Where the Rubber Meets the Road... Implementing the 2009 TNI Standard in your Laboratory

TNI Webinar Series
Day 2
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“The Plan”
- Understand “international speak”
- Review the organization of the Standard
- Look at requirements section by section
  - Discuss how you comply or how you can implement the requirement
- Work on your “issues” in work groups

Objectives
- Learn how to understand what the standard really says
- Help you to evaluate your current operations against the standard requirements
- Stimulate discussions on policies and procedures based on the standard
Day 1
Odd Terms and Usage
Standard Organization
Definitions
Technical Modules

Day 2
4.1 Organization
4.2 Management
Quality Manual
SOPs
4.3 Document Control
4.4 Review of Requests, Tender
and Contracts
4.5 Subcontracting
4.6 Purchasing
4.7 Service to Client
4.8 Complaints
4.9 Nonconforming Work
4.10 Improvement
4.11 Corrective Actions
4.12 Preventive Actions
4.13 Records Control
4.14 Internal Audits

Module 6 Radiochemistry

1.7.1 Instrument Calibration
1.7.2 Quality Control for Radiochemistry
1.7.3 Data Acceptance / Rejection
Criteria
1.7.4 Sample Handling

Radiochemistry Technical Requirements
1.7.1 Instrument Calibration

- Calibration frequency per method or laboratory SOP
- Must use reference standards with the same general characteristics as the samples

1.7.1 Instrument Calibration, Essential Elements

- Must have SOP with specific details on performing the calibration
- Must retain sufficient data to allow reconstruction of the ICAL
- Results must be calculated from the original ICAL unless otherwise allowed by regulation, method or program
- Verify ICAL with standard from second source and traceability to national standard

1.7.1 Instrument Calibration, Essential Elements, cont.

- Establish acceptance criteria for ICAL
- Unacceptable ICAL:
  - Perform Corrective Actions
  - Reanalyze associated samples or
  - Report with appropriate qualifiers
- If method does not specify the number of calibration standards, laboratory must have a procedure outlining their process for the number of points
• Calibration Verification (Performance Checks)
  – Use appropriate check sources
  – Monitor results with control or tolerance charts
  – Protect to prevent loss of activity or contamination

1.7.1 Instrument Calibration, cont.

• $\gamma$-ray perform on day of use detection efficiency, energy calibration, and peak resolution
• $\alpha$-particle perform a weekly check for energy calibration and a monthly check from detection efficiency

1.7.1 Instrument Calibration, Performance Checks, cont.

• Gas-Proportional or Liquid Scintillation perform detection efficiency on day of use
  – Count periods of >1 day – use a check at the beginning and end of the batch (duration ≤ one week)
• Scintillation Counters – perform calibration verification of detection efficiency on each day of use

1.7.1 Instrument Calibration, Performance Checks, cont.
• Measured on a regular basis
  – This is a long-term measurement
• Monitored via control or tolerance charts
• When determining sample activity subtract from total measured activity
• γ-ray and α-particle spectroscopy – perform at least once a month
• Gas Proportional counters at least quarterly
• Scintillation Counters – each day of use

**1.7.1 Instrument Calibration, Background Measurement**

• Must have a procedure for monitoring instruments for radioactive contamination
  – Frequency
  – Criteria for initiating corrective action

**1.7.1 Instrument Calibration, Contamination Monitoring**

• Any QC Failure must be addressed with appropriate corrective action
• Failure and corrective action must be noted in the lab report

**1.7.2 Quality Control**
• Method blanks must be processed identically to the associated samples
• Must have procedures to evaluate blank
  – Failed blank means reprocessing or reporting results with qualifiers
• Frequency: 1 per preparation batch of ≤ 20 environmental samples
  – Exceptions: gross α/β in solid samples and γ-ray spectroscopy

1.7.2.1 Negative Control

• Blank must be a quality system matrix that is similar to the associated samples and known to be free from analytes of interest
• Do not subtract method blank from sample results unless allowed by method of program
  – A background correction is not a method blank contamination
• Method blank must be similar in size to the samples

1.7.2.1 Negative Control, cont.

• LCS establishes the system performance
  – If unacceptable, samples must be reprocessed or reported with qualifiers
• One per preparation batch
• LCS Composition
  – Quality system matrix free from analytes of interest
  – Spiked with known concentration of target analytes
  – Matrix (sample) spikes may be used if acceptance criteria is as stringent as LCS

