



# Changing from the 2003 NELAC Standard

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To The New TNI Standard

Presented by: Marlene Moore

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# This Training

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- Presents major changes required to comply with the TNI standard.
- Presents changes to PT program and on-site assessments



# TNI Standard

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- Two Parts - Two Programs
  - Field Activities
    - NEFAP
  - Laboratory Activities
    - NELAP



# Standard Available

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- TNI = The NELAC Institute
- <http://www.nelac-institute.org/>
  - Left column “Standards”
  - Pending TNI standards
  - Purchase with ISO language for complete copy
- Checklist – available
  - 2003 NELAC with TNI standards

# Field Activities



How do you evaluate the competency of sample collection and field testing organizations?





# The Standard

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- Adopted May 2007 - TNI
  - Volume 1: General Requirements for Field Sampling and Measurement Organizations (FSMO-V1-2008)
  - Volume 2: General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations (FSMO-V2-2008)



# Accreditation Body

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- FSMO Specific Accreditation Process
- Detailed Application Specifications
- Allowances for Third Party Accreditation
- Assessment Conduct Specified



# Current Status

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- Standard Has Been Finalized
  - Commercially Available as an Integrated ISO Document
  - Available On TNI Website (Free) W/O ISO Language
- Accrediting Body Buy-In
  - Resources Required
  - Consistency of implementation
- FSMO Buy-In
  - Reasonable & Achievable
  - Communication of availability



# Laboratory Activities

How do you evaluate the competency of laboratory organizations?





# Volume 1: Laboratory Requirements (EL-V1M#-2008)

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- Module 1 - Proficiency Testing
- Module 2 - Quality Systems:
  - General Requirements
- Module 3 - Asbestos Testing
- Module 4 - Chemical Testing
- Module 5 - Microbiological Testing
- Module 6 - Radiochemical Testing
- Module 7 - Toxicity Testing

# Volume 2: Accrediting Body Requirements (EL-V2M#-2008)

- Module 1 - General Requirements 2
- Module 2 - Proficiency Testing
- Module 3 - On-site Assessment

Environmental Laboratory  
(EL) Standards adopted  
December 2007





# Proficiency Testing

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- Volume 3: General Requirements for Environmental Proficiency Test Providers (EL-V3-2008)
- Volume 4: General Requirements for an Accreditor of Environmental Proficiency Test Providers (EL-V4-2008)



# Accreditation Requirements

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- Lab Proficiency Testing Requirements
  - V1M1-2008, Formerly Chapter 2
- On-site Assessment
  - V2M3-2008, Formerly Chapter 3
- Accreditation Process
  - V2M1-2008; V2M2-2008,  
Formerly Chapters 4 and 6
- Proficiency Testing Providers
  - V3 and V4-2008, Formerly Chapter 2



# V1M1-2008 Laboratory PT

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- Definitions – 19
  - Experimental PT
  - TNI PT Board
  - Review others – Terms used are documented in each Volume/Module



# V1M1-2008 Laboratory PT

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- 4.1 – Initial Accreditation
  - 4.1.1 TNI compliant PT samples
  - 4.1.2 If none, lab must obtain from non-accredited PT provider
  - 4.1.3 within 18 months of application, last analysis must be within 6 months of application date. 15 calendar days apart



# V1M1-2008 Laboratory PT

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- 4.2 – Continued Accreditation
  - 4.2.1.a) 2 TNI compliant PTs per year at least 5 to 6 months between performance.  
Reinstate: PTs must be at least 15 days apart.
  - 4.2.1.b) successfully analyze 2 of the last three analysis
  - 4.2.1.c) obtain from non-accredited provider if accredited provider not available.



