Method Detection Limit (MDL);
- (3) Laboratory reagent blank (LRB), also referred to as method blank;
- (4) Laboratory fortified blank (LFB), also referred to as a spiked blank, or laboratory control sample (LCS);
- (5) Matrix spike, matrix spike duplicate, or laboratory fortified blank duplicate (LFBD) for suspected difficult matrices;
- (6) Internal standards, surrogate standards (for organic analysis) or tracers (for radiochemistry);



12 QC Checks (the last 6)

- (7) Calibration (initial and continuing), initial and continuing performance (ICP) solution also referred to as initial calibration verification (ICV) and continuing calibration verification (CCV);
- (8) Control charts (or other trend analyses of quality control results);
- (9) Corrective action (root cause analyses);
- (10) QC acceptance criteria;
- (11) Definitions of a batch (preparation and analytical); and
- (12) Specify a minimum frequency for conducting these QC checks.

23 Commenters Provided Concerns

- Vague, unclear: 14
- Conflicts with TNI/Standard Methods 7
- Control charts not needed 6
- Use the TNI Standard 5
- Etc.

EPA Response

- Not an issue since accreditation requirements follow the QC in the methods
- Most methods contain the requirements
- Clarification (6/14): “not our intent for approved methods with existing QA/QC to be updated to include additional QA/QC”

The 2009 TNI NELAP Standards

- Requirements for laboratories to be accredited under NELAP
  - Also includes requirements for Accreditation Bodies and PT Providers
- Includes requirements for:
  - Proficiency Testing
  - General Management Requirements
  - Technical Requirements for all types of labs
  - QC Requirements

Organization of the 2009 Standards

- Volume 1: Laboratories
  - Module 1: Proficiency Testing
  - **Module 2: General Requirements**
  - Module 3: Asbestos
  - **Module 4: Chemical**
  - Module 5: Microbiological
  - Module 6: Radiochemistry
  - Module 7: Toxicity
- Volume 2: Accreditation Bodies
- Volume 3: PT Providers
- Volume 4: PT Provider Accreditors

MUR and TNI Standard

- All 12 elements are already incorporated into the TNI standard for chemical analyses
  - Volume 1, Modules 2 and 4
- TNI Standard can be considered a "compendium" for QC
- NELAP Accredited Laboratories should be in full conformance to the standard with no additional efforts
- Laboratories not accredited could implement the QC requirements without conforming to the other requirements in Volume 1

Check 1: Demonstration of Capability

- 1.6 Demonstration of Capability
  - Required for all methods and all analysts
  - Required before samples are analyzed
  - Annual on-going demonstration

Check 2: MDL

- Section 1.5.2.1 Limit of Detection
  - Required if reporting data to LOQ
  - Procedure must be appropriate and relevant
  - Excludes some parameters (e.g., pH)
  - Requires verification
  - Verified annually

Check 3: Method Blank

- 1.7.3.1 Negative Control - Method Blank
  - Required for every batch of 20 samples or less
  - Excludes some parameters (e.g., pH)
- 1.7.4.1 Acceptance Criteria
  - Concentration > LOQ **AND** > 1/10 concentration of analyte in sample, or
  - Otherwise affects results
  - Corrective action required

Check 4: LCS

- 1.7.3.2 Positive Control – LCS
  - Defined as a spike in a clean matrix
  - Required for every batch of 20 samples or less
  - Excludes some parameters (e.g., pH)
  - Allows use of Matrix Spike or Certified Reference Materials as the LCS
  - Specifies the number of analytes for multi-analyte tests

Check 4: LCS

- 1.7.4.2 Acceptance Criteria
  - Based on published method limits or laboratory derived limits
  - Allows for Marginal Exceedances
  - Corrective action required

Check 5: Matrix Spikes

- 1.7.3.3 Sample Specific Controls
  - Designed to be Data Quality Indicators, not a measure of laboratory performance
  - Frequency based on method and/or client request
  - Specifies the number of analytes for multi-analyte tests
  - Types
    - Matrix Spikes (and MSD)
    - Matrix Duplicates

Check 5: MS Acceptance Criteria

- 1.7.4.3 Sample Specific Controls
  - Results used to document performance
  - Corrective action or data qualification required

Check 6: Internal and Surrogate Standards

- 1.7.3.3.3 and 1.7.4.3 Surrogates
  - Required for all appropriate methods
  - Should reflect chemistry of analytes measured
  - Added prior to any sample preparation
  - Results evaluation and corrective action required
- 1.7.1 Calibration
  - Requirements in methods (Internal Standard) must be followed

Check 7: Calibration

- 1.7.5.1 Initial Calibration
- 1.7.5.2 Continuing Calibration
  - Establishes essential elements
  - Allows flexibility
  - Method requirements supercede
  - Frequency specified
  - QC acceptance criteria required
  - Records required

Check 7: Acceptance Criteria

- 1.7.1 Initial Calibration
  - Second source verification
  - Acceptance criteria specified
  - Low point at or below LOQ
  - Results greater that high point must be qualified
- 1.7.2 Continuing Calibration
  - Acceptance criteria specified
  - Acceptable corrective actions provided

Check 8: Control Charts

- 5.9.1
  - *The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.*

Check 9: Corrective Action

- 4.11 Corrective Action
  - Required for non-conforming work or departures from policies and procedures
  - Requires root cause analysis
  - Implement and document corrective action
  - Monitor to ensure implementation

Check 10: Acceptance Criteria

- 5.9.3 Essential Quality Control
  - b) All quality control measures shall be assessed and evaluated on an on-going basis and quality control acceptance criteria shall be used.
  - c) The laboratory shall have procedures for the development of acceptance / rejection criteria where no method or regulatory criteria exist.

Check 11: Batch Definition

- 3.1 Additional Terms and Definitions
  - **Batch:** Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents.
  - A **preparation batch** is composed of 1 to 20 samples of the same quality systems matrix with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours.
  - An **analytical batch** is composed of prepared samples which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed 20 samples.

Check 12: Frequency

- Specified throughout Module 4, e.g.,
  - Daily calibration check
  - Method blanks: 1/20 or daily
  - LCS: 1/20 or daily
  - Surrogates: Every Sample

Summary

- The 2009 TNI Standard fully addresses all 12 Essential QC Elements of the MUR
- Requires following requirements in methods but provides additional flexibility and guidance
- An easy way for labs to come into compliance, even if they are not accredited

Next Steps

- Webinar on how to use the TNI standard to comply with the MUR
- Guidance document on how to use the TNI standard to comply with the MUR
- Request of EPA endorsement of TNI standard as one effective way
- Promote the use of the TNI standard for this purpose

Closing Thoughts

- The MUR only addresses chemical testing; the TNI standard has comparable requirement for other disciplines
- The 12 essential elements do not incorporate many other elements in the TNI standard, e.g:
  - Data Integrity
  - Internal Audits
  - Document Control
  - Method Validation
  - Limit of Quantitation
  - Client Requirements