1.7.2.2 Positive Control (LCS)
• May also be a medium with known and verified concentrations of targets or
  • Certified Reference Materials
  • Activity of LCS must be at least 10X the MDA and at the approximate level in the samples
  • Source of spiking solutions must be different from those used for calibration

1.7.2.2 Positive Control (LCS), cont.

• $\gamma$-Ray Spectroscopy and multiple analytes
  – LCS must contain $\gamma$-emitting radionuclides representing low, medium and high energy ranges
• Methods with more than one reportable analyte (except $\gamma$-Ray)
  – Only one isotope needs to be in the LCS
  – All analytes to be tested need to be spiked
• LCS must be of similar aliquot size as the samples

1.7.2.2 Positive Control (LCS), cont.

• Must have procedures for determining the effect of the sample matrix on method performance
• Procedure must address
  – Tracking, managing, and handling the QC criteria
  – Appropriate compounds and concentrations
  – Calculations and evaluations
  – How results are reported based on matrix QC Samples

1.7.2.3 Sample Specific Controls
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1.7.2.3 Matrix Spike

- Frequency specified by method or client
- Spike per method, client and regulatory requirements
- Insufficient sample size must be reported
- Activity of spiked analytes >5 time the MDA
- Spiked material source must be different from calibration material

1.7.2.3 Matrix Spike, cont.

- Spike known activity to sample after sub-sampling but before any other preparatory or analytical treatment.
  - Requirements for isotope spiking and multiple analytes are the same as LCS

1.7.2.3 Replicates, MSDs & LCSDs

- Precision of the method or sample can be determined from replicate analysis
- Follow method and/or client requirements for the frequency and types of replicates
- When low-level samples (<3 times MDA) are analyzed LCSDs are recommended.
• **Tracers and Carriers**
  - Add after aliquoting but before and preparatory or analytical step
  - Assess tracer or carrier yield against method (or SOP) requirements.
  - When yields are not met, take corrective action, and note problem and corrective measures in the report

**1.7.2.3 Tracers and Carriers**

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• Document all procedures that are used for data reduction.
• Report each result with its measurement uncertainty
  – Indicate whether reported value is combined standard or expanded uncertainty
  – When reporting expanded uncertainty, the coverage factor and/or the approximate confidence level
• Use TNI-identified procedures for uncertainty determination

**1.7.2.4 Data Reduction**

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• Use method specified reagent purity
  – Default is analytical reagent grade or better
  – Check labels to verify that purity meets method requirements
• Water quality must be monitored and must meet method requirements

**1.7.2.5 Reagent & Water Quality and Checks**
• Establish and maintain requirements for radionuclide standards
  – Reference standards must be from NIST, NIST-traceable or a foreign national standards lab
  – Commercial suppliers must conform to ANSI standards
  – Standards must have a certificate of calibration that conforms to ANSI N42.22
  • Consult with supplier if activity is different from certified value
  • Use only decay-corrected certified value
  – Have a written procedure for handling, storing and establishing expiration dates

1.7.2.5 Reagent & Water Quality & Checks

• Instruments must consistently operate within the method specifications
• Glassware
  – Must be cleaned to meet method sensitivity requirements
  – Cleaning and storage procedures not specified by methods must be documented in records and SOPs

1.7.2.6 Constant & Consistent Test Conditions

• Radiological Control Program
  – Procedures for segregating samples with widely varying levels of radioactivity
  – Explicitly address how low-level and high-level samples are identified, segregated and processed
  – Measures to continually monitor and evaluate background activity and contamination

1.7.2.6 Constant & Consistent Test Conditions
• Method blanks with hits must be evaluated, identifying the source and taking measures to eliminate or minimize future problems
  – Reprocess or
  – Qualify when
    • The absolute value of the activity in the blank exceeds 3Xs its standard uncertainty and is \( \geq \frac{1}{10} \) of the activity in the samples
    • Method blank affects the sample results per method or project-specific requirements

1.7.3 Data Acceptance/Rejection
1.7.3.1 Negative Controls

• Acceptance criteria needs to account for (compensate) different aliquot sizes
• Occurrence of failed blank and applicable corrective actions must be noted in the lab report

1.7.3 Data Acceptance/Rejection
1.7.3.1 Negative Controls

• Calculate LCS and compare to acceptance criteria
  – Criteria are found in the method, specified per client/program requirements or developed internally
• Acceptable LCS validates the method performance
• Failed LCS
  – Associated sample must be reprocessed and reanalyzed or reported with qualifier
  – Must be reported to the client in the lab report