# V1M1-2008 Laboratory PT

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- 4.2.2 – Continued Accreditation
  - Performance of experimental PTs
- 5.0 PT Sample Handling
  - 5.1.1 Sample analysis requirements
    - Process same as routine sample
    - Large Note in section
    - Test only per technology not method
  - 5.1.2- Not in standard – missing number



# V1M1-2008 Laboratory PT

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- 5.1.3 Prior to closing date of study
  - Not subcontract PT
  - Not knowingly receive or analyze a PT
  - Communicate to another lab about the PT
  - Attempt to obtain the value from the PTP (Proficiency testing provider)



# V1M1-2008 Laboratory PT

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- 5.2 Sample Reporting
  - 5.2.1 – Must be above LOQ
    - Multi point and single point curves define how to report result
  - 5.2.3 – Report before closing date
  - 5.2.4 – Lab authorization to report data directly to primary AB



# V1M1-2008 Laboratory PT

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- 5.3 PT Record Retention
  - 5.3.1 PT records 5 years
    - No statement about regulatory programs that have longer retention. (Statement removed from TNI standard)
  - 5.3.2 Reporting forms used must be retained.
    - Includes copy of on-line data entry summary or similar documentation of entry.
  - 5.3.3 Records available for primary AB



# V1M1-2008 Laboratory PT

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- 6.0 Corrective Action
  - Handling “not acceptable” results
  - Must follow other sections – 15 days apart
- 7.0 Complaint Resolution
  - 7.1 Submit to PTP if not resolved the PTPA
  - 7.2 If Not resolved take to Primary AB
    - Then appeal to TNI (Appeals process)



# V1M1-2008 Laboratory PT

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- 8.0 Reinstatement
  - 8.1 Suspension – lab must meet requirements of continued accreditation as defined in 4.2 of this module
  - 8.2 Revocation - lab must meet requirements of initial accreditation as defined in 4.1 of this module



# V2M3-2008 On-site

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- ISO 17011 language added
  - Notes to explain also added throughout
- 3.0 Definitions
  - ISO/IEC 17011 definitions added
  - Conformity Assessment Body (CAB)
  - Types of assessments defined



# V2M3-2008 On-site

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- 4.0 Human Resources (AB)
  - 4.1 Procedures for assigning assessors
  - 4.2 Education and Training requirements
    - Passing score on general assessments and technical – each technology
  - 4.3 Records of assessors
  - 4.4 Professional conduct



# V2M3-2008 On-site

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- 5.0 Assessment Frequency
  - 5.1 Every 2 years  $\pm$  6 months
    - Unannounced allowed
  - 5.2 Initial assessments are announced



# V2M3-2008 On-site

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- 6.0 Process
  - 6.1 Resource Review
  - 6.2 Subcontracting
  - 6.3 Preparation for assessment
  - 6.4 Document and Record Review
  - 6.5 Documents provided to CAB
  - 6.6 Confidential Business Information
  - 6.7 Length of Assessment



# V2M3-2008 On-site

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- 6.0 Process
  - 6.8 Opening Conference
  - 6.9 Assessment Activities
  - 6.10 Analysis of Findings and Assessment Report
  - 6.11 Closing Conference
  - 6.12 Reporting Procedures
  - 6.13 Reassessment and Surveillance



# V2M3-2008 On-site

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- 7.0 Changes to CAB Capabilities
  - 30 day notice to AB of items listed in ISO 17011, 8.1.2



# V2M3-2008 On-site

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- Many elements from Chapter 3 NELAC removed from TNI – not all presented
  - No requirement for refresher training (3.2.1)
  - No requirement for content of basic or technical training (3.2.3, Appendix A and B)
  - No requirement for consistent and uniform on-site assessment by NELAP (3.1)
  - No requirement for assessors to have knowledge of methods, data review, records and conversant with the tests being assessment (3.2.1)



## V2M3-2008 On-site

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- Many elements from Chapter 3 NELAC removed from TNI – not all presented
  - Security clearances (3.3.4)
  - Pre-assessment activities not defined in same detail (3.4.1)
  - Documents no longer required prior to site visit, COI, assessor credentials, assigned assessors, attendance sheet opening and closing meeting (3.4.4)



# V2M3-2008 On-site

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- Many elements from Chapter 3 NELAC removed from TNI – not all presented
  - CBI details removed (3.4.5)
  - Refusal to admit removed (3.5.2)
  - Items from 3.5.2 missing from opening conference
    - d records and procedures to be examined and lab person responsible
    - g waiver signed by assessor removed
    - j assessment appraisal form