1.7.3 Data Acceptance/Rejection
1.7.3.2 Positive Controls
1.7.3 Data Acceptance/Rejection

1.7.3.3 Sample Specific Controls

- Acceptability of thermally preserved identical previously discussed criteria
- Must have procedures for checking chemical preservation before and during samples prep/analysis

1.7.4 Sample Handling
Module 7 Toxicity Testing

Toxicity Technical Requirements

1.7.1 Quality Control

- 1.7.1 Quality Control
- 1.7.2 Data Acceptance / Rejection Criteria
- 1.7.3 Sample Handling

1.7.1 Quality Control

- General Considerations
  - Must have QC procedures to monitor the validity of the tests
    - Must be recorded so trends can be detected
    - Use statistical techniques to review results
  - Use of Certified Reference Material
  - Participation in PT program
  - Replicate tests with same or different methods
  - Retesting
  - Correlating results of different characteristics
General QC Principles for all tests require detailed written procedures for monitoring:
- Positive and negative controls
- Tests to define variability and repeatability
- Measures to evaluate method capability (PMSD)
- Use of appropriate data reduction formulae
- Use of appropriate reagents & standards
- Measures to assure selectivity
- Measures to assure constant and consistent test conditions

1.7.1.1 Essential QC

Assessment of QC on ongoing basis against acceptance criteria:
- Development of acceptance limits if none exist
- Using the TNI requirements unless more stringent requirements are stated

1.7.1.1 Essential QC, cont.

Positive Controls – Standard Reference Toxicant (SRT):
- Must demonstrate consistent results with SRTs
- Ongoing performance demonstrated by performing SRTs for each method, species and endpoint
- Frequency
  - If ≥ one test per month, conduct at least 1 SRT
  - If < one per month, conduct concurrently with test

1.7.1.2 Positive & Negative Controls
• Test organisms from outside source
  – Determine sensitivity with concurrent SRT test unless
  – Supplier has control chart data for the latest 5 SRTs that are not older than 6 months
• Use method-specified SRT & dilutions under same conditions as test
• SRT must follow method procedures

1.7.1.2 Positive Controls, SRTs, cont.

• Follow method-specified use, type and frequency
  – Evaluates test performance, and organism health and sensitivity
  – Control must go through the same sample adjustments as sample.

1.7.1.2 Negative Controls

• Use SRTs to determine precision

1.7.2 Test Variability/Reproducibility

• Calculate PMSD per method and report value with test results
• Report the point estimate value with confidence intervals

1.7.1.3 Test Sensitivity
1.7.1.5 Selection and use of Reagents & Standards

- Use grades specified by method
  - Reference standard – ARG or better
- Standards & reagents for chemical measurements must follow Module 5
- Reagent-grade water – distilled or deionized

1.7.1.6 Constant and Consistent Test Conditions, cont.

- Testing and culturing must be separated when using closed refrigerator sized incubators
- There must be sufficient space for the types and numbers of tests
  - The laboratory must have adequate heating, cooling and illumination
- Air for aeration, dilution water and cultures must be free from oil and fumes

1.7.1.6 Constant and Consistent Test Conditions, cont.

- Species must be positively identified annually by a taxonomic expert
  - Records must have the taxonomic reference and taxonomist
- Calibrate routine measurement equipment per mfg instructions
  - Chemical measurements must be consistent with Module 4
  - Measurements must be documented
• Temperature must be maintained per method.
  – Measure at least once in 24 hrs
  – For continuous flow toxicity, temperature must be recorded and monitored continuously
  – Electronic data loggers must set to monitor the temperature to capture temporal variations

1.7.1.6 Constant and Consistent Test Conditions, cont.

• Water
  – Reagent grade water must meet the method requirements
  – Dilution water use during testing must allow satisfactory survival, growth or reproduction as applicable
    • Use SRTs and negative controls to demonstrate usability
  – Test for toxic metals or organics if survival, growth or reproduction criteria are not met and no other causes are present

1.7.1.6 Constant and Consistent Test Conditions, cont.

• Food quality must allow satisfactory survival, growth or reproduction
  – Use SRTs and negative controls
  – Have procedures to evaluate food acceptance
  • For bioaccumulation tests, a subset of the organisms must be analyzed for the target analytes
  • Test chamber size and solution volume specified by method
    – All test chambers must be identical

1.7.1.6 Constant and Consistent Test Conditions, cont.
• Feeding times, quantity of food and added nutrients are specified by method
• Organisms for a test must be from the same source and lot
  – Use certified seeds for soil tests
• Organisms whether used in tests or as broodstock must appear healthy, show no signs of stress or disease and have acceptable survival in the 24 hours before using in tests

1.7.1.6 Constant and Consistent Test Conditions, cont.

• All materials that come in contact with the samples or any part of the test must be non toxic
  – Appropriate materials specified in methods
  – Appropriate cleaning is specified in methods

1.7.1.6 Constant and Consistent Test Conditions, cont.

• Light intensity
  – Maintain per method
  – Record measurements annually
  – Maintain photoperiod per method and document at least quarterly
  – For algal and plant tests, light intensity must be measured and recorded at the beginning of the test

1.7.1.6 Constant and Consistent Test Conditions, cont.
• Organism health and culturing conditions
  – Culture conditions include salinity, hardness, temperature, pH
  – Health include observations of stress, disease or mortality
• Purchased organisms
  – Above information must be obtained for each lot
  – Observation must be recorded upon receipt

1.7.1.6 Constant and Consistent Test Conditions, cont.

• Age and age range is specified in the method
  – Information to support this must be maintained
• Maximum holding time for first use is 36 hours
  – Renewal – up to 72 hours after first use
  – May be modified by method or regulation
• Number of replicates specified by method must be followed

1.7.1.6 Constant and Consistent Test Conditions, cont.

• For chronic effluent or receiving water tests, control population of Ceriodaphnia must be ≤20% male
• C. dubia culturing must be able to establish blocking by parentage
• DO and pH must be within method range at the beginning of the test
  – Provide minimal aeration if DO cannot be maintained
1.7.1.6 Constant and Consistent Test Conditions, cont.

- Soils or sediments used for testing must be within the organism's geochemical tolerance range.
- If environmental conditions fall outside the method range, an individual test may still be conditionally acceptable.
  - Depends on the degree of the variation.
  - Acceptability depends on technical director and the permitting authority.

1.7.2 Data Acceptance/Rejection Positive Controls

- Control charts must be used for performance and statistical endpoints.
- Point estimates:
  - Calculate cumulative mean.
  - Chart cumulative mean with control limits at the upper and lower 95% confidence limits.

- Endpoints from hypothesis tests:
  - Calculate PMSD.
  - Plot values with control limits of +/- one concentration interval around the central tendency.
- Evaluate data falling just outside acceptance limits for usability.
- Unacceptable SRTs require evaluation of tests, corrective action and repeat test (if necessary).

1.7.2 Data Acceptance/Rejection Positive Controls, cont.
• Evaluate precision against method or laboratory criteria
• Determine laboratory precision though control charting

1.7.2 Data Acceptance/Rejection
Positive Controls, cont.

• Method-specified test acceptability criteria must be met for both the SRT and the environmental sample.

1.7.2 Data Acceptance/Rejection
Negative Controls

• Use the data analysis and reporting requirements specified by regulation, permit or method
• Plot toxicity data on semi-log graph paper relating time, mortality and concentration

1.7.2 Data Acceptance/Rejection
Selecting Appropriate Statistics

• Samples must be chilled to 0 - 6°C during or immediately after collection
  – Method or regulatory requirements take precedence

1.7.3 Sample Handling
Complying with the TNI Standard
Standard Organization

• TNI EL V1M2
  – Terms and Definitions
  – Management Requirements
    • Requirements to manage your quality system
  – Technical Requirements
    • Specifications for performing work
• TNI EL V2M3-7
  – Specific Technology-based requirements

Laboratory Organization
Management Responsibilities
Document and Records Control
Client Interactions
Purchasing/Contracting
Handling Departures (complaints, failed QC, etc)
  Corrective Action
  Preventive Actions
  Improvement
  Reviews and Audits
Data Integrity

Management Requirements

Personnel Qualifications and Training
Laboratory Environment and Equipment
Methods and Method Validation
Calibration
Measurement Traceability
Sample Collection
Sample Handling Requirements
Quality Assurance Requirements
Reporting Requirements