# V2M3-2008 On-site

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- Many elements from Chapter 3 NELAC removed from TNI – not all presented
  - Items from 3.5.2 from opening conference changed to may
    - E roles and responsibilities of key managers
    - F CBI
    - G safety procedures review
  - Specific items 3.5.3 no longer in standard. General statement – Records reviewed for accuracy, completeness and use of proper method



## V2M3-2008 On-site

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- Many elements from Chapter 3 NELAC removed from TNI – not all presented
  - Assessment reports no longer require identification of participants (3.7.2)
  - No longer require report, checklists and lab responses to be retained for five years (3.7.5)
- Many items are required by ISO 17011, however it allows the ABs to decide how it will be addressed. – Removed consistency ? We will see....



# Quality System Requirements

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- Changes to Management System
  - V1M2 (Formerly 5.4)
- Changes to Technical Requirements
  - V1M2 (Formerly 5.5)



# Summary

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- Obtain the TNI Standards
- Develop plan for review and changes:
  - Update Quality Manual for Management System changes
  - Update SOPs as applicable
- Perform Internal Audit to the TNI Standard



# Changes to look for

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- 78 definitions removed
  - Many are administrative or moved to other modules
  - Not presented
- 6 definitions added



# Added Definitions (EL-V1M2)

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- **Analytical Uncertainty:** A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis.
- **Bias:** The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).



# Added Definitions

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- **Matrix Duplicate:** A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision
- **Method:** A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.



# Added Definitions

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- **Quality Assurance [Project] Plan (QAPP):** a formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EPA-QAD)



# Added Definitions

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- **Sampling:** Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure



# Module 2 - Quality Systems

## General Requirements

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- 1.0 Introduction, Scope And Applicability
  - Introduction And Scope
- 2.0 Normative References
- 3.0 Terms And Definitions
  - Additional Terms and Definitions, Definition Sources, and Exclusions and Exceptions



# Module 2 - Quality Systems

## General Requirements

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- 4.0 Management Requirements
- 5.0 Technical Requirements



## 4.0 Management Requirements

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- 4.1 Organization
- 4.2 Management
- 4.3 Document Control
- 4.4 Review Of Request, Tenders And Contracts
- 4.5 Subcontracting Of Environmental Tests
- 4.6 Purchasing Services And Supplies
- 4.7 Service To The Client
- 4.8 Complaints



## 4.0 Management Requirements

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- 4.9 Control Of Nonconforming Environmental Testing Work
- 4.10 Improvement
- 4.11 Corrective Action
- 4.12 Preventive Action
- 4.13 Control Of Records
- 4.14 Internal Audits
- 4.15 Management Reviews
- 4.16 Data Integrity Investigations



# Major Changes from NELAC 2003

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- NELAC 2003 Reorganization
  - All Technical Requirements moved to Technical Modules
  - Elements of Quality Manual in section 4.2.8
  - Calibration Requirements in Technical Module
    - Except for support equipment



# Major Changes from NELAC 2003

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- **NELAC 2003 Reorganization**
  - Combination of Requirements from NELAC 2003, Chapter 5 and Appendix C and D
  - Format Consistent in all Technical Modules
  - All Testing Related to Technology in Module
  - Support Equipment Requirements in Module 2
- **Add ISO/IEC 17025 2005 language**



# Major Changes from NELAC 2003

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- ISO 17025:2005 Changes
  - Some elements that were shall are not should
  - Addition of section on Improvement (4.10)
  - Management System = Quality System
  - Client = Customer
  - Nonconformances = nonconformities
  - Management system items added
    - Communication and feedback
  - Training effectiveness evaluated
  - Quality control data analyzed



# ISO 17025 2005 changes

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- 5.4.1.4 NELAC shall to should
  - 5.4.1.4 A now TNI Note 1
  - 5.4.1.4 B now TNI Note 2
- 5.4.1.5.d policy and procedure required
- 5.4.1.5.h TD no longer required to certify personnel
- 5.4.2.2 policy issued by top management not chief executive



# ISO 17025 2005 changes

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- Title page contents not specified in TNI
- TNI Removed “The relationship between management, technical operations, support services and the quality system” (NELAC 5.4.2.3a-c)
- Accreditation status not required to be reviewed for subcontracting. (5.4.4.1.b)



# Major Changes from NELAC 2003

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- Major Items

- Initial Demonstration of Capability and Ongoing Demonstration of Capability
- Technical Requirements include:
  - Calibration
  - Quality Control
  - Data Reduction
  - Acceptance/Rejection Criteria
  - Sample Handling



# Major Changes from NELAC 2003

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- 4.2.8 Additional Management System Requirements
  - 4.2.8.3 The quality manual shall contain:
    - a) document title;
    - b) laboratory's full name and address;
    - c) name, address of individual (s) responsible for the laboratory;
    - d) identification of all major organizational units and the effective date of the version;



# Major Changes

## The Quality Manual (cont'd)

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- e) identification of the laboratory's approved signatories;
- f) the signed and dated concurrence of all responsible parties;
- 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 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.



# Major Changes

## The Quality Manual (cont'd)

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- 4.2.8.4 The quality manual shall contain or reference:
  - a) all maintenance, calibration and verification procedures;
  - 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, use of reference materials and internal quality control schemes;
  - d) procedures for reporting analytical results;
  - e) the organization and management structure



# Major Changes

## The Quality Manual (Cont'd)

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- f) procedures to ensure that all records are retained and procedures for control and maintenance of documentation;
- g) job descriptions;
- h) procedures for traceability;
- i) a list of all test methods;
- j) procedures for reviews all new work;
- k) procedures for handling samples;
- l) procedures for corrective action when discrepancies are detected, or departures from documented policies and procedures occur;



# Major Changes

## The Quality Manual (Cont'd)

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- m) policy for permitting departures from documented policies and procedures;
- n) procedures for dealing with complaints
- o) procedures for protecting confidentiality;
- p) procedures for audits and data review;
- q) procedures for personnel experience and needed training;  
and
- r) policy addressing the use of unique electronic signatures.



# Sample Handling Records

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- 5.4.12.2.5.1 removed specific records
  - appropriateness of sample container and compliance with holding time requirement
  - pertaining to sample identification, receipt, acceptance or rejection and log-in
  - including shipping receipts, sample transmittal forms
  - including all provisions necessary to protect the integrity of samples



# Records

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- 5.4.12.2.5.2 removed specific records
  - Archived SOPs
  - Correspondence relating to laboratory activities for a specific project
  - All corrective action reports, audits and audit responses
- 5.4.13.3 removed from TNI “agreed time frame as indicated in the quality manual and/or SOP's”



# Records

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- 5.4.15 removed from TNI “with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity: (internal audit)



## 5.0 Technical Requirements

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- 5.1 General
- 5.2 Personnel
- 5.3 Accommodation and Environmental Conditions
- 5.4 Environmental Test Methods and Method Validation
- 5.5 Calibration Requirements



## 5.0 Technical Requirements

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- 5.6 Measurement Traceability
- 5.7 Collection of Samples
- 5.8 Handling Samples and Test Items
- 5.9 Quality Assurance for Environmental Testing
- 5.10 Reporting the Results



## 5.2 Personnel Requirements

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- 5.5.2.1 Removed: “adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, test methods, quality assurance/quality control procedures and records management”



# Personnel Requirements

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- Job description required (TNI 5.2.4)
- Many items of 5.5.2.6.c 1 to 3 removed
- TNI 5.2.5 and appendices does not include all items in wording of the NELAC standard.



# Equipment

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- 5.5.2.7 removed from TNI “Effectively implementing the specific requirements of the procedures”



# Other Changes

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- TNI removed NELAC 5.5.3.6 work areas
- TNI uses LOQ, LOD not Detection limit for inclusion in the method SOP
- TNI does not require the method be available to others in section 5.4.2 (NELAC 5.5.4.2.1.c)



# Other Changes

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- TNI technical module (1.6) for DOC does not require initial DOC if method is in use 1 year before applying for accreditation. (NELAC 5.5.4.2.2.c)
- Work cells removed from TNI
- TNI implies some items, but not stated in the same way as NELAC



# Other Changes

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- 5.5.5.2.1.d requires NIST traceable references – Removed in TNI 5.5.13.1.d
- 5.5.5.2.2.1 changed in TNI – Lowest calibration standard must be above LOQ
- 5.5.5.2.2.1 requires 2 standard in calibration. TNI M4 1.7.1.1 requires 3
- 5.5.5.5 TNI removed maintenance requirement for date received, placed in service and condition when received.