Technical Requirements
EL V1M2 4.0: Management Requirements

4.1 Organization

- How is your lab organized?
- What resources do you have to run a lab?
- Do you have any conflicts of interest?
- Does your laboratory meet the basic requirements outlined in 4.1.5?
- Are your basic technical and quality manager responsibilities consistent with the Standard?
4.1.1 - Legally Responsible
4.1.2 - Must meet the standard requirements, satisfy customer, regulatory or accreditation requirements
4.1.3 - Scope includes:
   - Temporary and mobile labs
   - Sites not connected to permanent facilities
4.1.4 - Must identify potential conflicts of interest if part of a larger organization that performs other activities

**Organization**

4.1.5 - Summarizes the requirements of your laboratory organization and structure
   - Each statement describes a condition
     • You must be able to demonstrate that each is implemented
     • Information, descriptions, procedures and policies for most are described elsewhere
   - Use to help identify weaknesses or gaps in your organizational structure and record

**Organization**
4.2 Management

Management Topics

- Establishing a quality management system
- Documenting policies, procedures, and SOPs
- Quality Policy
- Commitment, Communication and Accessibility
- Quality Manual
- Standard Operating Procedures
- Data Integrity

4.2.1 - Your management system must
- Be suitable for your activities
- Document policies, systems, programs, procedures and instructions for the purposes of assuring the quality of results
- Ensure communication, understanding, availability and implementation
4.2.2 - Quality Policy issued by “Top Management”
- Found in Quality Manual
- Reviewed annually
- Reflect overall objectives of laboratory as they relate to quality.

Management

4.2.2 - Quality Policy Contents
- commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;
- statement of the laboratory’s standard of service;
- the purpose of the management system related to quality;

Management

4.2.2 - Quality Policy Contents
- a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and
- commitment to comply with this Standard
- commitment to continually improve the effectiveness of the management system.

Management
Top Management must:
4.2.3 - Provide evidence of commitment to developing, implementing and continual improving the QS
4.2.4 - Communicate importance of meeting customer, statutory and regulatory requirements

Management

4.2.5 - Quality Manual
- Includes or refers to procedures
- Outlines structure of documentation
4.2.6 - Technical manager and QM roles and responsibilities
- Must be outlined in QM
- Specifically states the responsibility with ensuring compliance with the standard

Management

4.2.8.3 - Required Contents of QM
4.2.8.4 - QM Contents or Reference

A good summary of what needs to be incorporated into your daily activities

Management
4.2.8.3 The quality manual shall contain:
   a) document title;
   b) laboratory's full name and address;
   c) name, address (if different from above), and telephone number of individual(s) responsible for the laboratory;
   d) identification of all major organizational units which are to be covered by this quality manual and the effective date of the version;
   e) identification of the laboratory's approved signatories;
   f) the signed and dated concurrence (with appropriate names and titles), of all responsible parties including the quality manager(s), technical manager(s), and the agent who is in charge of all laboratory activities, such as the laboratory director or laboratory manager;
   g) the objectives of the quality system and contain or reference the laboratory's policies and procedures;
   h) the laboratory's official quality policy statement, which shall include quality system objectives and management's commitment to ethical laboratory practices and to upholding the requirements of this Standard; and
   i) a table of contents, and applicable lists of references, glossaries and appendices.

4.2.8.4 The quality manual shall contain or reference:
   a) all maintenance, calibration and verification procedures used by the laboratory in conducting tests;
   b) major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests;
   c) verification practices, which may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;
   d) procedures for reporting analytical results;
   e) the organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts;
   f) procedures to ensure that all records required under this Standard are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all standard operating procedures (SOPs), manuals, or documents clearly indicate the time period during which the procedure or document was in force;
   g) job descriptions of key staff and reference to the job descriptions of other laboratory staff;
   h) procedures for achieving traceability of measurements;
   i) a list of all methods under which the laboratory performs its accredited testing;
   j) procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;
   k) procedures for handling samples;
   l) procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;
   m) policy for permitting departures from documented policies and procedures or from standard specifications;
   n) procedures for dealing with complaints;
   o) procedures for protecting confidentiality (including national security concerns), and proprietary rights;
   p) procedures for audits and data review;
   q) procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training; and
   r) policy addressing the use of unique electronic signatures, where applicable.

4.2.7 - Top Management must ensure the integrity of the management system – Changes are planned and implemented
4.2.8.1 - Data Integrity System Elements
- Training
- Signed documentation
- Periodic in-depth data integrity monitoring
- Data integrity procedures documentation
  • Signed by top management
  • Reviewed annually

Management

Data Integrity
The condition that exists when data are sound, correct and complete and accurately reflect activities and requirements.