# Other Changes

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- Expiration date documented elsewhere as indicated in the laboratory's quality manual or SOP removed from TNI standard. (NELAC 5.5.6.4.f)
- TNI 5.8.3 requires only abnormalities or conditions to be recorded not departures.
- TNI 5.8.7.4 includes retaining chain of custody



# Other Changes

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- TNI 5.8.6 does not require circumstances under which samples are accepted or rejected.
- TNI 5.10.2.g does not require the time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 72 hours



# Other Changes

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- TNI does not include the following from NELAC
  - “any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify the reporting unit such as ug/l or mg/kg; and for Whole Effluent Toxicity, identify the statistical package used to provide data”
  - Date of issue (report)
  - Name or number of subcontractor on the report, although subcontract results must be identified.



# Calibration

## General Requirements

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- 5.5.13 Additional Requirements and Clarifications
  - Calibration requirements for analytical support equipment are included in this Section. Support Equipment is all devices that may not be the actual test instrument, but are necessary to support laboratory operations.
  - Requirements for instrument (testing) calibration are included in technical modules (i.e., Asbestos, Chemistry, Microbiology, Radiochemistry and Toxicology).



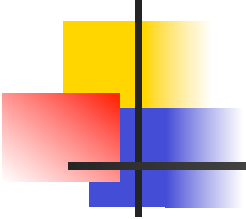
# Technical Requirements

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Where's D.5 (Air)?

It's in V1M4  
Chemical

- Changes to Asbestos
  - V1M3, Formerly D.6
- Changes to Chemical
  - V1M4, Formerly D.1
- Changes to Microbiology
  - V1M5, Formerly D.3
- Changes to Radiochemical
  - V1M6, Formerly D.4
- Changes to Toxicity
  - V1M7, Formerly D.2



# TNI Quality System Standards Format

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- Technical modules are specific for the technology
- Modules 3 to 7 - Asbestos, Chemistry, Microbiology, Radiochemistry, and Toxicity
- No ISO language
- Specific to Testing Activity
- Consistent Format and Structure in all Technical Modules



# TNI Quality System Standards Technology Format

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- 1.1 Introduction
- 1.2 Scope
- 1.3 Terms and Definitions
- 1.4 Method Selection
- 1.5 Method Validation
  - Validation of Methods,
  - Limit of Detection,
  - Limit of Quantitation,
  - Evaluation of Precision and Bias
  - Evaluation of Selectivity



# TNI Quality System Standards Technology Format

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- 1.6 Demonstration of Capability (DOC)
  - General, Initial DOC, and Ongoing DOC
- 1.7 Technical Requirements
  - Initial Calibration, Continuing Calibration,
  - Quality Control for Chemistry
  - Data Reduction
  - Reagent Quality, Water Quality and Checks
  - Data Acceptance/Rejection Criteria
  - Sample Handling



# TNI Quality System Standards

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- 1.6.1 General

- Prior to acceptance and institution of any method for which data will be reported, a satisfactory initial DOC is required (see Section 1.6.2).
- Thereafter, ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples) is required.



# TNI Quality System Standards

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- 1.6.1 General (continued)
  - In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the ongoing DOC shall be acceptable.



# TNI Quality System Standards

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- 1.6.1 General (Continued)
  - The laboratory shall have records on file to demonstrate that a DOC is not required.
  - For the initial DOC, appropriate records as discussed in Section 1.6.2 shall be completed.
  - An initial DOC shall be completed each time there is a change in instrument type, personnel, or method.



# TNI Quality System Standards

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- 1.6.1 General (Continued)
  - All demonstrations shall be documented.
  - All data applicable to the demonstration shall be retained and readily available at the laboratory.