Definition as proposed in final standard revisions

• Data Integrity Investigations (4.16)
• Data Integrity Training and Documentation (5.2.7)
• Confidential reporting procedures
  – Assures confidentiality
  – Receptive environment
• Process for laboratory management to be informed of ethical concerns and the need for further investigation

Management

Data Integrity, cont.
4.2.8.5 - SOPs
- Must reflect all laboratory activities
- Written so that another person could use it to perform the procedure
  - Could be equipment manuals or other documents
  - Details (where options are discussed) must be included
- Must be accessible to affected personnel

Management

4.2.8.5 – SOPs
- Must be controlled with
  - Effective date
  - Revision Number
  - Signature(s)
- Must have an SOP for each accredited analyte or method

4.2.8.5.f – SOPs Contents
- 23 different topics should be discussed
- Not all may be relevant to the SOP type

Management - SOPs, cont.

1. identification of the method;
2. applicable matrix or matrices;
3. limits of detection and quantitation;
4. scope and application, including parameters to be analyzed;
5. summary of the method;
6. definitions;
7. interferences;
8. safety;
9. equipment and supplies;
10. reagents and standards;
11. sample collection, preservation, shipment and storage;
12. quality control;
13. calibration and standardization;
14. procedure;
15. data analysis and calculations;
16. method performance;
17. pollution prevention;
18. data assessment and acceptance criteria for quality control measures;
19. corrective actions for out-of-control data;
20. contingencies for handling out-of-control or unacceptable data;
21. waste management;
22. references; and
23. any tables, diagrams, flowcharts and validation data.
4.3 Document Control

- You must have procedures to control documents that form your management system
  - Policies and Procedures
  - Regulations
  - Method references and manuals
  - Equipment manuals and SOPs
  - References
  - Others???
  - Procedures will identify those documents you will control

4.3.2 - Document Approval & Use
4.3.2.1 - Standards relative to use:
  - Must be reviewed and approved before issuing
  - Must have a master list (or some other procedure) to identify controlled documents
    - Current revision
    - Distribution
  - Must discourage use of invalid or obsolete documents
• 4.3.2.2 – Performance standards for the control system
  1. Current copies must be available in the areas where they are used
  2. Must be reviewed and revised (if necessary) to make sure that the contents are up-to-date and reflect current requirements and actual procedures
  3. Ensure that all invalid or obsolete documents are not used (removal suggested)
  4. Obsolete documents that are retained must be noted as such.

Document Control

• 4.3.2.3 - Unique Identification
  - Must include
    • Date of Issue and/or revision identification
    • Page numbering that includes total number of pages (mark to signify end of document)
    • Issuing Authority(ies)

Document Control

4.3.3 - Document Changes
4.3.3.1 - Must be reviewed and approved in the same manner as the original
  - Reviewer and approver must have access to background information on document
4.3.3.2 - Identify altered or new text

Document Control
To Summarize:

- Document control means having a procedure to manage (organize) all the documents related to your quality system.
- Before releasing to the laboratory:
  - All documents must be reviewed.
  - All documents must be approved.

Document Control

- You must have a procedure to remove obsolete documents from use and a way to ensure that they are clearly marked as obsolete.
- You need a process to periodically review/revise documents.
- You must have a system to uniquely identify your documents.

Document Control

Summary, cont.
4.4 Review of Requests, Tenders and Contracts

4.4.1 - Establish a policy and a procedure to review the proposal.
Consider:
- How well the requirements are defined and understood including methods (refer also to 5.4.2, method selection)
- Your capability, capacity and resources to fulfill the proposal
- If the identified methods can meet the customers needs (also see 5.4.2)
4.4.2 - Records
- Review and changes
- Discussions (correspondence) concerning requirements or results of work
- The note seems to imply "results of work during the period of execution of contract" refers to the process by which contracted work is reviewed

4.4.3 - Subcontracted work must be reviewed
4.4.4 - Inform the customer of deviations from the contract
4.4.5 - Amendments must be reviewed using the process for original reviews
   - Inform all affected parties

4.5 Subcontracting of Environmental Tests
4.5.1 and 4.5.5 – Use a competent laboratory
- Laboratory must be accredited for the tests to be performed or
- The lab must meet statutory and regulatory requirements
- Subcontracted lab results must be indicated on final report
- Original lab report must be available

Subcontracting tests

Responsibilities to the customer:
4.5.2 - You must inform the customer in writing of the intent to use a subcontractor, and receive approval
4.5.3 - You are responsible for the subcontracted lab except when the customer or regulatory authority specifies the lab

Subcontracting tests

4.5.4 - You must have a list of subcontracted labs
- Must have a record of the evidence of complying with the standard for the work to be performed.