# TNI Quality System Standards

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- 1.6.2 Initial DOC
  - Conducted
    - Prior to using method
    - Change in instrument type, personnel or method
    - If not performed by an analyst within 12 months



# TNI Quality System Standards

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- 1.6.3 Ongoing DOC
  - 1.6.3.1 Procedure needed
  - Analyst(s) demonstrates on-going capability
    - Meets QC requirements
    - Document other approaches to DOC if not per method, Lab SOP, regulation, client specifications



# Calibration – Technical Modules

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- Technical Modules
- 1.7 Technical Requirements
  - 1.7.1 Initial Calibration
  - 1.7.2 Continuing Calibration



# V1M3-2008 Asbestos

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- TNI required
- 1.7.2.1.1.c the laboratory have a set of reference asbestos materials from which a set of reference diffraction and X-ray spectra have been developed



# V1M3-2008 Asbestos

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- TNI required
- 1.7.4.2.a blind recounts by the same analyst performed on 10% of the filters counted



# V1M3-2008 Asbestos

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- TNI required
- 1.7.7.2.3 fiber counts above 1300 fibers/mm<sup>2</sup> and fiber counts from samples with >50% of the filter area covered with particulate reported as “uncountable” or “probably biased”



# V1M3-2008 Asbestos

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- TNI required
- 1.7.7.3.2 point counting and/or visual estimates are used, is a table of reasonable expanded errors generated for different concentrations of asbestos



# V1M4-2008 Chemical

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- 1.4 Method Selection
  - Defines the adding of analytes to reference method
- 1.5 Method Validation
  - Procedure for validation required
  - Procedure for LOD, LOQ (however named) is required



# V1M4-2008 Chemical

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- 1.5 Method Validation
  - Evaluation of
    - LOD – defined
      - Initial every instrument
      - Annual QS matrix, technology, and analyte
      - TNI uses 3x and 4x not range
    - LOQ – defined a
    - Precision and bias
    - Selectivity



# V1M4-2008 Chemical

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- 1.6 Demonstration of Capability
  - General
  - Initial or at least 1 per 12 months to remain qualified in method
  - On-going DOC (not proficiency)
    - Source of QC sample not stated
  - No more form in standard
  - Combines Appendix C and D with relevant parts of Chapter 5
  - TNI does not require copy in personnel file



# V1M4-2008 Chemical

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## Demonstration of Capability

- a) analyst(s) involved in preparation and/or analysis;
- b) matrix;
- c) analyte(s), class of analyte(s), or measured parameter(s);
- d) identification of test method(s) performed;
- e) identification of laboratory-specific SOP used for analysis, including revision number;
- f) date(s) of analysis; and
- g) summary of analyses, including information outlined in Section 1.6.2.2.c.



# V1M4-2008 Chemical

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- 1.7.1 Initial Calibration
- 1.7.2 Continuing Calibration
- 1.7.3 Quality Control
- 1.7.4 Data Acceptance/Rejection Criteria
- 1.7.5 Sample Handling



# V1M4-2008 Chemical

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- 1.7.3.2.3 Note in NELAC 2003 – LCS a requirement in TNI.
- The LCS is a controlled matrix, known to be free of analytes of interest, spiked with known and verified concentrations of analytes.
- Alternatively the LCS may consist of a media containing known and verified concentrations of analytes or as Certified Reference Material (CRM).
- All analyte concentrations shall be within the calibration range of the methods.



# V1M4-2008 Chemical

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- 1.7.3.3. Note is now a TNI requirement
- Matrix specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method.
- The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch.
- (If MS is used rather than LCS – MS control criteria must be same as LCS criteria.)