Subcontracting tests
4.6 Purchasing Services and Supplies

4.6.1 - You need a policy and procedure for selecting and purchasing services and supplies
   - You need procedures for receiving and storing reagents and consumables

4.6.2 - You must determine that the supplies are inspected and or verified to meet specifications.

4.6.3 - "Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered."
   - Must be reviewed and approved

4.6.4 - You must evaluate the suppliers
   - Retain evaluations
   - Have a list of approved suppliers
4.7 Service to the Client

4.7.1 - Must be willing to cooperate
- Clarifying requests
- Monitoring lab performance

4.7.2 - Solicit positive and negative feedback
- Use for improvement

4.1.5 c) - Client confidentiality

Service to the Client

4.8 Complaints
4.8 - Have a policy and procedure for resolving complaints
   - Must have records of
     • Complaint
     • Investigation (if applicable)
     • Corrective actions (4.11)

4.9 Control of Nonconforming Environmental Testing Work

- 4.9.1 - Must have a policy and procedure that is used when
  - the action/result is not consistent with your procedures or acceptance criteria
  - the action/result does not meet client requirements

Complaints

Nonconforming Work
• Policies and Procedures must:
  – Identify actions
  – Identify responsibility and authority
    - Evaluate impact of problem
    - Correct problem immediately
    - Determine acceptability
    - Notify customer
    - Recall work
    - Authorize resumption of work
  Others??

Nonconforming Work

4.9.2 - If the problem could happen again, or
If the laboratory is not following the QM, policies or procedure,

You must begin the corrective action process (4.11)

Nonconforming Work

• Related Processes
  – Corrective Action
  – Preventive Actions
  – Continuous Improvement
  – Data Integrity
• Think about the interrelationships between these

Nonconforming Work
• 4.2.8.4.4 m) - Permitting Departures
• You must have a policy for allowing deviations from your policies, procedures or acceptance criteria

Nonconforming Work

4.10 Improvement

• You must continually improve the effectiveness of your management system
  - Quality Policy
  - Quality Objective
  - Audit Results
  - Data analysis
  - Corrective Actions
  - Preventive Actions
  - Management Reviews

Improvement
4.11 Corrective Action

4.11.1 & 4.11.6 - You must have a policy and procedure for implementing corrective actions when a problem is identified
   – Identify appropriate authority
     • Identify positions responsible for assessing each type of QC measure
     • Identify positions responsible for initiating corrective actions
     • Identify positions responsible for recommending corrective actions

4.11.2 - A root cause analysis must be performed
4.11.7 - Needs only to be performed when the problem is a systemic problem
Random vs. Systematic

- **RANDOM ERRORS** are produced by unpredictable and unknown variations in the test measurement or activity. Examples might include fluctuations in room temperature, fluctuations in line voltage, mechanical vibrations, cosmic rays, etc.

- **SYSTEMATIC ERRORS** are predictable, and typically constant or proportional to the true value and always affect the results of a test measurement or procedure in a predictable direction. Systematic errors are caused by imperfect calibration of measurement instruments or imperfect methods of observation, or interference of the environment with the measurement process.

Corrective Action

4.11.3 - Identify appropriate corrective action(s)
- Should be procedure(s) that will most likely eliminate the problem
- Must be appropriate to the magnitude and the risk of the problem
- Document all activities
- Implement changes

Corrective Action

4.11.4 - You must monitor outcomes to determine effectiveness
4.11.5 - Additional Audits may be warranted
- If the problem is a deviation from policies, procedures, or competency
- Usually a serious problem – you make your decision

Corrective Action
4.12 Preventive Action

4.12.1 - Must identify both technical and administrative
   - Areas of needed improvement
   - Potential sources of problems
   - Develop action plans when opportunities are identified or preventive actions are required

4.12.2 - Procedure must include
   - Initiation
   - Process to ensure they are effective.
4.13 Control of Records

What is a Record?
In general:
4.13.1.1 - You must have procedures for the following activities as they relate to quality and technical records
- Identification
- Collection
- Indexing
- Access
- Filing
- Storage
- Maintenance
- Disposal

Records Control

• 4.13.1.2 - Record condition and storage
  - Must be legible
  - Must be readily retrievable
  - Storage areas must have an environment to prevent damage and deterioration
    • Access log for archived information
  - Must prevent loss
  - Establish retention times
    • 5 years from generation of last entry

Records Control
4.13.1.3 - Records shall be held secure
and in confidence
4.13.1.4 - Procedures for electronic
records
- Protect and back-up records
- Prevent unauthorized access
- Prevent amendments of records
- Archived electronic records must be
retrievable.

Records Control

• 4.13.2.1 - Performance Requirements
  - Establish Audit Trail
  - Facilitate uncertainty factors
  - Repeat test under same conditions as
    original
  - Understand/trace history of sample and
data
    • Historical reconstructions

Records Control

Technical Records

4.13.2.1 Record Types

- Inter lab transfer of samples
  and extracts
- Sample ID Code
- Bluff Records
  - DOC
  - Initials/signature for
    responsible individuals
- Sample receipt
- Sample preparation
  - Volumes, weights
  - Cleanup/separation
  - Incubation periods
  - ID codes, reagents
- Original observations (raw data) both hardcopy or
  electronic
  - Worksheets, data output
  - Method
  - Analysis Date
  - Analysis Time
  - Method Performance criteria
  - Expected QC Requirements
  - Derived data
  - Formulae to arrive at reported value
  - Manual calculations
  - Statistical calculations
  - Test Results
- Data Review and Verification
  - QC measures and assessments
  - Data Verification
- Instrument ID & operating
  conditions
- Calibration Records
- Test Report

Records Control

Technical Records
4.13.2.2 - Observations, data and calculations must be recorded when they are made
- Linked to a specific task

4.13.2.3 - Mistakes (errors)
- Must be crossed out
  - Don’t erase, make illegible or delete
- Enter correct value
- Initial and date
- Note reason(s) for correction
- For electronic records, original data cannot be lost or changed

Records Control

4.13.3. c) - Accreditation body has access to records
4.13.3 h) - Transfer of ownership or going out of business
- Must have a plan to address records
  - Records must be maintained or transferred
  - Must follow relevant legal or statutory requirements

Records Control

4.14 Internal Audits
4.14.1 - Overall Requirements
- Perform internal audits according to a predetermined schedule and procedure
  - Annually
- Goal is to determine compliance with the management system and the standard
- Must address all elements of the management system

4.14.1 - Overall Requirements
- QA Managers plans and organizes
  - Based on schedule and/or management requests
- Auditor credentials
  - Trained and qualified
  - Independent of the audited activity

4.14.2 - When the audit indicates that
- The operations are not effective or
- Data validity is questioned
- Must
  - Take corrective action
  - Notify customers in writing
    - Must have a policy specifying time frame
    - Management must ensure that notifications are complete
4.14.3 - Audited activity(ies), findings and corrective actions must be recorded
4.14.4 - Follow-up audits must verify and record implementation and effectiveness of corrective action

**Internal Audits**

**4.15 Management Reviews**

- 4.15.1 - Must be performed with a predetermined schedule and procedure
  - Review must be completed annually
  - Purpose:
    - Review Management System
    - Review lab activities for suitability and effectiveness
    - Introduce changes or improvements

**Management Reviews**
4.15.2 - Findings and actions must be recorded
- Management must ensure that actions are completed within the specified time period

Management Reviews

- the suitability of policies and procedures;
- reports from managerial and supervisory personnel;
- the outcome of recent internal audits;
- corrective and preventive actions;
- assessments by external bodies;
- the results of interlaboratory comparisons or proficiency tests;
- changes in the volume and type of the work;
- customer feedback;
- complaints;
- recommendations for improvement;
- other relevant factors, such as quality control activities, resources, and staff training.

Management Reviews

4.16 Data Integrity Investigations
Data Integrity

Data Integrity is not just Ethical Behavior
- What procedures/processes do you have in place to monitor data integrity?
- What training is available to staff on the subject of data integrity.

Investigations must be
- Confidential until complete
- Documented
- Notify clients if data are affected

Data Integrity Investigations
Next Steps and Homework

• Think about what was discussed
  – Formulate “how to” questions based on your laboratory operations
  – Keep thinking of processes or procedures you would like to improve/implement

• Email me at: elcatllc@centurylink.net

Thank you!

See you next week!