# V1M4-2008 Chemical

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- TNI requirement - NELAC recommendation
- 1.7.4.3 c - Surrogates
  - surrogates outside the acceptance criteria evaluated for the effect indicated for the individual sample results
  - results reported from analyses with surrogate recoveries outside the acceptance criteria include appropriate data qualifiers



# Removed -

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- Not specifically stated in TNI standard
- NELAC D.1.6 b
  - Glassware cleaning and storage procedure
  - Cleaned to meet test sensitivity



# V1M5-2008 Microbiology

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- 1.4 Method Selection
- 1.5 Method Validation
  - Defines Accuracy, Precision and Selectivity
- 1.6 Demonstration of Capability
  - Use of 4 aliquots plus other techniques
- 1.7 Technical Requirements
  - Many same as NELAC



# V1M5-2008 Microbiology

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- 1.5 requires all in order to demonstrate proficiency with the test method prior to first use
  - comparison to a method already approved for use in the laboratory,
  - by analyzing a minimum of ten spiked samples whose matrix is representative of those normally submitted to the laboratory,
  - by analyzing and passing one proficiency test series provided by an approved proficiency sample provider



# V1M5-2008 Microbiology

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- 1.7.3.5.d No longer need to record amount of media prepared.
- 1.7.3.5.d No longer need to record amount of media received.
- NELAC D.3.8.b.6 Removed: Time after test sample addition required to re-establish equilibrium conditions in incubator or waterbath



# V1M6-2008 Radiochemical

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- 1.4 Method Selection
- 1.5 Method Validation
  - Specific section on DW
  - Standard Method: MDA and Precision and bias
  - Non Standard Method: Intended use
- 1.6 Demonstration of Capability
- 1.7 Technical Requirements



# V1M6-2008 Radiochemical

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- 1.7.1.b.iii Note removed from NELAC text
  - Note: Verification of instrument calibration does not directly verify secondary calibrations, e.g., the mass efficiency curve or the quench curve



# V1M6-2008 Radiochemical

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- 1.7.2.2.e Wording modified from NELAC
- The activity of the laboratory control sample shall be:
  - (1) at least ten (10) times the MDA, and
  - (2) at a level comparable to that of routine samples when such information is available if the sample activities are expected to exceed ten times the MDA.



# V1M6-2008 Radiochemical

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- 1.7.2.3.b Wording modified from NELAC
  - The frequency of the analysis of matrix replicates and duplicates are as specified by the test method or may be determined as part of the contract review process
- NELAC 2003 requires prep batch



# V1M6-2008 Radiochemical

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- 1.7.2.4.b & c Wording modified from NELAC related to measurement uncertainties
  - The procedures for determining the measurement uncertainty shall be documented and shall be consistent
    - ISO Guide 98: 1995, Guide to the Expression of Uncertainty in Measurement (GUM)
    - Chapter 19 of the Multi-Agency Radiological Laboratory Analytical Protocols Manual (MARLAP) Volume I (EPA 402-B-04-001A), Volume II (EPA 402-B-04-001B), Volume III (EPA 402-B-04-001C), July 2004.



# V1M6-2008 Radiochemical

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- 1.7.3.2.a The frequency of the analysis of matrix spikes are as specified by the test method or may be determined as part of the contract review process.
- NELAC 2003 requires prep batch



# V1M6-2008 Radiochemical

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- 1.7.3.2.c Wording modified from NELAC
  - A LCS that is determined to be within the criteria effectively establishes that the analytical system is in control and validates system performance for the samples in the associated batch. Samples analyzed along with a LCS determined to be “out of control” shall be considered suspect and the samples reprocessed and re-analyzed or the data reported with appropriate data qualifying codes.



# V1M7-2008 Toxicity

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- 1.4 Method Selection
- 1.5 Method Validation
  - Definition only
- 1.6 DOC
  - Initial or at least 1 per 12 months to remain qualified in method
  - On-going
- 1.7 Technical Requirements



# V1M7-2008 Toxicity

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- 1.7.1.2 Number of standard reference toxicants (SRT) not specified as in the NELAC standard (5 for initial)
- 1.7.2 Former NELAC criteria found in on-going performance and not initial demonstration.
- SMSD now termed PMSD (percent minimum significant difference)



# V1M7-2008 Toxicity

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- NELAC D.2.5 removed
  - Dose or concentration response curves
- NELAC D.2.8.h removed
  - Expected chronic value based on professional judgment and the best available scientific data



# Thank you

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Marlene Moore  
Advanced Systems, Inc.  
302 368 1211  
[mmoore@advancedsys.com](mailto:mmoore@advancedsys.com)

